EPA Jacket 70051-108

Inert ingredient information may be entitled to confidential treatment
Product ingredient source information may be entitled to confidential treatment

Cerrelli, Susanne

From: Dively, Chris [cdively@certisusa.com]
Sent: Friday, June 28, 2013 3:00 PM
To: Cerrelli, Susanne
Cc: Dively, Chris
Subject: RE: 70051-108 - MSDS sheets - please

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Susanne,
Regarding ingredient sources for the inerts in 70051-108, in the case of [redacted], this source was listed as an alternate on the primary CSF and was just bumped up to the primary source in the new CSF (Notification). For the ingredient [redacted], the company just had a name change. We will need to contact [redacted] for the MSDS. For the other inert in the product, we can also as the source for a copy of the updated CSF.
I will work on this action next week.

Have a great vacation...be safe.

Chris

From: Cerrelli, Susanne [mailto:Cerrelli.Susanne@epa.gov]
Sent: Friday, June 28, 2013 2:33 PM
To: Dively, Chris
Subject: 70051-108 - MSDS sheets - please

I was waiting for you to submit or email MSDS sheets for your pending CSF Notification. (submission dated April 9, 2013.

Did you mail them in to EPA, already? I need the information for the NOP review.

-Regards,

Susanne Cerrelli
Regulatory Action Leader
Biopesticides Pollution Prevention Division
703-308-8077

Cerrelli, Susanne

From: Dively, Chris [cdively@certisusa.com]
Sent: Monday, May 20, 2013 4:12 PM
To: Cerrelli, Susanne
Cc: Dively, Chris
Subject: FW: Message from "Exec-Copier"
Attachments: 20130520160016829.pdf

Susanne,
Per your request, I have revised the active ingredient declaration in CSF column #10 to include the CFU/g so that it is consistent with the label declaration.
We will find the MSDS and send them to you for the alternate supplier of the tow inerts in question if you need them.

Thanks and hope that you daughter is definitely feeling better!

Chris

-----Original Message-----
From: scanner@certisusa.com [mailto:scanner@certisusa.com]
Sent: Monday, May 20, 2013 4:00 PM
To: Dively, Chris
Subject: Message from "Exec-Copier"

This E-mail was sent from "Exec-Copier" (MP 3352).

Scan Date: 05.20.2013 16:00:16 (-0400)
Queries to: scanner@certisusa.com

Confidential Statement of Formula may be entitled to confidential treatment

Material Sent for Data Extraction

Reg. # 70051-108

Description: Label Amendment + CSF Notification

☐ Material(s) Sent to Data Extraction Contractors:

- ☒ New Stamped Label Dated 5/16/13
- ☐ Notification Dated _____
- ☐ New CSF(s) Dated 4/19/13
- ☐ Other: _____

☐ Decision #: D474101 +

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Susanne Correll

Phone: _____ Division: BPPD

Date: _____

Cerrelli, Susanne

From: Dively, Chris [cdively@certisusa.com]
Sent: Monday, May 20, 2013 4:12 PM
To: Cerrelli, Susanne
Cc: Dively, Chris
Subject: FW: Message from "Exec-Copier"
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Sent: Monday, May 20, 2013 4:00 PM
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Subject: Message from "Exec-Copier"

This E-mail was sent from "Exec-Copier" (MP 3352).

Scan Date: 05.20.2013 16:00:16 (-0400)
Queries to: scanner@certisusa.com

Confidential Statement of Formula may be entitled to confidential treatment

Receipt for Section 3

S: 934096

Resubmission: ○ Yes ◉ No

Print Letter

Enter More Information

Tracking

Regulatory Type: Product Registration - Section 3

Fee For Service: ○ Yes ◉ No

Application Type: Notification

Company: 70051 CERTIS USA, LLC V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92

Product #: 70051-108 Product Name: CX-9030

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 19-Apr-2013 OPP Rec'vd Date: 19-Apr-2013

Front End Date: 19-Apr-2013 Risk Manager Send Date: 19-Apr-2013

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Receipt Content	Des
CSF	

Fast Track: ☐ New Ingredient: ☐

View/Edit

Receipt Description:

Notification of change in source on inert ingredients per PR Notice 98-10

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date: Form B: ☐ Signature Date:

→ Ask Dively
Are they
main tances
the other formula
that was
Identified as
Basic
ON Oct 18, 2011
?

33J: Notification

Susanne

Check
w/ Pfeifer @ "Organic"

The new one + CSF changes
will be basic, is it OK??
the old basic will become Alt #2

Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046

(301) 604-7340

Fax: 301-604-7015
www.certisusa.com

April 19, 2013

Document Process Desk (NOTIF)
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7540P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
Attn: Kimberly Nesci

Re: Certis USA L.L.C. (EPA Company No. 70051)
Notification of change in source of inert ingredients per PR-Notice 98-10
Product: CX-9030 (EPA Reg. No. 70051-108)

On behalf of Certis USA, L.L.C., I am respectfully submitting a Notification to update the suppliers of several inert ingredients used in the formulation of the registered pesticide product CX-9030 (ABN: Double Nickel 55). This formulation, previously identified as an alternate, is now the basic formulation for this product.

The following revisions have been made to this CSF:

- The supplier for [redacted] has been revised to identify [redacted]. as the primary source, and listed a new alternate source as [redacted]
- The supplier for [redacted] has been revised to identify [redacted] as the primary source, and listed a new alternate source as [redacted]
- The source of the [redacted] has been updated to reflect the new company name [redacted] (formerly known as [redacted])

No other changes have been made to this CSF. Included with this submission to support this Notification is the following documents:

- EPA Form 8570-1, with attached Certification Statament
- 2 original and signed Confidential Statements of Formula

Please do not hesitate to contact me if you have any questions about this submission. I can be reached by telephone at 301-483-3806 or by email at cdively@certisusa.com.

Sincerely,

Christine A. Dively
Director of Regulatory Affairs

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70051-108	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) CX-9030 (ABN: Double Nickel 55)	PM# Microbial Pesticides Branch	
5. Name and Address of Applicant *(Include ZIP Code)* Certis USA L.L.C. 9145 Guilford Rd., Suite 175, Columbia MD 21046 [ ] *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

"Notification of change in source of inert ingredients per PR Notice 98-10."

See attached Certification Statement

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes*	[ ] Yes	[ ] Yes	[ ] Metal
[X] No	[X] No	[X] No	[X] Plastic
			[ ] Glass
			[ ] Paper
			[ ] Other (Specify) _____
	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

** Certification must be submitted*

3. Location of Net Contents Information [X] Label [ ] Container	4. Size(s) Retail Container 5 lbs	5. Location of Label Directions [X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [X] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Christine A. Dively	Director of Reg. Affairs	301-483-3806

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature Christine A. Dively	3. Title Director of Regulatory Affairs
4. Typed Name Christine Dively	5. Date Apr 19, 2013

NOTIFICATION STATEMENT

CX-9030 (ABN: Double Nickel 55)
EPA Registration Number 70051-108
Notification of change in source of inert ingredients per PR-Notice 98-10

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Pages 12-13*Confidential Statement of Formula may be entitled to confidential treatment*

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OFCHEMICAL
SAFETY AND POLUTION
PREVENTION

May 30, 2013

I, Kimberly Nesci, Microbial Pesticides Branch, Biopesticides & Pollution Prevention Division, Office of Pesticide Programs, Office of Chemical Safety and Polution Prevention, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., Brazil) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

Certis Usa, LLC
9145 Guilford Road, Suite 175
Columbia, MD 21046

EPA Registration Number: 70051-108
Name of Product: CX-9030

Kimberly Nesci
Risk Manager 92
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division
(7511P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OFCHEMICAL
SAFETY AND POLUTION
PREVENTION

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Certis Usa, LLC
9145 Guilford Road, Suite 175
Columbia, MD 21046

EPA Registration Number: 70051-108
Name of Product: CX-9030

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Risk Manager 92
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division
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WASHINGTON, D.C. 20460

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Certis Usa, LLC
9145 Guilford Road, Suite 175
Columbia, MD 21046

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Name of Product: CX-9030

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Biopesticides & Pollution Prevention Division
(7511P)

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WASHINGTON, D.C. 20460

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SAFETY AND POLUTION
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EPA has issued registration numbers for the product(s) listed below to:

Certis Usa, LLC
9145 Guilford Road, Suite 175
Columbia, MD 21046

EPA Registration Number: 70051-108
Name of Product: CX-9030

Kimberly Nesci
Risk Manager 92
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division
(7511P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OFCHEMICAL
SAFETY AND POLUTION
PREVENTION

May 30, 2013

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EPA has issued registration numbers for the product(s) listed below to:

Certis Usa, LLC
9145 Guilford Road, Suite 175
Columbia, MD 21046

EPA Registration Number: 70051-108
Name of Product: CX-9030

Kimberly Nesci
Risk Manager 92
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division
(7511P)

From: Gallager, Susan [sgallager@certisusa.com]
Sent: Tuesday, May 28, 2013 4:40 PM
To: Williams, Bettyr
Subject: FW: CX-9030 Gold Seals

Ms. Williams,

Thank you for your call this morning. Please let me know you receive the email below!

Thanks,
Susan

Susan Gallager
Regulatary Affairs Assaciate
Certis USA L.L.C.
9145 Guilfard Raad, Suite 175
Calumbia, MD 21046
Ph: 301-483-3810

KN

From: Gallager, Susan
Sent: Thursday, May 23, 2013 8:17 AM
To: 'Williams.Bettyr@epamail.epa.gov'
Subject: CX-9030 Gold Seals

Hi Ms. Williams,

I left you a voicemail a few moments ago regarding a submission for Gold Seals for the product CX-9030 (EPA Reg. No. 70051-108) The submission was just made yesterday so likely it has not been received by you yet. I have one change to my request. I would like one of the Gold Seals to display the country Spain- instead of "South Africa" that is written in the cover letter. So the five Gold Seal Certificates will be for:

1. Peru
2. Costa Rica
3. Nicaragua
4. Spain
5. Brazil

I very much appreciate this revision. If there are any questions please let me know.

Kind Regards,
Susan

Susan Gallager
Regulatary Affairs Associate
Certis USA L.L.C.
914S Guilfard Raad, Suite 175
Calumbia, MD 21046
Ph: 301-483-3810

Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046

(301) 604-7340

Fax: 301-604-7015
www.certisusa.com

May 21, 2013

U.S. Environmental Protection Agency
Document Processing Desk (CERT)
Office of Pesticide Programs (7504P)
1200 Pennsylvania Avenue, N.W.
Washington DC 20460-0001
Attn: Ms. Betty Williams

KN

Re: Certis USA L.L.C. Request for Gold Seals (PRIA 3 Category: M006)
CX-9030 (EPA Registration No. 70051-108)

On behalf of Certis USA L.L.C., I am respectfully requesting Gold Seal Certification Letters for the registered pesticide product CX-9030 (EPA Registration No. 70051-108). **Please display the alternate brand name AMYLO-X on the Gold Seal.** I am requesting five (5) Gold Seals covered by this PRIA fee. The Gold Seals will be to support registration activity of Amylo-X in the following countries:

1. Peru
2. Costa Rica
3. Nicaragua
4. ~~South Africa~~ Spain (see email)
5. Brazil

Included with this submission are the following documents:

- 8570-5 Form
- EPA Approved Notification Label dated July 27, 2012
- CX-9030 Stamped Approved label displaying the ABN Amylo-X
- Credit card receipt as proof of payment

Please return the Gold Seal Letters to my attention, at the address on this letterhead. If you have any questions about this submission, I can be reached by telephone at 301-483-3810, or by email at sgallager@certisusa.com.

Sincerely,

Susan Gallager

Susan Gallager
Regulatory Affairs Associate

CC: Christine A. Dively
Director of Regulatory Affairs

Receipt for Section 3

S: 936045

Resubmission: Yes No

Regulatory Type: Product Registration - Section 3

Fee For Service: Yes No

Application Type: Amendment

Billable: Yes No

Company: 70051 CERTIS USA, LLC

Print Letter

Enter More Information

Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92

Product #: 70051-108 Product Name: CX-9030

Overridet:

Me Too Section3: Me Too Product Name:

Application Date: 21-May-2013 OPP Reo'vd Date: 28-May-2013

Front End Date: 28-May-2013 Risk Manager Send Date: 29-May-2013

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Receipt Content	Des
Other	Gold Seal Certificate

View/Edit

Fast Track: New Ingredient:

Receipt Description:

Gold Seal Certificate

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date: Form B: Signature Date:

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70051-108	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) CX-9030	PM# Microbial Pesticides Branch	
5. Name and Address of Applicant *(include ZIP Code)* Certis USA L.L.C. 9145 Guilford Road, Suite 175, Columbia MD 21046 [ ] *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Request for five (5) Certificates of Registration (Gold Seal Letters)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	5 lbs	[X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [X] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Christine A. Dively	Director of Reg. Affairs	301-483-3806

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature Christine A. Dively	3. Title Director of Regulatory Affairs
4. Typed Name Christine A. Dively	5. Date Jan 24, 2013

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25AS3E2D
Agency Tracking ID: 74453203320
Transaction Date and Time: 05/21/2013 15:02 EDT

Payment Summary

Address Information

Account Holder Name: Certis USA L.L.C.
Billing Address: 9145 Guilford Road, Suite 175
Billing Address 2:
City: Columbia
State / Province: MD
Zip / Postal Code: 21046
Country: USA

Account Information

Card Type: American Express
Card Number: **********1018
Decision Number:
Registration Number: 70051-108
Company Name: Certis U.S.A. L.L.C.
Company Number: 70051
Action Code: M006

Payment Information

Payment Amount: $250.00
Transaction Date and Time: 05/21/2013 15:02 EDT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 29, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-479165
EPA File Symbol or Registration Number: 70051-108
Product Name: CX-9030
EPA Receipt Date: 28-May-2013
EPA Company Number: 70051
Company Name: CERTIS USA, LLC

SUSAN GALLAGER
CERTIS USA, LLC
9145 GUILFORD ROAD, SUITE 175
COLUMBIA, MD 21046

SUBJECT: Receipt of Request for Gold Seal Certification Letter(s)

Dear Registrant:

The Office of Pesticide Programs has received your request for Gold Seal Certification letter(s) that is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The action has been identified as action code M006:

UP TO 5 GOLD SEAL CERTIFICATION LETTERS PER REGISTRATION

No additional payment is due at this time. If you have any questions, please contact Betty Williams at (703) 308-0132.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 16 2013

Christine A. Dively
Certis U.S.A., L.L.C.
9145 Guilford Road, Suite 175
Columbia, MD 21046

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

RE: Revised Label for CX-9030
EPA Reg. No.: 70051-108
OPP Decision Number: D474101

Dear Ms. Dively:

The Agency has reviewed your request to amend the CX-9030 label to add the "Bacstar ™" alternate brand name; to update the crop listing to add corn, cereal grains, sugar beets and oilseed crops, and to add seed production at specified sites.

The label amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Submit two (2) copies of the final printed labeling prior to releasing the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA § 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any further questions regarding this, please do not hesitate to contact Susanne Cerrelli, at 703-308-8077 (cerrelli.susanne@epa.gov).

Sincerely,

Kimberly Nesci
Chief
Biopesticides and Pollution Prevention Division
Microbial Pesticides Branch (7511P)

Enclosure

CONCURRENCES								
SYMBOL ►	7511P	7511P						
SURNAME ►	S Cerrelli	KNesci						
DATE ►	5/16/13	5/16/13						

EPA Form 1320-1A (1/90) OFFICIAL FILE COPY

ACCEPTED
MAY 16 2013

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 70051-108

CX-9030

BIOFUNGICIDE

Water Dispersible Granular Biofungicide
(Alt. Double Nickel 55™, Amylo-X™, Bacstar™)

FOR ORGANIC PRODUCTION

OMRI Listed

Active Ingredient:

Bacillus amyloliquefaciens strain D747* 25.0%

Other Ingredients 75.0%

Total 100.0%

*Contains a minimum of 5×10^{10} colony-forming units (cfu) per gram

EPA Reg. No. 70051-108
EPA Est. No. 70051-CA-001

Manufactured by: Certis USA, L.L.C.
9145 Guilford Rd., Suite. 175
Columbia, MD 21046

NET WEIGHT: 5 LBS Lot No:

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID - Agricultural Use

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product label with you when calling a poison control center or doctor.
Hot Line No.:1-800-255-3924 for additional information

PRECAUTIONARY STATEMENTS - Agricultural Use

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow manufacturer's instructions for cleaning and maintaining PPE. If no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS- Agricultural Use

Do not apply directly to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply when weather conditions favor drift or runoff from treated areas.

GENERAL INFORMATION

CX-9030 is a broad-spectrum preventative biofungicide for control or suppression of fungal and bacterial plant diseases. The active ingredient of CX-9030 is a naturally occurring strain (D747) of the beneficial rhizobacterium *Bacillus amyloliquefaciens*, which colonizes roots, leaves, and other plant surfaces. D747 rapidly colonizes plant root hairs, leaves, and other surfaces, preventing establishment of disease-causing fungi and bacteria.

CX-9030 can be applied alone or in combination and/or rotation with chemical fungicides as a tool for integrated disease management in agricultural crops, ornamental and nursery plants, and turfgrass, in accordance with the most restrictive of those label limitations and precautions. CX-9030 offers a valuable tool for management of resistance to chemical fungicides through its multiple and unique modes of action.

CX-9030 can be applied up to and including the day of harvest.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the State or Tribal Agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: cover-alls, waterproof gloves, shoes plus socks.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses. Keep unprotected persons out of treated areas until sprays have dried.

MIXING AND HANDLING INSTRUCTIONS

Mix the required amount of CX-9030 in cool water with sufficient agitation to maintain a uniform suspension in the spray or mixing tank. Tank should be cleaned prior to use. Do not use highly alkaline or highly acidic water to mix sprays. Use a buffering agent if necessary to maintain neutrality (pH 6 to 8) of water in the tank. Maintain agitation during application. Apply immediately after mixing; do not allow spray mix to stand overnight.

APPLICATION METHODS

Ground: CX-9030 can be applied in most commonly-used ground application equipment, such as tractor-mounted boom, airblast, high clearance, hose-end, backpack, and other pressurized sprayers; hose-end or hand-held sprayers; foggers or mist blowers; water wheel and other drench applicators; and shank or other soil injection method.

Aerial: CX-9030 can be applied by fixed or rotary winged aircraft in a minimum of 3 gallons of water per acre. Standard precautions should be taken to minimize spray drift.

Chemigation: CX-9030 can be applied through drip (trickle) and sprinkler type irrigation equipment. Refer to the section entitled "Chemigation Instructions" for detailed instructions.

Agricultural crops

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons	
Brassica vegetables such as broccoli, cabbage, cauliflower, Brussels sprouts, kohlrabi, and other cole crops (including those grown for seed production)	Pin rot complex (*Alternaria/Xanthomonas*)* Leaf spots (*Alternaria* spp., *Xanthomonas* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe polygoni*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Bulb vegetables such as onions, garlic, shallots, and others (including those grown for seed production)	*Botrytis* spp. (neck rot, leaf blight) Purple blotch (*Alternaria* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Rust (*Puccinia pori*)* White rot (*Sclerotium cepivorum*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Cucurbits such as cucumbers, squash (all types), cantaloupes, muskmelons, watermelons. and other melons (including those grown for seed production).	Powdery mildew (*Erisyphe* and *Sphaerotheca* spp.) Downy mildew (*Pseudoperonospora* spp.) Gummy stem blight (*Didymella bryoniae* and *Phoma cucurbitacearum*) See instructions below for "Soil application" against the following diseases: Vine decline (*Monosporascus cannonballus*)** Charcoal rot (*Macrophomina phaseoli*)** "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp.
Fruiting vegetables such as tomatoes, peppers, eggplant, tomatillo, okra, and others (including those grown for seed production).	Bacterial spot (*Xanthomonas* spp.)*[1] Bacterial speck (*Pseudomonas syringae* pv. *tomato*)*[1] Gray mold (*Botrytis cinerea*) Powdery mildew* (*Leveillula, Oidiopsis, Erisyphe*, and *Sphaerotheca* spp.) Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. Southern blight (*Sclerotium rolfsii*)* and**
Leafy vegetables such as head and leaf lettuce, celery, spinach, radicchio, arugula, watercress, and others (including leafy *Brassica* vegetables such as mustard and collard greens, kale, bok choi, and related crops), including those grown for seed production.	Downy mildew (*Bremia lactucae*, *Peronospora* spp.)* Powdery mildew (*Golovinomyces (Erysiphe) cichoracearum*)* Bacterial blights Head and leaf drop (*Sclerotinia* spp.)[2] Pink rot (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* spp.) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. Bottom rot (*Rhizoctonia solani*)
Legume vegetables succulent and dried beans and peas such as green, snap, shell, and Lima beans, garbanzo beans, chickpeas, soybeans, dry beans, peas, split peas, lentils, and other legumes, including those grown for seed production.	White mold (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea)* Powdery mildew (*Microsphaera diffusa*) Rusts*, including *Uromyces appendiculatus*, *Puccinia* spp., and Asian soybean rust (*Phayospora pachyrhizi*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Root, tuber, and corm vegetables such as potato, sweet potato, carrot, cassava, beets, ginger, radish, horseradish[22], ginseng, turnip, and other root, tuber and corm crops (including those grown for seed	Black root/crown rot (*Alternaria* spp.) Bacterial leaf blight (*Xanthomonas campestris*) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Gray mold (*Botrytis* spp.) White mold (*Sclerotinia sclerotiorum*)[2]

production).	Black leg /bacterial soft rot (*Erwinia carotovora*)** Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: Black scurf (*Rhizoctonia solani*) Cavity spot (*Pythium* spp.) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizactonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp.
Other vegetables such as sweet corn, popcorn, asparagus, peanut, and watercress	*Botrytis* spp. Rusts (*Puccinia* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* and *Cercosporidium* spp.)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Tree fruits and nuts	
Citrus such as orange, lemon, lime, grapefruit, tangerine (mandarin), tangelo, pummelo, and other citrus	*Alternaria* leaf spot (*Alternaria alternata*) Postbloom fruit drop (*Colletotrichum acutatum*)* Greasy spot (*Mycosphaerella citri*)*[3] Citrus canker (*Xanthomonas campestris* pv. *citri*)[1] Scab (*Elsinoe fawcetti*)*[4] Melanose (*Diaporthe citri*)*
Pome fruits such as apple, pear, crabapple, quince, and others	Powdery mildew (*Podosphaera leucotricha*)[5] Scab (*Venturia* spp.)* Flyspeck (*Zygophiala jamaicensis*)[6] ** Sooty blotch disease complex[6] ** Brooks spot (*Mycosphaerella pomi*)[6] ** Bot rot/white rot (*Botryosphaeria dothidea*)[6] ** Bitter rot (*Colletotrichum* spp.)[6] Cedar apple rust (*Gymnosporangium juniperi-virginianae*)[6] ** Fire blight (*Erwinia amylovora*)*[7]
Stone fruits such as apricot, cherry, nectarine, peach, plum, prune, pluot, and others	Powdery mildew (*Sphaerotheca* and *Podosphaera* spp.)*[8] Bacterial canker (*Pseudomonas* spp.) Brown rot blossom blight (*Monilinia laxa*)[9] Brown rot (*Monilinia fructicola*)*[10] Gray mold (*Botrytis cinerea*)[10] Peach leaf curl (*Taphrina deformons*) Bacterial leaf spot (*Xanthomonas arbicola* pv. *pruni*)[1] Rusty spot (*Podosphaera leucotricha*)[1]
Tree nuts such as almond, pistachio, pecan, walnut, filbert, hazelnut, chestnut, macadamia, and other tree nuts.	Walnut blight (*Xanthomonas campestris*)[11] Anthracnose (*Colletotrichum acutatum*)* Bacterial canker (*Pseudomonas syringae*) Shot hole (*Wilsonomyces carpophilus*)* Brown rot (*Monilinia* spp.)* Pecan scab (*Cladosprium caryigenum*)*[1] and **
Pomegranates	Leaf and fruit spots (*Cercospora*, *Gloeosporium* and *Pestalotia* spp.)[1] Fruit rots (*Alternaria*, *Botrytis*, and other spp.)[10] Powdery mildew (*Sphaerotheca pannosa*)
Other fruits	
Strawberry	Powdery mildew (*Sphaerotheca macularis*, *Erisyphe* spp.)*[12] Gray mold (*Botrytis cinerea*)*[11] Anthracnose (*Colletotrichum acutatum*) Angular leaf spot (*Xonthomonas fragariae*)[1] For the following diseases, see instructions below for "Soil application" (and also root dip instructions[22]): "Damping off" and root or crown diseases caused by *Rhizoctonia*, *Fusarium*, *Pythium*, *Phytophthora*, and/or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*)**

Berries, including blueberry, blackberry, raspberry, loganberry, huckleberry, kiwifruit, gooseberry, elderberry, cranberry (non-flooded fields), currant, and other berries	Mummy berry (*Monilinia vaccinii-corymbosi*)* Botrytis blight (*Botrytis cinerea*) Bacterial canker (*Pseudomonas* spp.)[13] Anthracnose fruit rot (*Colletotrichum acutatum*)[10] Sclerotinia (*Sclerotinia sclerotiorum*)
Grapes including wine grapes, table grapes, and raisins	Powdery mildew (*Erisyphe* (formerly *Uncinula*) *necator*)[14] Gray mold (*Botrytis cinerea*)[15] Sour rot complex[15] Downy mildew (*Plasmopara viticola*)* Phomopsis (*Phomopsis viticola*)[16] Eutypa (*Eutypa lata*)[17]
Tropical fruits such as avocado[18], mango[18], papaya[19], pineapple[19], banana, plantain, and others.	Anthracnose (*Colletotrichum* spp.) Scab (*Sphaceloma perseae*) Bacterial canker (*Xanthomonas campestris*) Sigatoka (*Mycosphaerella fijiensis*)[20]
Other Crops	
Herbs and spices such as basil, thyme, coriander, dill, cilantro, parsley, mint, and others (including those grown for seed production).	Powdery mildews (*Oidium* spp. and others) Downy mildews (*Peronospora* spp. and others)* Damping off diseases (*Rhizoctonia, Pythium, Alternaria*, and *Fusarium* spp.) Leaf spots (*Alternaria, Septoria, Colletotrichum*, and *Cercospora* spp.)* Bacterial diseases (*Erwinia, Xanthomonas*, and *Pseudomonas* spp.) Rusts (*Puccinia* spp. and others) "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Coffee	Coffee berry disease (*Colletotrichum coffeanum*)[1] Coffee rust (*Hemileia vastatrix*)[1**] Anthracnose (*Colletotrichum* spp.) *Botrytis* flower blight *Cercospora* leaf spot** and berry blotch** "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Tobacco	Angular leaf spot (*Pseudomonas* spp.) Anthracnose (*Colletotrichum* and *Glomerella* spp.) Blue mold or downy mildew (*Peronospora* spp.)* Brown spot (*Alternaria*) Barn spot/ frogeye leaf spot (*Cerrcospora nicotianae*)[10] Collar rot (*Sclerotinia slcerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Erysiphe cichoracearum*) Target spot (*Rhizoctonia solani*) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Olpidium, Phytophthora*, or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*) Black root rot (*Thielaviopsis basicola*) Black shank (*Phytophthora* spp.)* Southern blight/southern stem rot (*Sclerotium rolfsii*)*
Corn, including field corn, sweet corn, popcorn, sileage corn, seed corn, and other corn crops.	Commmon rust (*Puccinia sorghi*)* Southern leaf blight (*Bipolaris maydis/Cochliobolus heterostrophus/Helminthosporium maydis*)
Cereal grains, such as barley, millet, oats, rice, rye, sorghum, triticale, wheat, and other cereal grain crops (including those grown for seed).	Powdery mildew (*Erysiphe graminis*) Rust (*Puccinia* spp.)* Rice blast (*Pyricularia oryzae*) Sheath spot/blight (*Rhizoctonia* and *Thanatephorus* spp.) Smut (*Tilletia barclayana*) Bacterial blight/streak (*Xanthomonas* spp.) Stem rots (*Magnaporthe* and *Sclerotium* spp.) *Cercospora* leaf spot Brown rot/leaf spots/smuts (*Ceratobasidium, Cochliobolus, Dreschlera*, and *Entyloma* spp.)

Oilseed crops, including canola, castor, coconut, cotton, flax, oil palm, olive, peanut, rapeseed, safflower, sesame, sunflower, soybeans, and other oilseed crops, including those grown for seed production.	White mold/Stem rot (*Sclerotinia sclerotiarum*) Rusts*, including *Uromyces appendiculatus*, *Puccinia* spp., and Asian soybean rust (*Phayospora pachyrhizi*) Bacterial Speck (*Pseudomonas syringae* pv.*glycinea*) Bacterial Pustule (*Xanthamonas* spp.) Brown Spot (*Septoria glycines*) *Cercaspora* Leaf Spot Pod and Stem Blights (*Diaporthe* and *Phomopsis* spp.) Downy Mildew (*Peronaspora manshurica*)
Mint	Rust (*Puccinia* spp.)
Hops	Powdery mildew (*Sphaerotheca macularis*)[21]
Sugar beets (including crops grown for seed production)	Leaf spots (*Cercaspora* and *Ramularia* spp.) Powdery mildew (*Erysiphe* spp.) Rust (*Uromyces betae*)

Footnotes:

*Suppression only; for improved control mix or rotate with chemical fungicide approved for such use. **NOT FOR USE IN CALIFORNIA"

[1] Tank mix or rotate with copper-based fungicides at label rates for improved control.

[1]Apply at or immediately following planting (but before plant emergence) as a banded seedline treatment 4 to 6 inches wide. Make second application at thinning or cultivation in sufficient water and multiple nozzles to ensure thorough coverage of lower leaves and surrounding soil surface. Incorporation with light irrigation after application may improve disease control. Repeat at 10-14 day intervals if conditions promoting disease persist.

[1] For greasy spot suppression, apply at first new foliar flush and repeat with each new flush. Tank mix with spray oil or copper based fungicide at labeled rates.

[4] For suppression of citrus scab, start applications at first new foliage flush and repeat at petal fall and when fruit are ½ inch in diameter.

[5] Make first application at or before tight cluster if conditions favor disease development. Repeat at 7-10 day intervals through the second cover spray or longer on susceptible varieties or if environmental conditions favor rapid disease development.

[6] Begin applications before bloom when environmental conditions favor disease development, repeating at 7 to 14 day intervals or as needed. Control may be enhanced by addition of a surfactant to improve spray coverage. Use only surfactants known to be safe for use on the crop and for which such use is allowed.

[7]Rotate with antibiotics registered for fire blight control for improved performance. Begin applications at 1-5% open blossoms and repeat every 3-7 days as necessary until petal fall, when intervals can be increased to 7 days. CX-9030 can also be used in summer "cover spray" applications to control the shoot blight phase of fire blight and summer diseases. Can be mixed with copper fungicides to improve control.

[8]Make first application at popcorn stage and repeat every 7 days.

[9] Start applying at early bloom stage and repeat every 7 days through petal fall.

[10] Pre-harvest applications in sufficient water to cover fruit or other harvested plant parts may improve control of postharvest infections.

[11] Begin applications at or before pistillate bloom, repeating every 7-10 days. Apply before rainfall if possible, and tank mix or rotate with a copper-based bactericide registered for such use for improved control.

[12] Start applications at or just before flowering and repeat every 7-10 days as needed through harvest.

[13] Apply before fall rains and again during dormancy before spring growth.

[14] Start applications when new shoots are ½ to 1½ inches long. Repeat at 3-5 inches, 8-10 inches, and then at 7-10 day intervals until disease conditions no longer exist.

[15] Apply at bloom, before bunch closure, at veraison, and before harvest.

[16] Apply when shoots are ½ to 1 inch long and again when 6-8 inches long.

[17] Mix 1 ounce CX-9030 per gallon of water and apply to pruning wounds.

[18] Apply at budbreak and repeat on 14-21 day interval as needed through harvest.

[19] Apply at flowering and repeat on 14-21 day interval as needed through harvest

[20] Apply at first appearance of leaves and repeat at 7-21 day intervals as needed, in sufficient water to obtain thorough coverage of foliage. Tank mix with spray oil or other registered fungicides for improved control.

[21] Mix 0.5-1 lb CX-9030 per 100 gallons of water and apply in minimum of 20 gallons per acre from emergence to training, 50 gallons per acre from training to wire, and 100 gallons per acre from wire touch through harvest.

[22] For treatment of horseradish or strawberry roots immediately before transplanting: immerse bare roots (individually or in bunches) for 10 seconds in a suspension of 2-4 ounces CX-9030 per gallon of water.

Foliar application: For control of diseases on foliage, flowers, fruit, or other above-ground parts of plants: Mix CX-9030 in water and apply as a spray at a rate of **0.25 to 3 pounds per acre** in sufficient water to achieve thorough coverage of the crop canopy with minimal runoff. Begin applications at crop emergence, transplanting, or when conditions are conducive to development of disease. Repeat application every 7 to 10 days, or as needed, for as long as conditions favor disease development. Lower rates (0.25 to 1 pound per acre) may be applied under light disease pressure, to smaller (e.g. newly-emerged) plants, or when CX-9030 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (1 to 3 pounds per acre), apply more frequently (every 3 to 7 days), and mix or rotate CX-9030 with other fungicides for improved performance.

Soil application: For control of soilborne diseases infecting seeds, seedlings, roots, crown, stems, or other plant parts below ground or in contact with soil: Apply CX-9030 at **0.125 to 1 pound per acre**. Mix the required amount in sufficient water to apply by one of the following methods:

- Soil drench applied to transplants in flats or pots in the greenhouse or nursery any time prior to transplanting (see additional drench instructions under "Nurseries, greenhouses, shade houses, and ornamental plants" below).
- Soil drench at transplanting, using a "water wheel" injector, spray nozzles/hoses, or other method to drench each root ball and/or planting hole.
- Soil or seedline drench, or banded spray (in-furrow) at planting. See the section on "Banded (in-furrow) application" below for additional instructions.

Follow-up (post-planting) preventative applications can be made every 2-4 weeks by one or more of the following methods, if needed:

- Drip (trickle) or any type of sprinkler irrigation, any time after planting or transplanting. See Chemigation Instructions for additional information.
- Spray directly onto the soil surface and/or lower plant parts. If targeting root disease, follow immediately with sufficient overhead sprinkler irrigation to move CX-9030 to the root zone.
- Injection directly into the rooting zone using shanks or similar equipment.

Lower rates (0.125 to 0.5 pounds per acre) may be applied under light disease pressure, to smaller plants, or when CX-9030 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (0.5 to 1 pound per acre), apply more frequently (every 2 weeks), and mix or rotate CX-9030 with other fungicides for improved performance.

Banded (in-furrow) application: Use the table below to determine the correct application rate of CX-9030 per 1,000 row feet, based on row spacing and desired rate per acre. Mix the required amount of CX-9030 in water and apply as banded spray (4" to 6" wide) or seedline drench centered over the planting furrow. Apply directly over seeds in the furrow just before they are covered with soil. The volume of water required per acre or per 1,000 row feet will depend on the application equipment used. Consult your local cooperative extension service if you need assistance calibrating band spraying equipment.

Rates for banded (in-furrow) application: Find desired application rate in the left column. Read across that line to the correct row spacing indicated at the top to find the number of ounces (dry) per 1,000 row feet that will provide the desired application rate per acre. To convert to **level teaspoons**, multiply the number of ounces by 8.2. For **level tablespoons**, multiply the number of ounces by 2.75.

Rate/acre	Space between rows (inches)														
(pounds)	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
0.25	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3
0.5	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6
0.75	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9
1.0	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.2	1.2
1.25	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.4	1.5	1.5
1.5	0.6	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.7	1.8
1.75	0.6	0.7	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1
2.0	0.7	0.9	1.0	1.1	1.2	1.3	1.5	1.6	1.7	1.8	2.0	2.1	2.2	2.3	2.4
2.25	0.8	1.0	1.1	1.2	1.4	1.5	1.7	1.8	1.9	2.1	2.2	2.3	2.5	2.6	2.8
2.5	0.9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1
2.75	1.0	1.2	1.3	1.5	1.7	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.0	3.2	3.4
3.0	1.1	1.3	1.5	1.7	1.8	2.0	2.2	2.4	2.6	2.8	2.9	3.1	3.3	3.5	3.7

Nurseries, greenhouses, shadehouses, and ornamental plants:

Spray application: Mix **0.25 to 3 pounds of CX-9030 per 100 gallons of water** and apply as a foliar spray of sufficient volume to wet the entire plant with minimal runoff. Begin preventative applications at plant emergence and repeat every 3-28 days as needed (every 3-7 days if disease pressure is high or environmental conditions are highly favorable to disease outbreak, 10-28 days under low pressure or less conducive conditions).

Drench application: Mix **0.125 to 2 pounds of CX-9030 per 100 gallons of water** and apply as a drench or coarse spray to soil or other growing media in pots, flats, plugs, trays, or planting beds, for control or suppression of soilborne diseases of seedlings, cuttings, bedding plants, and transplants (including vegetables and other transplanted food crops). Make first application at or immediately before seeding, sticking, germination, or transplanting. Repeat applications every 14-28 days as needed. Transplants can be treated immediately before transplanting into field soils to protect against damping-off and other diseases that reduce plant establishment.

Cutting or root dip: Dip basal end of cuttings or bare roots (individually or in bunches) in a suspension of **1 to 2 pounds of CX-9030 per gallon of water**. Immerse for 5-10 seconds immediately before planting.

Chemigation: Mix **0.125 to 2 pounds of CX-9030 per 100 gallons of water** and apply via drip, handheld, or sprinkler irrigation systems. Refer to "Chemigation Instructions" for more details.

CROPS/USE SITES	DISEASES/PATHOGENS
Indoor, outdoor, and shade- or other cover-grown ornamental trees and shrubs, flowering plants, foliage plants, tropical plants, potted plants, potted or cut flowers, bedding plants, forestry seedlings, conifer production for reforestation, fruit trees, vegetables and other crops grown in greenhouses or nurseries.	Powdery mildews caused by *Erisyphe, Podosphaera, Sphaerotheca, Oidium,* and *Golovinomyces* spp.) Anthracnose (*Colletotrichum* spp.) Bacterial leaf spots caused by *Erwinia, Pseudomonas,* and *Xanthomonas* spp. Damping-off disease (*Rhizoctonia, Pythium, Fusarium* spp.) Late blight, blackeye, and root rots caused by *Phytophthora* spp. Gray mold and blight caused by *Botrytis cinerea* Black root rot (*Aspergillus* spp.) Black spot of roses (*Diplocarpon rosae*) Downy mildew (*Peronospora* spp.) Leaf spots caused by *Alternaria, Septoria, Cercospora, Entomosporium, Helminthosporium,* and *Myrothecium* spp.) Rust (*Puccinia* spp.) Scab (*Venturia* spp.) Root rot, bottom rot, or stem rot caused by *Rhizoctonia solani* *Sclerotinia* blight *Fusarium* wilts

Turfgrass application: For control of foliar diseases, apply CX-9030 at **0.5 to 1 ounce per 1,000 square feet** as a ground-directed spray in sufficient water to provide thorough coverage. To control root and crown diseases in or on the soil, immediately follow the spray with sufficient overhead sprinkler irrigation to move the product into the root zone.

USE SITES/CROPS	DISEASES/PATHOGENS
Turf, sod, lawns, golf course (fairways, roughs, greens, tees), grass seed production Including but not limited to: Bluegrass, Bentgrass, Bermudagrass (common & hybrid), Dichondra, Fescue, Orchardgrass, *Poa annua*, St. Augustine grass, Ryegrass, *Zoysia*, mixtures, and other grasses or ornamental turf	Anthracnose (*Colletotrichum graminicola*) Brown patch (*Rhizoctonia solani*) Dollar spot (*Lanzia* and *Moellerodiscus* spp., formerly *Sclerotinia homeocarpa*) Powdery mildew (*Erisyphe graminis*) Rust (*Puccinia* spp.) Gray leaf spot (*Pyricularia grisea*) "Damping off" or seedling blights caused by *Pythium*

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a dry area inaccessible to children. Store in original containers only. Keep container closed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CHEMIGATION INSTRUCTIONS

General information:

Apply this product only through drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (including impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

Drip (trickle) and micro-irrigation chemigation:

1. The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.

Sprinkler chemigation:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
8. Do not apply when wind speed favors drift beyond the area intended for treatment.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purpose referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the disease problem, condition of the crop, incompatibility with other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

File Symbol: 51-104 **Label Review** Date: 5/13/13 Reviewer: SGwell

[Site/Use]	[Res ✓ /Ag /Both] [Food /Non-Food /Both]
[Tox Categories:]	[AcOral: 4 /AcDerm: 4 /AcInhl: 4 /EyeIrr: 3 /SkinIrr: 4 DermSens:]

Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
Restricted Use Pesticide	----------	----------	X		Ch 6
1. Product Name				Is Bacstar & New name?	Pg 12-3
Compny Name and Info	✓			unchanged	Pg 15-1
Identification Numbers	✓				Ch 14
Net Contents	✓			CFU may work until to agree	Ch 17
1. Ingredients Statement	✓				Ch 5
Label Claims	✓				Pgs 4-5, 5-7 11-10 & Ch 12
Alternate Formula			✓		5-12

Precautionary Statements

Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
KOROC	✓			Same	3-1 & 9 7-3 & 4
Signal Word	✓				Ch 3 Ch 7 Ch 10
General Heading >PRECAUTIONARY STATEMENTS=	✓				Ch 7
First Aid (PRN 20001-1)	✓			Same	Ch 3 & 7

Hazards to Humans and Domestic Animals	✓				Ch 3, 7-3
PPE (WPS) Engineering Controls	✓				Ch 7, Pg 7-12 Pgs 10-4, 15
User Safety Requirements	✓			SAME	Ch 10
User Safety Recommendations	✓				Ch 10
Environmental Hazards	✓			Same	Ch 8
Physical and Chemical Hazards			✓		Pg 3-4 Ch 9

Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046

(301) 604-7340

Fax: 301-604-7015
www.certisusa.com

January 16, 2013

Biopesticides and Pollution Prevention Division (BPPD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: Certis USA L.L.C.
Submission of Final Printed Labeling for Registered Pesticide Products

On behalf of Certis USA, L.L.C., 9145 Guilford Road Suite 175 Columbia, MD 21046, I am respectfully submitting an 8570-1 Form and three copies of the final printed labels for each of the following registered pesticide products:

- Deliver (EPA Registration No. 70051-69)
- Double Nickel LC (CX-9032) (EPA Registration No. 70051-107)
- Double Nickel 55 (CX-9030) (EPA Registration No. 70051-108)
- CYD-X HP (CYD-X Plus) (EPA Registration No. 70051-112)

Please note that copies of OMRI certificates are included, when not previously submitted to the Agency.

Please do not hesitate to contact me if you have any questions about this submission. I can be reached by telephone at 301-483-3806 or by email at cdively@certisusa.com.

Sincerely,

Susan Gallagher for:

Christine A. Dively
Directory of Regulatory Affairs
Certis U.S.A. L.L.C.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70051-108	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) CX-9030	PM# Microbial Pesticides Branch	
5. Name and Address of Applicant *(Include ZIP Code)* Certis U.S.A. L.L.C. 9145 Guilford Rd. Suite 175, Columbia MD 21046 [ ] *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[X] Final printed labels in response to Agency letter dated July 27, 2012
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of three copies of final printed labels in response to EPA Stamped Approved Notification dated July 27, 2012.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No ** Certification must be submitted*	[ ] Yes [X] No If "Yes" Unit Packaging wgt. / No. per container	[ ] Yes [X] No If "Yes" Package wgt / No. per container	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	5 lbs	[X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [X] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Christine A. Dively	Director of Reg. Affairs	301-483-3806

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Christine A. Dively	Director of Regulatory Affairs
4. Typed Name	**5. Date**
Christine A. Dively	Jan 3, 2013

DoubleNickel55™

BIOFUNGICIDE

Water Dispersible Granular Biofungicide

FOR ORGANIC PRODUCTION

OMRI™ Listed
Organic Materials Review Institute

Active Ingredient:	
Bacillus amyloliquefaciens strain D747*	25.0%
Other Ingredients:	75.0%
Total	100.0%

*Contains a minimum of 5× 10^{10} colony-forming units (cfu) per gram

Net Contents: 5 Pounds
EPA Reg. No. 70051-108
EPA Est. No. 70051-CA-001

Lot No:

Manufactured by:
Certis USA, L.L.C.
9145 Guilford Rd, Suite 175
Columbia, MD 21046

CERTIS

Complies with EPA Accepted Labeling
MAY 14 2013
Date:
Reviewer: Susanne Cerrell

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID - Agricultural Use
If in eyes: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product label with you when calling a poison control center or doctor.

Hot Line No.: 1-800-255-3924 for additional information

PRECAUTIONARY STATEMENTS - Agricultural Use
HAZARDS TO HUMANS & DOMESTIC ANIMALS
CAUTION: Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)
Applicators and other handlers must wear:
- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow manufacturer's instructions for cleaning and maintaining PPE. If no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS
Users should:
- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS- Agricultural Use
Do not apply directly to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply when weather conditions favor drift or runoff from treated areas.

GENERAL INFORMATION
Double Nickel 55 is a broad-spectrum preventative biofungicide for control or suppression of fungal and bacterial plant diseases. The active ingredient of Double Nickel 55 is a naturally occurring strain (D747) of the beneficial rhizobacterium *Bacillus amyloliquefaciens*, which colonizes roots, leaves, and other plant surfaces. D747 rapidly colonizes plant root hairs, leaves, and other surfaces, preventing establishment of disease-causing fungi and bacteria.

Double Nickel 55 can be applied alone or in combination and/or rotation with chemical fungicides as a tool for integrated disease management in agricultural crops, ornamental and nursery plants, and turfgrass, in accordance with the most restrictive of those label limitations and precautions. Double Nickel 55 offers a valuable tool for management of resistance to chemical fungicides through its multiple and unique modes of action.

Double Nickel 55 can be applied up to and including the day of harvest.

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the State or Tribal Agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

AGRICULTURAL USE REQUIREMENTS
Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: cover-alls, waterproof gloves, shoes plus socks.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

NON-AGRICULTURAL USE REQUIREMENTS
The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses. Keep unprotected persons out of treated areas until sprays have dried.

MIXING AND HANDLING INSTRUCTIONS
Mix the required amount of Double Nickel 55 in cool water with sufficient agitation to maintain a uniform suspension in the spray or mixing tank. Tank should be cleaned prior to use. Do not use highly alkaline or highly acidic water to mix sprays. Use a buffering agent if necessary to maintain neutrality (pH 6 to 8) of water in the tank. Maintain agitation during application. Apply immediately after mixing; do not allow spray mix to stand overnight.

APPLICATION METHODS
Ground: Double Nickel 55 can be applied in most commonly-used ground application equipment, such as tractor-mounted boom, airblast, high clearance, hose-end, backpack, and other pressurized sprayers; hose-end or hand-held sprayers; foggers or mist blowers; water wheel and other drench applicators; and shank or other soil injection method.

Aerial: Double Nickel 55 can be applied by fixed or rotary winged aircraft in a minimum of 3 gallons of water per acre. Standard precautions should be taken to minimize spray drift.

Chemigation: Double Nickel 55 can be applied through drip (trickle) and sprinkler type irrigation equipment. Refer to the section entitled "Chemigation Instructions" for detailed instructions.

Agricultural crops

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons	
Brassica vegetables such as broccoli, cabbage, cauliflower, Brussels sprouts, kohlrabi, and other cole crops.	Pin rot complex (*Alternaria/Xanthomonas*)* Leaf spots (*Alternaria* spp., *Xanthomonas* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe polygoni*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").

(continued)

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons *(continued)*	
Bulb vegetables such as onions, garlic, shallots, and others.	*Botrytis* spp. (neck rot, leaf blight) Purple blotch (*Alternaria* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Rust (*Puccinia porri*)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").
Cucurbits such as cucumbers, squash (all types), cantaloupes, muskmelons, watermelons, and other melons.	Powdery mildew (*Erisyphe* and *Sphaerotheca* spp.) Downy mildew (*Pseudoperonospora* spp.) Gummy stem blight (*Didymella bryoniae* and *Phoma cucurbitacearum*) See instructions below for "Soil application" against the following diseases: Vine decline (*Monosporascus cannonballus*)** Charcoal rot (*Macrophomina phaseoli*)** "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp.
Fruiting vegetables such as tomatoes, peppers, eggplant, tomatillo, okra, and others.	Bacterial spot (*Xanthomonas* spp.)*[1] Bacterial speck (*Pseudomonas syringae* pv. *tomato*)*[1] Gray mold (*Botrytis cinerea*) Powdery mildew* (*Leveillula, Oidiopsis, Erisyphe,* and *Sphaerotheca* spp.) Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. Southern blight (*Sclerotium rolfsii*)* and**
Leafy vegetables such as head and leaf lettuce, celery, spinach, radicchio, arugula, watercress, and others (including leafy Brassica vegetables such as mustard and collard greens, kale, bok choi, and related crops).	Downy mildew (*Bremia lactucae, Peronospora* spp.)* Powdery mildew (*Golovinomyces (Erisyphe) cichoracearum*)* Bacterial blights Head and leaf drop (*Sclerotinia* spp.)[2] Pink rot (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* spp.) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. Bottom rot (*Rhizoctonia solani*)
Legume vegetables succulent and dried beans and peas such as green, snap, shell, and Lima beans, garbanzo beans, chickpeas, soybeans, dry beans, peas, split peas, lentils, and other legumes.	White mold (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Microsphaera diffusa*) Rusts*, including *Uromyces appendiculatus, Puccinia* spp., and Asian soybean rust (*Phayospora pachyrhizi*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").

(continued)

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons *(continued)*	
Root, tuber, and corm vegetables such as potato, sweet potato, carrot, cassava, beets, ginger, radish, horse-radish[22], ginseng, turnip, and other root, tuber and corm crops.	Black root/crown rot *(Alternaria* spp.) Bacterial leaf blight *(Xanthomonas campestris)* Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Gray mold (*Botrytis* spp.) White mold *(Sclerotinia sclerotiorum)*[2] Black leg /bacterial soft rot *(Erwinia carotovora)*** Early blight *(Alternaria solani)** Late blight *(Phytophthora infestans)** See instructions below for "Soil application" against the following diseases: Black scurf *(Rhizoctonia solani)* Cavity spot (*Pythium* spp.) "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp.
Other vegetables such as sweet corn, popcorn, asparagus, peanut, and watercress	*Botrytis* spp. Rusts (*Puccinia* spp.) White mold *(Sclerotinia sclerotiorum)*[2] Leaf spots (*Cercospora* and *Cercosporidium* spp.)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").
Tree fruits and nuts	
Citrus such as orange, lemon, lime, grapefruit, tangerine (mandarin), tangelo, pummelo, and other citrus	*Alternaria* leaf spot *(Alternaria alternata)* Postbloom fruit drop *(Colletotrichum acutatum)** Greasy spot *(Mycosphaerella citri)**[3] Citrus canker (*Xanthomonas campestris* pv. *citri*)[1] Scab *(Elsinoe fawcetti)**[4] Melanose *(Diaporthe citri)**
Pome fruits such as apple, pear, crabapple, quince, and others	Powdery mildew *(Podosphaera leucotricha)*[5] Scab (*Venturia* spp.)* Flyspeck *(Zygophiala jamaicensis)*[6]** Sooty blotch disease complex[6]** Brooks spot *(Mycosphaerella pomi)*[6]** Bot rot/white rot *(Botryosphaeria dothidea)*[6]** Bitter rot (*Colletotrichum* spp.)[6] Cedar apple rust *(Gymnosporangium juniperi-virginianae)*[6]** Fire blight *(Erwinia amylovora)**[7]
Stone fruits such as apricot, cherry, nectarine, peach, plum, prune, pluot, and others	Powdery mildew (*Sphaerotheca and Podosphaera* spp.)*[8] Bacterial canker (*Pseudomonas* spp.) Brown rot blossom blight *(Monilinia laxa)*[9] Brown rot *(Monilinia fructicola)**[10] Gray mold *(Botrytis cinerea)*[10] Peach leaf curl *(Taphrina deformans)* Bacterial leaf spot *(Xanthomonas arbicola* pv. *pruni)*[1] Rusty spot *(Podosphaera leucotricha)*[1]
Tree nuts such as almond, pistachio, pecan, walnut, filbert, hazelnut, chestnut, macadamia, and other tree nuts.	Walnut blight *(Xanthomonas campestris)*[11] Anthracnose *(Colletotrichum acutatum)** Bacterial canker *(Pseudomonas syringae)* Shot hole *(Wilsonomyces carpophilus)** Brown rot (*Monilinia* spp.)* Pecan scab *(Cladosprium caryigenum)**[1] and**
Pomegranates	Leaf and fruit spots (*Cercospora, Gloeosporium* and *Pestalotia* spp.)[1] Fruit rots (*Alternaria, Botrytis,* and other spp.)[10] Powdery mildew *(Sphaerotheca pannosa)*

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Other fruits	
Strawberry	Powdery mildew *(Sphaerotheca macularis, Erisyphe spp.)**[12] Gray mold *(Botrytis cinerea)**[11] Anthracnose *(Colletotrichum acutatum)* Angular leaf spot *(Xanthomonas fragariae)*[1] For the following diseases, see instructions below for "Soil application" (and also root dip instructions[22]): "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora,* and/or *Verticillium** spp. Charcoal rot *(Macrophomina phaseolina)***
Berries, including blueberry, blackberry, raspberry, loganberry, huckleberry, gooseberry, elderberry, cranberry (non-flooded fields), currant, and other berries	Mummy berry *(Monilinia vaccinii-corymbosi)** Botrytis blight *(Botrytis cinerea)* Bacterial canker (*Pseudomonas* spp.)[13] Anthracnose fruit rot *(Colletotrichum acutatum)*[10]
Grapes including wine grapes, table grapes, and raisins	Powdery mildew *(Erisyphe* (formerly *Uncinula) necator)*[14] Gray mold *(Botrytis cinerea)*[15] Sour rot complex[15] Downy mildew *(Plasmopara viticola)** Phomopsis *(Phomopsis viticola)*[16] Eutypa *(Eutypa lata)*[17]
Tropical fruits such as avocado[18], mango[18], papaya[19], pineapple[19], banana, plantain, and others.	Anthracnose (*Colletotrichum* spp.) Scab *(Spliaceloma perseae)* Bacterial canker *(Xanthomonas campestris)* Sigatoka *(Mycosphaerella fijiensis)*[20]
Other Crops	
Herbs and spices such as basil, thyme, coriander, dill, cilantro, parsley, mint, and others.	Powdery mildews (*Oidium* spp. and others) Downy mildews (*Peronospora* spp. and others)* Damping off diseases (*Rhizoctonia, Pythium, Alternaria,* and *Fusarium* spp.) Leaf spots (*Alternaria, Septoria, Colletotrichum,* and *Cercospora* spp.)* Bacterial diseases (*Erwinia, Xanthomonas,* and *Pseudomonas* spp.) Rusts (*Puccinia* spp. and others) "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora,* and/or *Verticillium** spp. (see instructions below for "Soil application").
Coffee	Coffee berry disease *(Colletotrichum coffeanum)*[1] Coffee rust** *(Hemileia vastatrix)*[1] Anthracnose (*Colletotrichum* spp.) *Botrytis* flower blight *Cercospora* leaf spot** and berry blotch** "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora,* and/or *Verticillium** spp. (see instructions below for "Soil application").

(continued)

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Other fruits *(continued)*	
Tobacco	Angular leaf spot (*Pseudomonas* spp.) Anthracnose (*Colletotrichum* and *Glomerella* spp.) Blue mold or downy mildew (*Peronospora* spp.)* Brown spot *(Alternaria)* Barn spot/ frogeye leaf spot *(Cercospora nicotianae)*[10] Collar rot *(Sclerotinia sclerotiorum)*[2] Gray mold *(Botrytis cinerea)* Powdery mildew *(Erysiphe cichoracearum)* Target spot *(Rhizoctonia solani)* See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Olpidium, Phytophthora,* or *Verticillium** spp. Charcoal rot *(Macrophomina phaseolina)* Black root rot *(Thielaviopsis basicola)* Black shank (*Phytophthora* spp.)* Southern blight/southern stem rot *(Sclerotium rolfsii)**
Mint	Rust (*Puccinia* spp.)
Hops	Powdery mildew *(Sphaerotheca macularis)*[21]

Footnotes:

*Suppression only; for improved control mix or rotate with chemical fungicide approved for such use. **NOT FOR USE IN CALIFORNIA

1 Tank mix or rotate with copper-based fungicides at label rates for improved control.

2 Apply at or immediately following planting (but before plant emergence) as a banded seedline treatment 4 to 6 inches wide. Make second application at thinning or cultivation in sufficient water and multiple nozzles to ensure thorough coverage of lower leaves and surrounding soil surface. Incorporation with light irrigation after application may improve disease control. Repeat at 10-14 day intervals if conditions promoting disease persist.

3 For greasy spot suppression, apply at first new foliar flush and repeat with each new flush. Tank mix with spray oil or copper based fungicide at labeled rates.

4 For suppression of citrus scab, start applications at first new foliage flush and repeat at petal fall and when fruit are ½ inch in diameter.

5 Make first application at or before tight cluster if conditions favor disease development. Repeat at 7-10 day intervals through the second cover spray or longer on susceptible varieties or if environmental conditions favor rapid disease development.

6 Begin applications before bloom when environmental conditions favor disease development, repeating at 7 to 14 day intervals or as needed. Control may be enhanced by addition of a surfactant to improve spray coverage. Use only surfactants known to be safe for use on the crop and for which such use is allowed.

7 Rotate with antibiotics registered for fire blight control for improved performance. Begin applications at 1-5% open blossoms and repeat every 3-7 days as necessary until petal fall, when intervals can be increased to 7 days. Double Nickel 55 can also be used in summer "cover spray" applications to control the shoot blight phase of fire blight and summer diseases. Can be mixed with copper fungicides to improve control.

8 Make first application at popcorn stage and repeat every 7 days.

9 Start applying at early bloom stage and repeat every 7 days through petal fall.

10 Pre-harvest applications in sufficient water to cover fruit or other harvested plant parts may improve control of postharvest infections.

11 Begin applications at or before pistillate bloom, repeating every 7-10 days. Apply before rainfall if possible, and tank mix or rotate with a copper-based bactericide registered for such use for improved control.

12 Start applications at or just before flowering and repeat every 7-10 days as needed through harvest.

(continued)

Footnotes: *(continued)*

13 Apply before fall rains and again during dormancy before spring growth.

14 Start applications when new shoots are ½ to 1½ inches long. Repeat at 3-5 inches, 8-10 inches, and then at 7-10 day intervals until disease conditions no longer exist.

15 Apply at bloom, before bunch closure, at veraison, and before harvest.

16 Apply when shoots are ½ to 1 inch long and again when 6-8 inches long.

17 Mix 2 fluid ounces Double Nickel 55 per gallon of water and apply to pruning wounds.

18 Apply at budbreak and repeat on 14-21 day interval as needed through harvest.

19 Apply at flowering and repeat on 14-21 day interval as needed through harvest

20 Apply at first appearance of leaves and repeat at 7-21 day intervals as needed, in sufficient water to obtain thorough coverage of foliage. Tank mix with spray oil or other registered fungicides for improved control.

21 Mix 6 to 10 fluid ounces Double Nickel 55 per 100 gallons of water and apply in minimum of 20 gallons per acre from emergence to training, 50 gallons per acre from training to wire, and 100 gallons per acre from wire touch through harvest.

22 For treatment of horseradish or strawberry roots immediately before transplanting: immerse bare roots (individually or in bunches) for 10 seconds in a suspension of 1 to 2 pints Double Nickel 55 per gallon of water.

Foliar application: For control of diseases on foliage, flowers, fruit, or other above-ground parts of plants: Mix Double Nickel 55 in water and apply as a spray at a rate of **0.25 to 3 pounds per acre** in sufficient water to achieve thorough coverage of the crop canopy with minimal runoff. Begin applications at crop emergence, transplanting, or when conditions are conducive to development of disease. Repeat application every 7 to 10 days, or as needed, for as long as conditions favor disease development. Lower rates (0.25 to 1 pound per acre) may be applied under light disease pressure, to smaller (e.g. newly-emerged) plants, or when Double Nickel 55 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (1 to 3 pounds per acre), apply more frequently (every 3 to 7 days), and mix or rotate Double Nickel 55 with other fungicides for improved performance.

Soil application: For control of soilborne diseases infecting seeds, seedlings, roots, crown, stems, or other plant parts below ground or in contact with soil: Apply Double Nickel 55 at **0.125 to 1 pound per acre.** Mix the required amount in sufficient water to apply by one of the following methods:

- Soil drench applied to transplants in flats or pots in the greenhouse or nursery any time prior to transplanting (see additional drench instructions under "Nurseries, greenhouses, shade houses, and ornamental plants" below).
- Soil drench at transplanting, using a "water wheel" injector, spray nozzles/hoses, or other method to drench each root ball and/or planting hole.
- Soil or seedline drench, or banded spray (in-furrow) at planting. See the section on "Banded (in-furrow) application" below for additional instructions.

Follow-up (post-planting) preventative applications can be made every 2-4 weeks by one or more of the following methods, if needed:

- Drip (trickle) or any type of sprinkler irrigation, any time after planting or transplanting. See Chemigation Instructions for additional information.
- Spray directly onto the soil surface and/or lower plant parts. If targeting root disease, follow immediately with sufficient overhead sprinkler irrigation to move Double Nickel 55 to the root zone.
- Injection directly into the rooting zone using shanks or similar equipment.

Lower rates (0.125 to 0.5 pounds per acre) may be applied under light disease pressure, to smaller plants, or when Double Nickel 55 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when

environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (0.5 to 1 pound per acre), apply more frequently (every 2 weeks), and mix or rotate Double Nickel 55 with other fungicides for improved performance.

Banded (in-furrow) application: Use the table below to determine the correct application rate of Double Nickel 55 per 1,000 row feet, based on row spacing and desired rate per acre. Mix the required amount of Double Nickel 55 in water and apply as banded spray (4" to 6" wide) or seedline drench centered over the planting furrow. Apply directly over seeds in the furrow just before they are covered with soil. The volume of water required per acre or per 1,000 row feet will depend on the application equipment used. Consult your local cooperative extension service if you need assistance calibrating band spraying equipment.

Rates for banded (in-furrow) application: Find desired application rate in the left column. Read across that line to the correct row spacing indicated at the top to find the number of ounces (dry) per 1,000 row feet that will provide the desired application rate per acre. To convert to **level teaspoons**, multiply the number of ounces by 8.2. For **level tablespoons**, multiply the number of ounces by 2.75.

Rate/acre (pounds)	Space between rows (inches)														
	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
0.25	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3
0.5	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6
0.75	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9
1.0	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.2	1.2
1.25	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.4	1.5	1.5
1.5	0.6	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.7	1.8
1.75	0.6	0.7	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1
2.0	0.7	0.9	1.0	1.1	1.2	1.3	1.5	1.6	1.7	1.8	2.0	2.1	2.2	2.3	2.4
2.25	0.8	1.0	1.1	1.2	1.4	1.5	1.7	1.8	1.9	2.1	2.2	2.3	2.5	2.6	2.8
2.5	0.9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1
2.75	1.0	1.2	1.3	1.5	1.7	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.0	3.2	3.4
3.0	1.1	1.3	1.5	1.7	1.8	2.0	2.2	2.4	2.6	2.8	2.9	3.1	3.3	3.5	3.7

Nurseries, greenhouses, shadehouses, and ornamental plants

Spray application: Mix **0.25 to 3 pounds of Double Nickel 55 per 100 gallons of water** and apply as a foliar spray of sufficient volume to wet the entire plant with minimal runoff. Begin preventative applications at plant emergence and repeat every 3-28 days as needed (every 3-7 days if disease pressure is high or environmental conditions are highly favorable to disease outbreak, 10-28 days under low pressure or less conducive conditions).

Drench application: Mix **0.125 to 2 pounds of Double Nickel 55 per 100 gallons of water** and apply as a drench or coarse spray to soil or other growing media in pots, flats, plugs, trays, or planting beds, for control or suppression of soilborne diseases of seedlings, cuttings, bedding plants, and transplants (including vegetables and other transplanted food crops). Make first application at or immediately before seeding, sticking, germination, or transplanting. Repeat applications every 14-28 days as needed. Transplants can be treated immediately before transplanting into field soils to protect against damping-off and other diseases that reduce plant establishment.

Cutting or root dip: Dip basal end of cuttings or bare roots (individually or in bunches) in a suspension of **1 to 2 pounds of Double Nickel 55 per gallon of water.** Immerse for 5-10 seconds immediately before planting.

Chemigation: Mix **0.125 to 2 pounds of Double Nickel 55 per 100 gallons of water** and apply via drip, handheld, or sprinkler irrigation systems. Refer to "Chemigation Instructions" for more details.

CROPS/USE SITES	DISEASES/PATHOGENS
Indoor, outdoor, and shade- or other cover-grown ornamental trees and shrubs, flowering plants, foliage plants, tropical plants, potted plants, potted or cut flowers, bedding plants, forestry seedlings, conifer production for reforestation, fruit trees, vegetables and other crops grown in greenhouses or nurseries.	Powdery mildews caused by *Erisyphe, Podosphaera, Sphaerotheca, Oidium,* and *Golovinomyces* spp.) Anthracnose (*Colletotrichum* spp.) Bacterial leaf spots caused by *Erwinia, Pseudomonas,* and *Xanthomonas* spp. Damping-off disease (*Rhizoctonia, Pythium, Fusarium* spp.) Late blight, blackeye, and root rots caused by *Phytophthora* spp. Gray mold and blight caused by *Botrytis cinerea* Black root rot (*Aspergillus* spp.) Black spot of roses (*Diplocarpon rosae*) Downy mildew (*Peronospora* spp.) Leaf spots caused by *Alternaria, Septoria, Cercospora, Entomosporium, Helminthosporium,* and *Myrothecium* spp.) Rust (*Puccinia* spp.) Scab (*Venturia* spp.) Root rot, bottom rot, or stem rot caused by *Rhizoctonia solani* *Sclerotinia* blight *Fusarium* wilts

Turfgrass application: For control of foliar diseases, apply Double Nickel 55 at **0.5 to 1 ounce per 1,000 square feet** as a ground-directed spray in sufficient water to provide thorough coverage. To control root and crown diseases in or on the soil, immediately follow the spray with sufficient overhead sprinkler irrigation to move the product into the root zone.

USE SITES/CROPS	DISEASES/PATHOGENS
Turf, sod, lawns, golf course (fairways, roughs, greens, tees), grass seed production Including but not limited to: Bluegrass, Bentgrass, Bermudagrass (common & hybrid), Dichondra, Fescue, Orchardgrass, *Poa annua*, St Augustine grass, Ryegrass, *Zoysia*, mixtures, and other grasses or ornamental turf	Anthracnose *(Colletotrichum graminicola)* Brown patch *(Rhizoctonia solani)* Dollar spot *(Lanzia and Moellerodiscus* spp., formerly *Sclerotinia homeocarpa)* Powdery mildew *(Erisyphe graminis)* Rust *(Puccinia* spp.) Gray leaf spot *(Pyricularia grisea)* "Damping off" or seedling blights caused by *Pythium*

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a dry area inaccessible to children. Store in original containers only. Keep container closed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CHEMIGATION INSTRUCTIONS

General information:

Apply this product only through drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (including impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

Drip (trickle) and micro-irrigation chemigation

1. The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.

Sprinkler chemigation:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.

5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
8. Do not apply when wind speed favors drift beyond the area intended for treatment.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purpose referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the disease problem, condition of the crop, incompatibility with other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

Fee for Service

{9288429~

This package includes the following

- ○ New Registration
- ◉ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ◉ BPPD
- ○ RD

Risk Mgr. 92

Receipt No. S- 928842

EPA File Symbol/Reg. No. 70051-108

Pin-Punch Date: 1/3/2013

☒ This item is NOT subject to FFS action.

Action Code:

Requested: —

Granted: —

Amount Due: $ —

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Shannon Borges Date: 1/10/13

Remarks:

Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046

(301) 604-7340

Fax: 301-604-7015
www.certisusa.com

CERTIS

January 3, 2013

RECEIPT

Address: **U.S. Environmental Protection Agency**
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: **Sheryl K. Reilly, Ph.D.**
Acting Branch Chief, Microbial Pesticide Branch

RE: **CX-9030/EPA Registration Number 70051-108**
Fast-Track Amendment Submission

Mail Enclosures Received by:

Elizabeth Cayle
Signature

1/3/2013 1:09pm
Date and Time

Emailed —

JAN 0 3 2013

Certis USA
9145 Guilford Road
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Columbia, MD 21046

(301) 604-7340

Fax: 301-604-7015
www.certisusa.com

CERTIS

January 3, 2013

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Office of Pesticide Programs
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Arlington, VA 22202-4501

Attn: **Sheryl K. Reilly, Ph.D.**
Acting Branch Chief, Microbial Pesticide Branch

RE: **CX-9030/EPA Registration Number 70051-108**
Fast-Track Amendment Submission

Mail Enclosures Received by:

_____ _____
Signature **Date and Time**

CERTIS

By Courier

December 31, 2012

Sheryl K. Reilly, Ph.D.
Acting Branch Chief, Microbial Pesticide Branch
Biopesticides & Pollution Prevention Division (7504P)
Office of Pesticide Programs
US Environmental Protection Agency

Re: CX-9030/EPA Registration Number 70051-10B/Fast-Track Amendment Submission

Dear Dr. Reilly:

On behalf of Certis U.S.A. L.L.C., (9145 Guilford Road, Suite 175, Columbia, Maryland 21046), I am respectfully submitting the following information to support the amendment for CX-9032:

- EPA Form 8570-1– Application for Pesticide
- Three copies (3) of the revised label
- Copy of the label with highlighted changes
- EPA stamped Notification Label

This label amendment consists of the addition of certain food crops to the EPA stamped accepted food crop sub-label of CX-9032 Master Label. Application rates are within the ranges previously reviewed and accepted by EPA. There are no changes to the First Aid or Precautionary Statements, Personal Protective Equipment (PPE) or Worker Protection required text, or Re-entry Interval (REI) language.

Please do not hesitate to contact me if you have any questions about this submission. I can be reached by email at cdively@certisusa.com or telephone at 301-483-3806.

Sincerely,

Christine A. Dively

Christine A. Dively
Director of Regulatory Affairs
Certis USA

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70051-108	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification ☒ None ☐ Restricted
4. Company/Product (Name) CX-9030	PM# MP8	
5. Name and Address of Applicant *(Include ZIP Code)* Certis U.S.A. L.L.C. 9145 Guilford Road, Suite 175 Columbia, Maryland 21046 ☐ *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

☒ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Addition of crops and corresponding use directions. No change to formulation, REI, Worker Protection language, First Aid or other Precautionary Statements text or Storage and Disposal Statements.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No ** Certification must be submitted*	☐ Yes ☒ No If "Yes" Unit Packaging wgt. / No. per container	☐ Yes ☒ No If "Yes" Package wgt / No. per container	☐ Metal ☐ Plastic ☐ Glass ☒ Paper ☐ Other (Specify) _____

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	5 lbs.	☒ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☒ Other Filed

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Christine A. Dively	Director of Reg. Affairs	301-483-3806

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature Christine A. Dively	3. Title Director of Reg. Affairs
4. Typed Name Christine A. Dively	5. Date December 28, 2012

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

CX-9030

BIOFUNGICIDE

Water Dispersible Granular Biofungicide

FOR ORGANIC PRODUCTION

OMRI Listed

Active Ingredient:

Bacillus amyloliquefaciens strain D747* 25.0%

Other Ingredients 75.0%

Total 100.0%

*Contains a minimum of 5×10^{10} colony-forming units (cfu) per gram

EPA Reg. No. 70051-108
EPA Est. No. 70051-CA-001

Manufactured by: Certis USA, L.L.C.
9145 Guilford Rd., Suite. 175
Columbia, MD 21046

NET WEIGHT: 5 LBS Lot No:

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID - Agricultural Use

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product label with you when calling a poison control center or doctor.
Hot Line No.:1-800-255-3924 for additional information

PRECAUTIONARY STATEMENTS - Agricultural Use

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow manufacturer's instructions for cleaning and maintaining PPE. If no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. AS soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS- Agricultural Use

Do not apply directly to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply when weather conditions favor drift or runoff from treated areas.

GENERAL INFORMATION

CX-9030 is a broad-spectrum preventative biofungicide for control or suppression of fungal and bacterial plant diseases. The active ingredient of CX-9030 is a naturally occurring strain (D747) of the beneficial rhizobacterium *Bacillus amyloliquefaciens*, which colonizes roots, leaves, and other plant surfaces. D747 rapidly colonizes plant root hairs, leaves, and other surfaces, preventing establishment of disease-causing fungi and bacteria.

CX-9030 can be applied alone or in combination and/or rotation with chemical fungicides as a tool for integrated disease management in agricultural crops, ornamental and nursery plants, and turfgrass, in accordance with the most restrictive of those label limitations and precautions. DOUBLE NICKEL 55™ offers a valuable tool for management of resistance to chemical fungicides through its multiple and unique modes of action.

CX-9030 can be applied up to and including the day of harvest.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the State or Tribal Agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: cover-alls, waterproof gloves, shoes plus socks.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses. Keep unprotected persons out of treated areas until sprays have dried.

MIXING AND HANDLING INSTRUCTIONS

Mix the required amount of CX-9030 in cool water with sufficient agitation to maintain a uniform suspension in the spray or mixing tank. Tank should be cleaned prior to use. Do not use highly alkaline or highly acidic water to mix sprays. Use a buffering agent if necessary to maintain neutrality (pH 6 to 8) of water in the tank. Maintain agitation during application. Apply immediately after mixing; do not allow spray mix to stand overnight.

APPLICATION METHODS

Ground: CX-9030 can be applied in most commonly-used ground application equipment, such as tractor-mounted boom, airblast, high clearance, hose-end, backpack, and other pressurized sprayers; hose-end or hand-held sprayers; foggers or mist blowers; water wheel and other drench applicators; and shank or other soil injection method.

Aerial: CX-9030 can be applied by fixed or rotary winged aircraft in a minimum of 3 gallons of water per acre. Standard precautions should be taken to minimize spray drift.

Chemigation: CX-9030 can be applied through drip (trickle) and sprinkler type irrigation equipment. Refer to the section entitled "Chemigation Instructions" for detailed instructions.

Agricultural crops

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons	
Brassica vegetables such as broccoli, cabbage, cauliflower, Brussels sprouts, kohlrabi, and other cole crops (including those grown for seed production).	Pin rot complex (*Alternario/Xanthomonos*)* Leaf spots (*Alternaria* spp., *Xanthomonas* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe polygoni*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Bulb vegetables such as onions, garlic, shallots, and others (including those grown for seed production)	*Botrytis* spp. (neck rot, leaf blight) Purple blotch (*Alternaria* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Rust (*Puccinia porri*)* White rot (*Sclerotium cepivorum*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Cucurbits such as cucumbers, squash (all types), cantaloupes, muskmelons, watermelons, and other melons (including those grown for seed production).	Powdery mildew (*Erisyphe* and *Sphaerotheca* spp.) Downy mildew (*Pseudoperonospora* spp.) Gummy stem blight (*Didymella bryoniae* and *Phoma cucurbitacearum*) See instructions below for "Soil application" against the following diseases: Vine decline (*Monosporascus cannonballus*)** Charcoal rot (*Macrophomina phaseoli*)** "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp.
Fruiting vegetables such as tomatoes, peppers, eggplant, tomatillo, okra, and others (including those grown for seed production).	Bacterial spot (*Xanthomonas* spp.)*[1] Bacterial speck (*Pseudomonas syringae* pv. *tomato*)*[1] Gray mold (*Botrytis cinerea*) Powdery mildew* (*Leveillula, Oidiopsis, Erisyphe*, and *Sphaerotheca* spp.) Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. Southern blight (*Sclerotium rolfsii*)* and**
Leafy vegetables such as head and leaf lettuce, celery, spinach, radicchio, arugula, watercress, and others (including leafy *Brossica* vegetables such as mustard and collard greens, kale, bok choi, and related crops), including those grown for seed production.	Downy mildew (*Bremia lactucae*, *Peronospora* spp.)* Powdery mildew (*Golovinomyces (Erisyphe) cichoracearum*)* Bacterial blights Head and leaf drop (*Sclerotinia* spp.)[2] Pink rot (*Sclerotinio sclerotiorum*)[2] Leaf spots (*Cercospora* spp.) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. Bottom rot (*Rhizoctonia solani*)
Legume vegetables succulent and dried beans and peas such as green, snap, shell, and Lima beans, garbanzo beans, chickpeas, soybeans, dry beans, peas, split peas, lentils, and other legumes, including those grown for seed production.	White mold (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Microsphaera diffusa*) Rusts*, including *Uromyces appendiculatus*, *Puccinia* spp., and Asian soybean rust (*Phayospora pachyrhizi*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Root, tuber, and corm vegetables such as potato, sweet potato, carrot, cassava, beets, ginger, radish, horseradish[22], ginseng, turnip, and other root, tuber and corm crops (including those grown for seed	Black root/crown rot (*Alternaria* spp.) Bacterial leaf blight (*Xanthomonas campestris*) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Gray mold (*Botrytis* spp.) White mold (*Sclerotinia sclerotiorum*)[2]

production).	Black leg /bacterial soft rot (*Erwinia carotovora*)** Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: Black scurf (*Rhizoctonia solani*) Cavity spot (*Pythium* spp.) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusorium*, *Phytophthora*, or *Verticillium** spp.
Other vegetables such as sweet corn, popcorn, asparagus, peanut, and watercress	*Botrytis* spp. Rusts (*Puccinia* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* and *Cercosporidium* spp.)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Tree fruits and nuts	
Citrus such as orange, lemon, lime, grapefruit, tangerine (mandarin), tangelo, pummelo, and other citrus	*Alternaria* leaf spot (*Alternaria alternata*) Postbloom fruit drop (*Colletotrichum acutatum*)* Greasy spot (*Mycosphaerella citri*)*[3] Citrus canker (*Xanthomonas campestris* pv. *citri*)[1] Scab (*Elsinoe fawcetti*)*[4] Melanose (*Diaporthe citri*)*
Pome fruits such as apple, pear, crabapple, quince, and others	Powdery mildew (*Podosphaera leucotricha*)[5] Scab (*Venturia* spp.)* Flyspeck (*Zygophiala jamaicensis*)[6] ** Sooty blotch disease complex[6] ** Brooks spot (*Mycosphaerella pomi*)[6] ** Bot rot/white rot (*Botryosphaeria dothidea*)[6] ** Bitter rot (*Colletotrichum* spp.)[6] Cedar apple rust (*Gymnosporangium juniperi-virginianae*)[6] ** Fire blight (*Erwinia amylovora*)*[7]
Stone fruits such as apricot, cherry, nectarine, peach, plum, prune, pluot, and others	Powdery mildew (*Sphaerotheca* and *Podosphaera* spp.)*[8] Bacterial canker (*Pseudomonas* spp.) Brown rot blossom blight (*Monilinia laxo*)[9] Brown rot (*Monilinia fructicola*)*[10] Gray mold (*Botrytis cinerea*)[10] Peach leaf curl (*Taphrina deformans*) Bacterial leaf spot (*Xanthomonas arbicola* pv. *pruni*)[1] Rusty spot (*Podosphaera leucotricha*)[1]
Tree nuts such as almond, pistachio, pecan, walnut, filbert, hazelnut, chestnut, macadamia, and other tree nuts.	Walnut blight (*Xanthomonas campestris*)[11] Anthraenose (*Colletotrichum acutatum*)* Bacterial canker (*Pseudomonas syringae*) Shot hole (*Wilsonomyces carpophilus*)* Brown rot (*Monilinia* spp.)* Pecan scab (*Cladosprium caryigenum*)*[1] and **
Pomegranates	Leaf and fruit spots (*Cercospora, Gloeosporium* and *Pestalotia* spp.)[1] Fruit rots (*Alternaria, Botrytis*, and other spp.)[10] Powdery mildew (*Sphaerotheca pannosa*)
Other fruits	
Strawberry	Powdery mildew (*Sphaerotheca macularis, Erisyphe* spp.)*[12] Gray mold (*Botrytis cinerea*)*[11] Anthracnose (*Colletotrichum acutatum*) Angular leaf spot (*Xanthomonas fragariae*)[1] For the following diseases, see instructions below for "Soil application" (and also root dip instructions[22]): "Damping off" and root or crown diseases caused by *Rhizoctonia*, *Fusarium*, *Pythium*, *Phytophthora*, and/or *Verticillium** spp. Charcoal rot (*Mocrophomino phoseolina*)**

Berries, including blueberry, blackberry, raspberry, loganberry, huckleberry, kiwifruit, gooseberry, elderberry, cranberry (non-flooded fields), currant, and other berries	Mummy berry (*Manilinia voccinii-coryimbosi*)* Botrytis blight (*Botrytis cinerea*) Bacterial canker (*Pseudomonas* spp.)[13] Anthracnose fruit rot (*Colletotrichum acutotum*)[10] • Sclerotinia (*Sclerotinia sclerotiorum*)
Grapes including wine grapes, table grapes, and raisins	Powdery mildew (*Erisyphe* (formerly *Uncinula*) *necator*)[14] Gray mold (*Botrytis cinerea*)[15] Sour rot complex[15] Downy mildew (*Plasmopara viticola*)* Phomopsis (*Phomapsis viticola*)[16] Eutypa (*Eutypo loto*)[17]
Tropical fruits such as avocado[18], mango[18], papaya[19], pineapple[19], banana, plantain, and others.	Anthracnose (*Colletotrichum* spp.) Scab (*Sphaceloma perseae*) Bacterial canker (*Xanthomonas campestris*) Sigatoka (*Mycosphaerella fijiensis*)[20]
Other Crops	
Herbs and spices such as basil, thyme, coriander, dill, cilantro, parsley, mint, and others (including those grown for seed production).	Powdery mildews (*Oidium* spp. and others) Downy mildews (*Peronospora* spp. and others)* Damping off diseases (*Rhizoctonia, Pythium, Alternaria*, and *Fusarium* spp.) Leaf spots (*Alternoria, Septoria, Colletotrichum*, and *Cercospara* spp.)* Bacterial diseases (*Erwinia, Xanthomonas*, and *Pseudomonas* spp.) Rusts (*Puccinia* spp. and others) "Damping off" and root or crown diseases caused by *Rhizoctonio, Fusarium, Pythium, Phytophthoro*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Coffee	Coffee berry disease (*Colletotrichum coffeanum*)[1] Coffee rust (*Hemileia vostatrix*)[1] Anthracnose (*Colletotrichum* spp.) *Botrytis* flower blight *Cercospara* leaf spot and berry blotch "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Tobacco	Angular leaf spot (*Pseudomonns* spp.) Anthracnose (*Colletotrichum* and *Glomerella* spp.) Blue mold or downy mildew (*Peranospora* spp.)* Brown spot (*Alternaria*) Barn spot/ frogeye leaf spot (*Cerrcospora nicotianoe*)[10] Collar rot (*Sclerotinia sicerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Erysiphe cichorocearum*) Target spot (*Rhizoctonia solani*) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Olpidium, Phytophthoro*, or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*) Black root rot (*Thielaviopsis bosicola*) Black shank (*Phytophthoro* spp.)* Southern blight/southern stem rot (*Sclerotium rolfsii*)*
Corn, including field corn, sweet corn, popcorn, sileage corn, seed corn, and other corn crops.	Commmon rust (*Puccinia sorghi*)* Southern leaf blight (*Bipoloris maydis/Cochliobolus heterastrophus/Helminthosporium maydis*)
Cereal grains, such as barley, millet, oats, rice, rye, sorghum, triticale, wheat, and other cereal grain crops (including those grown for seed).	Powdery mildew (*Erysiphe graminis*) Rust (*Puccinia* spp.)* Rice blast (*Pyriculario oryzae*) Sheath spot/blight (*Rhizoctonia* and *Thanatephorus* spp.) Smut (*Tilletia barclayona*) Bacterial blight/streak (*Xanthomonos* spp.) Stem rots (*Magnoparthe* and *Sclerotium* spp.) *Cercospora* leaf spot Brown rot/leaf spots/smuts (*Ceratobasidium, Cochliobolus, Dreschlera*, and *Entyloma* spp.)

Oilseed crops, including canola, castor, coconut, cotton, flax, oil palm, olive, peanut, rapeseed, safflower, sesame, sunflower, soybeans, and other oilseed crops, including those grown for seed production.	White mold/Stem rot (*Sclerotinia sclerotiorum*) Rusts*, including *Uromyces appendiculatus*, *Puccinia* spp., and Asian soybean rust (*Phayaspora pachyrhizi*) Bacterial Speck (*Pseudamonas syringae* pv.*glycinea*) Bacterial Pustule (*Xanthamonas* spp.) Brown Spot (*Septoria glycines*) *Cercospora* Leaf Spot Pod and Stem Blights (*Diaporthe* and *Phomopsis* spp.) Downy Mildew (*Peranospora mansherica*)
Mint	Rust (*Puccinia* spp.)
Hops	Powdery mildew (*Sphaerotheca macularis*)[21]
Mushrooms	Green mold (*Trichoderma harzianum*)*
Sugar beets (including crops grown for seed production)	Leaf spots (*Cercospora* and *Ramularia* spp.) Powdery mildew (*Erysiphe* spp.) Rust (*Uromyces betae*)

Footnotes:

*Suppression only; for improved control mix or rotate with chemical fungicide approved for such use. ****NOT FOR USE IN CALIFORNIA"**

[1] Tank mix or rotate with copper-based fungicides at label rates for improved control.

[2] Apply at or immediately following planting (but before plant emergence) as a banded seedline treatment 4 to 6 inches wide. Make second application at thinning or cultivation in sufficient water and multiple nozzles to ensure thorough coverage of lower leaves and surrounding soil surface. Incorporation with light irrigation after application may improve disease control. Repeat at 10-14 day intervals if conditions promoting disease persist.

[3] For greasy spot suppression, apply at first new foliar flush and repeat with each new flush. Tank mix with spray oil or copper based fungicide at labeled rates.

[4] For suppression of citrus scab, start applications at first new foliage flush and repeat at petal fall and when fruit are ½ inch in diameter.

[5] Make first application at or before tight cluster if conditions favor disease development. Repeat at 7-10 day intervals through the second cover spray or longer on susceptible varieties or if environmental conditions favor rapid disease development.

[6] Begin applications before bloom when environmental conditions favor disease development, repeating at 7 to 14 day intervals or as needed. Control may be enhanced by addition of a surfactant to improve spray coverage. Use only surfactants known to be safe for use on the crop and for which such use is allowed.

[7] Rotate with antibiotics registered for fire blight control for improved performance. Begin applications at 1-5% open blossoms and repeat every 3-7 days as necessary until petal fall, when intervals can be increased to 7 days. Double Nickel 55™ can also be used in summer "cover spray" applications to control the shoot blight phase of fire blight and summer diseases. Can be mixed with copper fungicides to improve control.

[8] Make first application at popcorn stage and repeat every 7 days.

[9] Start applying at early bloom stage and repeat every 7 days through petal fall.

[10] Pre-harvest applications in sufficient water to cover fruit or other harvested plant parts may improve control of postharvest infections.

[11] Begin applications at or before pistillate bloom, repeating every 7-10 days. Apply before rainfall if possible, and tank mix or rotate with a copper-based bactericide registered for such use for improved control.

[12] Start applications at or just before flowering and repeat every 7-10 days as needed through harvest.

[13] Apply before fall rains and again during dormancy before spring growth.

[14] Start applications when new shoots are ½ to 1½ inches long. Repeat at 3-5 inches, 8-10 inches, and then at 7-10 day intervals until disease conditions no longer exist.

[15] Apply at bloom, before bunch closure, at veraison, and before harvest.

[16] Apply when shoots are ½ to 1 inch long and again when 6-8 inches long.

[13] Mix 1 ounce Double Nickel 55™ per gallon of water and apply to pruning wounds.

[18] Apply at budbreak and repeat on 14-21 day interval as needed through harvest.

[19] Apply at flowering and repeat on 14-21 day interval as needed through harvest

[20] Apply at first appearance of leaves and repeat at 7-21 day intervals as needed, in sufficient water to obtain thorough coverage of foliage. Tank mix with spray oil or other registered fungicides for improved control.

[21] Mix 0.5-1 lb Double Nickel 55™ per 100 gallons of water and apply in minimum of 20 gallons per acre form emergence to training, 50 gallons per acre from training to wire, and 100 gallons per acre from wire touch through harvest.

[22] For treatment of horseradish or strawberry roots immediately before transplanting: immerse bare roots (individually or in bunches) for 10 seconds in a suspension of 2-4 ounces Double Nickel 55™ per gallon of water.

Foliar application: For control of diseases on foliage, flowers, fruit, or other above-ground parts of plants: Mix CX-9030 in water and apply as a spray at a rate of **0.25 to 3 pounds per acre** in sufficient water to achieve thorough coverage of the crop canopy with minimal runoff. Begin applications at crop emergence, transplanting, or when conditions are conducive to development of disease. Repeat application every 7 to 10 days, or as needed, for as long as conditions favor disease development. Lower rates (0.25 to 1 pound per acre) may be applied under light disease pressure, to smaller (e.g. newly-emerged) plants, or when CX-9030 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (1 to 3 pounds per acre), apply more frequently (every 3 to 7 days), and mix or rotate CX-9030 with other fungicides for improved performance.

Soil application: For control of soilborne diseases infecting seeds, seedlings, roots, crown, stems, or other plant parts below ground or in contact with soil: Apply CX-9030 at **0.125 to 1 pound per acre**. Mix the required amount in sufficient water to apply by one of the following methods:

- Soil drench applied to transplants in flats or pots in the greenhouse or nursery any time prior to transplanting (see additional drench instructions under "Nurseries, greenhouses, shade houses, and ornamental plants" below).
- Soil drench at transplanting, using a "water wheel" injector, spray nozzles/hoses, or other method to drench each root ball and/or planting hole.
- Soil or seedline drench, or banded spray (in-furrow) at planting. See the section on "Banded (in-furrow) application" below for additional instructions.

Follow-up (post-planting) preventative applications can be made every 2-4 weeks by one or more of the following methods, if needed:

- Drip (trickle) or any type of sprinkler irrigation, any time after planting or transplanting. See Chemigation Instructions for additional information.
- Spray directly onto the soil surface and/or lower plant parts. If targeting root disease, follow immediately with sufficient overhead sprinkler irrigation to move CX-9030 to the root zone.
- Injection directly into the rooting zone using shanks or similar equipment.

Lower rates (0.125 to 0.5 pounds per acre) may be applied under light disease pressure, to smaller plants, or when CX-9030 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (0.5 to 1 pound per acre), apply more frequently (every 2 weeks), and mix or rotate CX-9030 with other fungicides for improved performance.

Banded (in-furrow) application: Use the table below to determine the correct application rate ofCX-9030 per 1,000 row feet, based on row spacing and desired rate per acre. Mix the required amount of DOUBLE CX-9030 in water and apply as banded spray (4" to 6" wide) or seedline drench centered over the planting furrow. Apply directly over seeds in the furrow just before they are covered with soil. The volume of water required per acre or per 1,000 row feet will depend on the application equipment used. Consult your local cooperative extension service if you need assistance calibrating band spraying equipment.

Rates for banded (in-furrow) application: Find desired application rate of CX-9032 per acre in the left column. Read across that line to the correct row spacing indicated at the top to find the number of fluid ounces per 1,000 row feet that will provide the desired application rate per acre.

Rate/acre		Space between rows (inches)														
Pints	fl oz	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
0.5	8	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6
0.75	12	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9
1.0	16	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.2	1.2
1.25	20	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.4	1.5	1.5
1.5	24	0.6	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.7	1.8
1.75	28	0.6	0.7	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1
2.0	32	0.7	0.9	1.0	1.1	1.2	1.3	1.5	1.6	1.7	1.8	2.0	2.1	2.2	2.3	2.4
2.25	36	0.8	1.0	1.1	1.2	1.4	1.5	1.7	1.8	1.9	2.1	2.2	2.3	2.5	2.6	2.8
2.5	40	0.9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1
2.75	44	1.0	1.2	1.3	1.5	1.7	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.0	3.2	3.4
3.0	48	1.1	1.3	1.5	1.7	1.8	2.0	2.2	2.4	2.6	2.8	2.9	3.1	3.3	3.5	3.7
3.25	52	1.2	1.4	1.6	1.8	2.0	2.2	2.4	2.6	2.8	3.0	3.2	3.4	3.6	3.8	4.0
3.5	56	1.3	1.5	1.7	1.9	2.1	2.4	2.6	2.8	3.0	3.2	3.4	3.6	3.9	4.1	4.3
3.75	60	1.4	1.6	1.8	2.1	2.3	2.5	2.8	3.0	3.2	3.4	3.7	3.9	4.1	4.4	4.6
4.0	64	1.5	1.7	2.0	2.2	2.4	2.7	2.9	3.2	3.4	3.7	3.9	4.2	4.4	4.7	4.9
4.25	68	1.6	1.8	2.1	2.3	2.6	2.9	3.1	3.4	3.6	3.9	4.2	4.4	4.7	4.9	5.2
4.5	72	1.7	1.9	2.2	2.5	2.8	3.0	3.3	3.6	3.9	4.1	4.4	4.7	5.0	5.2	5.5

Mushrooms

Mushrooms spawn grains: Mix **2 to 4 pounds of CX-9030** with 80 – 100 pounds of gypsum, limestone, or chalk. Coat approximately 1,600 units of spawn grains using this mixture before mixing the spawn into the mushroom growing substrate. Apply treated spawn to approx. 8,000 square feet of bed surface at spawning.

Mushroom growing supplement: Mix **2 to 4 pounds of CX-9030** with 80 – 100 pounds of gypsum, limestone, or chalk. Coat approximately 2,000 pounds of supplement using this mixture before mixing the supplement into the mushroom growing substrate. Apply treated supplement to approx. 8,000 square feet of bed surface at spawning.

Mushroom growing beds: Mix **1 to 3 pounds of CX-9030** per 100 gallons of irrigation water and apply as a drench at approximately 20 gallons per 1,000 square feet of bed surface (1 gallon of drench will treat approximately 50 square feet). Maintain sufficient agitation/circulation in the irrigation to ensure uniform mixing. Depending on disease pressure, apply at one or more of the following timings: before first flush, between first and second flush, and/or between second and third flush.

Nurseries, greenhouses, shadehouses, and ornamental plants:

Spray application: Mix **0.25 to 3 pounds of CX-9030 per 100 gallons of water** and apply as a foliar spray of sufficient volume to wet the entire plant with minimal runoff. Begin preventative applications at plant emergence and repeat every 3-28 days as needed (every 3-7 days if disease pressure is high or

environmental conditions are highly favorable to disease outbreak, 10-28 days under low pressure or less conducive conditions).

Drench application: Mix **0.125 to 2 pounds of CX-9030 per 100 gallons of water** and apply as a drench or coarse spray to soil or other growing media in pots, flats, plugs, trays, or planting beds, for control or suppression of soilborne diseases of seedlings, cuttings, bedding plants, and transplants (including vegetables and other transplanted food crops). Make first application at or immediately before seeding, sticking, germination, or transplanting. Repeat applications every 14-28 days as needed. Transplants can be treated immediately before transplanting into field soils to protect against damping-off and other diseases that reduce plant establishment.

Cutting or root dip: Dip basal end of cuttings or bare roots (individually or in bunches) in a suspension of **1 to 2 pounds of CX-9030 per gallon of water**. Immerse for 5-10 seconds immediately before planting.

Chemigation: Mix **0.125 to 2 pounds of CX-9030 per 100 gallons of water** and apply via drip, handheld, or sprinkler irrigation systems. Refer to "Chemigation Instructions" for more details.

CROPS/USE SITES	DISEASES/PATHOGENS
Indoor, outdoor, and shade- or other cover-grown ornamental trees and shrubs, flowering plants, foliage plants, tropical plants, potted plants, potted or cut flowers, bedding plants, forestry seedlings, conifer production for reforestation, fruit trees, vegetables and other crops grown in greenhouses or nurseries.	Powdery mildews caused by *Erisyphe, Podosphaera, Sphaerotheca, Oidium,* and *Golovinomyces* spp.) Anthracnose (*Colletotrichum* spp.) Bacterial leaf spots caused by *Erwinia, Pseudomonas,* and *Xanthomonas* spp. Damping-off disease (*Rhizoctonia, Pythium, Fusarium* spp.) Late blight, blackeye, and root rots caused by *Phytophthora* spp. Gray mold and blight caused by *Botrytis cinerea* Black root rot (*Aspergillus* spp.) Black spot of roses (*Diplocarpon rosae*) Downy mildew (*Peronospora* spp.) Leaf spots caused by *Alternaria, Septoria, Cercospora, Entomosporium, Helminthosporium,* and *Myrothecium* spp.) Rust (*Puccinia* spp.) Scab (*Venturia* spp.) Root rot, bottom rot, or stem rot caused by *Rhizoctonia solani* *Sclerotinia* blight *Fusarium* wilts

Turfgrass application: For control of foliar diseases, apply CX-9030 at **0.5 to 1 ounce per 1,000 square feet** as a ground-directed spray in sufficient water to provide thorough coverage. To control root and crown diseases in or on the soil, immediately follow the spray with sufficient overhead sprinkler irrigation to move the product into the root zone.

USE SITES/CROPS	DISEASES/PATHOGENS
Turf, sod, lawns, golf course (fairways, roughs, greens, tees), grass seed production Including but not limited to: Bluegrass, Bentgrass, Bermudagrass (common & hybrid), Dichondra, Fescue, Orchardgrass, *Poa annua*, St. Augustine grass, Ryegrass, *Zoysia*, mixtures, and other grasses or ornamental turf	Anthracnose (*Colletotrichum graminicola*) Brown patch (*Rhizoctonia solani*) Dollar spot (*Lanzia* and *Moellerodiscus* spp., formerly *Sclerotinia homeocarpa*) Powdery mildew (*Erisyphe graminis*) Rust (*Puccinia* spp.) Gray leaf spot (*Pyricularia grisea*) "Damping off" or seedling blights caused by *Pythium*

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a dry area inaccessible to children. Store in original containers only. Keep container closed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CHEMIGATION INSTRUCTIONS

General information:

Apply this product only through drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (including impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

Drip (trickle) and micro-irrigation chemigation:

1. The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.

Sprinkler chemigation:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
8. Do not apply when wind speed favors drift beyond the area intended for treatment.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purpose referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the disease problem, condition of the crop, incompatibility with other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OFCHEMICAL
SAFETY AND POLUTION
PREVENTION

March 13, 2013

I, Kimberly Nesci, Microbial Pesticides Branch, Biopesticides & Pollution Prevention Division, Office of Pesticide Programs, Office of Chemical Safety and Polution Prevention, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., Guatemala) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

Certis Usa, LLC
9145 Guilford Road, Suite 175
Columbia, MD 21046

EPA Registration Number: 70051-108
Name of Product: CX-9030

Kimberly Nesci
Risk Manager 92
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division
(7511P)

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(7511P)

Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046

(301) 604-7340

Fax: 301-604-7015
www.certisusa.com

March, 4 2013

Document Processing Desk (REGFEE)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard Room S-4900
2777 South Crystal Drive
Arlington, VA 22202
Attn: Ms. Betty Williams

Re: Certis USA L.L.C. Request for Gold Seals (PRIA 3 Category: M006) KN

Dear Ms. Williams,

On behalf of Certis USA L.L.C., I am respectfully requesting Gold Seal Certification Letters for the registered pesticide product CX-9030 (EPA Registration No. 70051-108). Please display the alternate brand name AMYLO-X on the Gold Seal. I am requesting the maximum number of Gold Seals (5) covered by one PRIA fee. The Gold Seals will be to support registration activity of Amylo-X in the following countries:

1. Dominican Republic
2. Colombia
3. Ecuador
4. Panamá
5. Guatemala

Included with this submission are the following documents:

- 8570-5 Form
- EPA Approved Notification Label dated July 27, 2012
- CX-9030 Stamped Approved label displaying the ABN Amylo-X
- Credit card receipt as proof of payment

Please note- This PRIA payment was made on January 28th, 2013. The payment appeared to not have completed, and the submission was never made. The Certis credit card statement received recently shows proof of this payment being processed. We would like to apply the payment made on January 28th to this submission.

Please return the Gold Seal Letters to my attention, at the address on this letterhead.

If you have any questions about this submission, I can be reached by telephone at 301-483-3810, or by email at sgallager@certisusa.com.

Sincerely,

Susan Gallager

Susan Gallager
Regulatory Affairs Associate

CC: Christine A. Dively
Director of Regulatory Affairs

Transaction Date:	01/30/2013 Wed
Transaction Description:	EPA 000000002 WASHINGTON DC 999999930 74404033523 20460 01/29/19 Fees ROC NUMBER 999999303000009
Amount $:	250.00
Doing Business As:	FIFRA SERVICE FEES
Merchant Address:	1200 PENNSYLVANIA AVE NW WASHINGTON DC 20460 UNITED STATES
Reference Number:	005398720130130
Category:	Other - Government Services

Original payment attempt made on January 28, 2013.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70051-108	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) CX-9030	PM# Microbial Pesticides Branch	
5. Name and Address of Applicant *(Include ZIP Code)* Certis USA L.L.C. 9145 Guilford Road, Suite 175, Columbia MD 21046 [ ] *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Request for five (5) Certificates of Registration (Gold Seal Letters)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes*	[ ] Yes	[ ] Yes	[ ] Metal
[X] No	[X] No	[X] No	[X] Plastic
			[ ] Glass
			[ ] Paper
			[ ] Other (Specify) _____
	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

** Certification must be submitted*

3. Location of Net Contents Information [X] Label [ ] Container	4. Size(s) Retail Container 5 lbs	5. Location of Label Directions [X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [X] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Christine A. Dively	Director of Reg. Affairs	301-483-3806

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature Christine A. Dively	3. Title Director of Regulatory Affairs
4. Typed Name Christine A. Dively	5. Date Jan 24, 2013

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (Original) Yellow - Applicant Copy

Receipt for Section 3

S: 931902

Resubmission: Yes No

Regulatory Type: Product Registration - Section 3

Fee For Service: Yes No

Application Type: Amendment

Billable: Yes No

Company: 70051 CERTIS USA, LLC

Print Letter

Enter More Information

Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92

Product #: 70051-108 Product Name: CX-9030

Overrides:

Me Too Section3: Me Too Product Name:

Application Date: 04-Mar-2013 OPP Rec'vd Date: 05-Mar-2013

Front End Date: 05-Mar-2013 Risk Manager Send Date: 07-Mar-2013

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Receipt Content	Des
Other	Gold Seal

Fast Track: New Ingredient:

View/Edit

Receipt Description:

Gold Seal Certificate

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date: Form B: Signature Date:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 7, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-475927
EPA File Symbol or Registration Number: 70051-108
Product Name: CX-9030
EPA Receipt Date: 05-Mar-2013
EPA Company Number: 70051
Company Name: CERTIS USA, LLC

CHRISTINE A. DIVELY
CERTIS USA, LLC
9145 GUILFORD ROAD, SUITE 175
COLUMBIA, MD 21046

SUBJECT: Receipt of Request for Gold Seal Certification Letter(s)

Dear Registrant:

The Office of Pesticide Programs has received your request for Gold Seal Certification letter(s) that is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The action has been identified as action code M006:

UP TO 5 GOLD SEAL CERTIFICATION LETTERS PER REGISTRATION

No additional payment is due at this time. If you have any questions, please contact Betty Williams at (703) 308-0132.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Material Sent for Data Extraction

Reg. # 70051-108

Description: Notification

☑ Material(s) Sent to Data Extraction Contractors:

- ☐ New Stamped Label Dated _____
- ☑ Notification Dated 6/8/12 (pen-punched)
- ☐ New CSF(s) Dated _____
- ☐ Other: _____

☑ Decision #: 466360

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Susanne Cervelli

Phone: 703-308-8077 Division: BPPD

Date: 7/27/12

FW: 70051-108 Copy of notification
Dively, Chris
to:
Susanne Cerrelli
07/30/2012 12:11 PM
Cc:
"Dively, Chris", Alan Reynolds
Hide Details
From: "Dively, Chris" <cdively@certisusa.com>

To: Susanne Cerrelli/DC/USEPA/US@EPA

Cc: "Dively, Chris" <cdively@certisusa.com>, Alan Reynolds/DC/USEPA/US@EPA

1 Attachment

DNstampedLabelDPR.cd07122012.pdf

Hi Susanne,
I know that you are not in the office today, but I thought I would go ahead and send the final print label for Double Nickel that I sent to you on Friday last. This label has the text Not For Use in California" as indicated by DPR (and you stamped as a Notification), but the text "Hawaii Only" opposite coffee, has been deleted so that the label is identical to the EPA stamped label. We do not need this text, and wanted to be consistent with the label that is currently in channels of trade (except in CA at the moment). No need to file an amendment, but want to make sure this is the label that is in PPLS. If I need to file another Notification deleting the "Hawaii only" text I can do so...hope that I don't but can send electronically if you need??

Thanks for your help and I apologize again for any misunderstanding.

Regards,
Chris

From: Dively, Chris
Sent: Friday, July 27, 2012 1:32 PM

To: 'Susanne Cerrelli'
Subject: RE: 70051-108 Copy of notification

Hi Susanne,
This is the final print label for Double Nickel incorporating the " Not For Use in California" with asteriks text, but we have deleted the reference to Hawaii only for Coffee. This text was not on the EPA stamped label and it is now the commercial label that we have on product in channels of trade. Rather than change, we have just stuck with the same text as on the stamped label.

Please let me know if you need anything from me such as a letter stating that we would like to delete the Hawaii only text in the previous Notification request, or can we not use this text anyway because it is not on the stamped label? I am hoping that we can just do this electronically.

Thanks for your answer and I apologize .....wasn't aware of the change back to the original label text for the coffee entry.

Regards and have a good week-end.

From: Susanne Cerrelli [mailto:Cerrelli.Susanne@epamail.epa.gov]
Sent: Friday, July 27, 2012 9:00 AM
To: Dively, Chris
Subject: Fw: 70051-108 Copy of notification

Here is a copy of what you requested a while ago.

Regards,

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)
---- Forwarded by Susan

Please open the attached document. This document was digitally sent to you using an HP Digital Sending device. *(See attached file: [Untitled].pdf)*

Rhodes

DoubleNickel55™

BIOFUNGICIDE

Water Dispersible Granular Biofungicide

FOR ORGANIC PRODUCTION

OMRI™ Listed
Organic Materials Review Institute

Active Ingredient:
Bacillus amyloliquefaciens strain D747* 25.0%
Other Ingredients: 75.0%
Total 100.0%
*Contains a minimum of 5×10^{10} colony-forming units (cfu) per gram

Net Contents: 5 Pounds
EPA Reg. No. 70051-108
EPA Est. No. 70051-CA-001
Lot No:

Manufactured by:
Certis USA, L.L.C.
9145 Guilford Rd, Suite 175
Columbia, MD 21046

CERTIS

Complies with EPA Accepted Labeling
AUG - 2 2012
Date: _____
Reviewer: _____

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID - Agricultural Use
If in eyes: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product label with you when calling a poison control center or doctor.

Hot Line No.: 1-800-255-3924 for additional information

PRECAUTIONARY STATEMENTS - Agricultural Use
HAZARDS TO HUMANS & DOMESTIC ANIMALS
CAUTION: Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)
Applicators and other handlers must wear:
- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow manufacturer's instructions for cleaning and maintaining PPE. If no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS
Users should:
- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS - Agricultural Use
Do not apply directly to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply when weather conditions favor drift or runoff from treated areas.

GENERAL INFORMATION
Double Nickel 55 is a broad-spectrum preventative biofungicide for control or suppression of fungal and bacterial plant diseases. The active ingredient of Double Nickel 55 is a naturally occurring strain (D747) of the beneficial rhizobacterium *Bacillus amyloliquefaciens*, which colonizes roots, leaves, and other plant surfaces. D747 rapidly colonizes plant root hairs, leaves, and other surfaces, preventing establishment of disease-causing fungi and bacteria.

Double Nickel 55 can be applied alone or in combination and/or rotation with chemical fungicides as a tool for integrated disease management in agricultural crops, ornamental and nursery plants, and turfgrass, in accordance with the most restrictive of those label limitations and precautions. Double Nickel 55 offers a valuable tool for management of resistance to chemical fungicides through its multiple and unique modes of action.

Double Nickel 55 can be applied up to and including the day of harvest.

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the State or Tribal Agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

AGRICULTURAL USE REQUIREMENTS
Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: cover-alls, waterproof gloves, shoes plus socks.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

NON-AGRICULTURAL USE REQUIREMENTS
The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses. Keep unprotected persons out of treated areas until sprays have dried.

MIXING AND HANDLING INSTRUCTIONS
Mix the required amount of Double Nickel 55 in cool water with sufficient agitation to maintain a uniform suspension in the spray or mixing tank. Tank should be cleaned prior to use. Do not use highly alkaline or highly acidic water to mix sprays. Use a buffering agent if necessary to maintain neutrality (pH 6 to 8) of water in the tank. Maintain agitation during application. Apply immediately after mixing; do not allow spray mix to stand overnight.

APPLICATION METHODS
Ground: Double Nickel 55 can be applied in most commonly-used ground application equipment, such as tractor-mounted boom, airblast, high clearance, hose-end, backpack, and other pressurized sprayers; hose-end or hand-held sprayers; foggers or mist blowers; water wheel and other drench applicators; and shank or other soil injection method.

Aerial: Double Nickel 55 can be applied by fixed or rotary winged aircraft in a minimum of 3 gallons of water per acre. Standard precautions should be taken to minimize spray drift.

Chemigation: Double Nickel 55 can be applied through drip (trickle) and sprinkler type irrigation equipment. Refer to the section entitled "Chemigation Instructions" for detailed instructions.

Agricultural crops

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons	
Brassica vegetables such as broccoli, cabbage, cauliflower, Brussels sprouts, kohlrabi, and other cole crops.	Pin rot complex (*Alternaria/Xanthomonas*)* Leaf spots (*Alternaria* spp., *Xanthomonas* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe polygoni*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").

(continued)

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons *(continued)*	
Bulb vegetables such as onions, garlic, shallots, and others.	*Botrytis* spp. (neck rot, leaf blight) Purple blotch (*Alternaria* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Rust (*Puccinia porri*)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").
Cucurbits such as cucumbers, squash (all types), cantaloupes, muskmelons, watermelons, and other melons.	Powdery mildew (*Erisyphe and Sphaerotheca* spp.) Downy mildew (*Pseudoperonospora* spp.) Gummy stem blight (*Didymella bryoniae* and *Phoma cucurbitacearum*) See instructions below for "Soil application" against the following diseases: Vine decline (*Monosporascus cannonbalus*)** Charcoal rot (*Macrophomina phaseoli*)** "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp.
Fruiting vegetables such as tomatoes, peppers, eggplant, tomatillo, okra, and others.	Bacterial spot (*Xanthomonas* spp.)*[1] Bacterial speck (*Pseudomonas syringae* pv. *tomato*)*[1] Gray mold (*Botrytis cinerea*) Powdery mildew* (*Leveillula, Oidiopsis, Erisyphe,* and *Sphaerotheca* spp.) Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. Southern blight (*Sclerotium rolfsii*)* and**
Leafy vegetables such as head and leaf lettuce, celery, spinach, radicchio, arugula, watercress, and others (including leafy Brassica vegetables such as mustard and collard greens, kale, bok choi, and related crops).	Downy mildew (*Bremia lactucae, Peronospora* spp.)* Powdery mildew (*Golovinomyces (Erisyphe) cichoracearum*)* Bacterial blights Head and leaf drop (*Sclerotinia* spp.)[2] Pink rot (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* spp.) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. Bottom rot (*Rhizoctonia solani*)
Legume vegetables succulent and dried beans and peas such as green, snap, shell, and Lima beans, garbanzo beans, chickpeas, soybeans, dry beans, peas, split peas, lentils, and other legumes.	White mold (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Microsphaera diffusa*) Rusts*, including *Uromyces appendiculatus, Puccinia* spp., and Asian soybean rust (*Phayospora pachyrhizi*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").

(continued)

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons *(continued)*	
Root, tuber, and corm vegetables such as potato, sweet potato, carrot, cassava, beets, ginger, radish, horse-radish[22], ginseng, turnip, and other root, tuber end corm crops.	Black root/crown rot (*Alternaria* spp.) Bacterial leaf blight (*Xanthomonas campestris*) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Gray mold (*Botrytis* spp.) White mold (*Sclerotinia sclerotiorum*)[1] Black leg /bacterial soft rot (*Erwinia carotovora*)** Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: Black scurf (*Rhizoctonia solani*) Cavity spot (*Pythium* spp.) "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp.
Other vegetables such as sweet corn, popcorn, asparagus, peanut, and watercress	*Botrytis* spp. Rusts (*Puccinia* spp.) White mold (*Sclerotinia sclerotiorum*)[1] Leaf spots (*Cercospora* and *Cercosporidium* spp.)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").
Tree fruits and nuts	
Citrus such as orange, lemon, lime, grapefruit, tangerine (mandarin), tangelo, pummelo, and other citrus	*Alternaria* leaf spot (*Alternaria alternata*) Postbloom fruit drop (*Colletotrichum acutatum*)* Greasy spot (*Mycosphaerella citri*)*[3] Citrus canker (*Xanthomonas campestris* pv. *citri*)[1] Scab (*Elsinoe fawcetti*)*[1] Melanose (*Diaporthe citri*)*
Pome fruits such as apple, pear, crabapple, quince, and others	Powdery mildew (*Podosphaera leucotricha*)[5] Scab (*Venturia* spp.)* Flyspeck (*Zygophiala jamaicensis*)[5]** Sooty blotch disease complex[5]** Brooks spot (*Mycosphaerella pomi*)[5]** Bot rot/white rot (*Botryosphaeria dothidea*)[5]** Bitter rot (*Colletotrichum* spp.)[5] Cedar apple rust (*Gymnosporangium juniperi-virginianae*)[5]** Fire blight (*Erwinia amylovora*)*[1]
Stone fruits such as apricot, cherry, nectarine, peach, plum, prune, pluot, and others	Powdery mildew (*Sphaerotheca* and *Podosphaera* spp.)*[6] Bacterial canker (*Pseudomonas* spp.) Brown rot blossom blight (*Monilinia laxa*)[9] Brown rot (*Monilinia fructicola*)*[10] Gray mold (*Botrytis cinerea*)[10] Peach leaf curl (*Taphrina deformans*) Bacterial leaf spot (*Xanthomonas arboricola* pv. *pruni*)[1] Rusty spot (*Podosphaera leucotricha*)[1]
Tree nuts such as almond, pistachio, pecan, walnut, filbert, hazelnut, chestnut, macadamia, and other tree nuts.	Walnut blight (*Xanthomonas campestris*)[11] Anthracnose (*Colletotrichum acutatum*)* Bacterial canker (*Pseudomonas syringae*) Shot hole (*Wilsonomyces carpophilus*)* Brown rot (*Monilinia* spp.)* Pecan scab (*Cladosprium caryigenum*)*[1] and**
Pomegranates	Leaf and fruit spots (*Cercospora, Gloeosporium* and *Pestalotia* spp.)[1] Fruit rots (*Alternaria, Botrytis,* and other spp.)[10] Powdery mildew (*Sphaerotheca pannosa*)

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Other fruits	
Strawberry	Powdery mildew (*Sphaerotheca macularis, Erisyphe spp.*)*[12] Gray mold (*Botrytis cinerea*)*[1] Anthracnose (*Colletotrichum acutatum*) Angular leaf spot (*Xanthomonas fragariae*)[1] For the following diseases, see instructions below for "Soil application" (and also root dip instructions[22]): "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora,* and/or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*)**
Berries, including blueberry, blackberry, raspberry, loganberry, huckleberry, gooseberry, elderberry, cranberry (non-flooded fields), currant, and other berries	Mummy berry (*Monilinia vaccinii-corymbosi*)* Botrytis blight (*Botrytis cinerea*) Bacterial canker (*Pseudomonas* spp.)[13] Anthracnose fruit rot (*Colletotrichum acutatum*)[10]
Grapes including wine grapes, table grapes, and raisins	Powdery mildew (*Erisyphe* (formerly *Uncinula*) *necator*)[1] Gray mold (*Botrytis cinerea*)[15] Sour rot complex[15] Downy mildew (*Plasmopara viticola*)* Phomopsis (*Phomopsis viticola*)[16] Eutypa (*Eutypa lata*)[17]
Tropical fruits such as avocado[18], mango[11], papaya[19], pineapple[19], banana, plantain, and others.	Anthracnose (*Colletotrichum* spp.) Scab (*Sphaceloma perseae*) Bacterial canker (*Xanthomonas campestris*) Sigatoka (*Mycosphaerella fijiensis*)[20]
Other Crops	
Herbs and spices such as basil, thyme, coriander, dill, cilantro, parsley, mint, and others.	Powdery mildews (*Oidium* spp. and others) Downy mildews (*Peronospora* spp. and others)* Damping off diseases (*Rhizoctonia, Pythium, Alternaria,* and *Fusarium* spp.) Leaf spots (*Alternaria, Septoria, Colletotrichum,* and *Cercospora* spp.)* Bacterial diseases (*Erwinia, Xanthomonas,* and *Pseudomonas* spp.) Rusts (*Puccinia* spp. and others) "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora,* and/or *Verticillium** spp. (see instructions below for "Soil application").
Coffee	Coffee berry disease (*Colletotrichum coffeanum*)[1] Coffee rust** (*Hemileia vastatrix*)[1] Anthracnose (*Colletotrichum* spp.) Botrytis flower blight Cercospora leaf spot** and berry blotch** "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora,* and/or *Verticillium** spp. (see instructions below for "Soil application").

(continued)

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Other fruits *(continued)*	
Tobacco	Angular leaf spot (*Pseudomonas* spp.) Anthracnose (*Colletotrichum* and *Glomerella* spp.) Blue mold or downy mildew (*Peronospora* spp.)* Brown spot (*Alternaria*) Barn spot/ frogeye leaf spot (*Cercospora nicotianae*)[10] Collar rot (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Erysiphe cichoracearum*) Target spot (*Rhizoctonia solani*) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Olpidium*, *Phytophthora*, or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*) Black root rot (*Thielaviopsis basicola*) Black shank (*Phytophthora* spp.)* Southern blight/southern stem rot (*Sclerotium rolfsii*)*
Mint	Rust (*Puccinia* spp.)
Hops	Powdery mildew (*Sphaerotheca macularis*)[21]

Footnotes:

*Suppression only; for improved control mix or rotate with chemical fungicide approved for such use. **NOT FOR USE IN CALIFORNIA

1 Tank mix or rotate with copper-based fungicides at label rates for improved control.

2 Apply at or immediately following planting (but before plant emergence) as a banded seedline treatment 4 to 6 inches wide. Make second application at thinning or cultivation in sufficient water and multiple nozzles to ensure thorough coverage of lower leaves and surrounding soil surface. Incorporation with light irrigation after application may improve disease control. Repeat at 10-14 day intervals if conditions promoting disease persist.

3 For greasy spot suppression, apply at first new foliar flush and repeat with each new flush. Tank mix with spray oil or copper based fungicide at labeled rates.

4 For suppression of citrus scab, start applications at first new foliage flush and repeat at petal fall and when fruit are ½ inch in diameter.

5 Make first application at or before light cluster if conditions favor disease development. Repeat at 7-10 day intervals through the second cover spray or longer on susceptible varieties or if environmental conditions favor rapid disease development.

6 Begin applications before bloom when environmental conditions favor disease development, repeating at 7 to 14 day intervals or as needed. Control may be enhanced by addition of a surfactant to improve spray coverage. Use only surfactants known to be safe for use on the crop and for which such use is allowed.

7 Rotate with antibiotics registered for fire blight control for improved performance. Begin applications at 1-5% open blossoms and repeat every 3-7 days as necessary until petal fall, when intervals can be increased to 7 days. Double Nickel 55 can also be used in summer "cover spray" applications to control the shoot blight phase of fire blight and summer diseases. Can be mixed with copper fungicides to improve control.

8 Make first application at popcorn stage and repeat every 7 days.

9 Start applying at early bloom stage and repeat every 7 days through petal fall.

10 Pre-harvest applications in sufficient water to cover fruit or other harvested plant parts may improve control of postharvest infections.

11 Begin applications at or before pistillate bloom, repeating every 7-10 days. Apply before rainfall if possible, and tank mix or rotate with a copper-based bactericide registered for such use for improved control.

17 Start applications at or just before flowering and repeat every 7-10 days as needed through harvest.

(continued)

Footnotes: *(continued)*

13 Apply before fall rains and again during dormancy before spring growth.

14 Start applications when new shoots are ½ to 1½ inches long. Repeat at 3-5 inches, 9-10 inches, and then at 7-10 day intervals until disease conditions no longer exist.

15 Apply at bloom, before bunch closure, at veraison, and before harvest.

16 Apply when shoots are ½ to 1 inch long and again when 6-8 inches long.

17 Mix 2 fluid ounces Double Nickel 55 per gallon of water and apply to pruning wounds.

18 Apply at budbreak and repeat on 14-21 day interval as needed through harvest.

19 Apply at flowering and repeat on 14-21 day interval as needed through harvest

20 Apply at first appearance of leaves and repeat at 7-21 day intervals as needed, in sufficient water to obtain thorough coverage of foliage. Tank mix with spray oil or other registered fungicides for improved control.

21 Mix 6 to 10 fluid ounces Double Nickel 55 per 100 gallons of water and apply in minimum of 20 gallons per acre from emergence to training, 50 gallons per acre from training to wire, and 100 gallons per acre from wire touch through harvest.

22 For treatment of horseradish or strawberry roots immediately before transplanting: immerse bare roots (individually or in bunches) for 10 seconds in a suspension of 1 to 2 pints Double Nickel 55 per gallon of water.

Foliar application: For control of diseases on foliage, flowers, fruit, or other above-ground parts of plants: Mix Double Nickel 55 in water and apply as a spray at a rate of 0.25 to 3 pounds per acre in sufficient water to achieve thorough coverage of the crop canopy with minimal runoff. Begin applications at crop emergence, transplanting, or when conditions are conducive to development of disease. Repeat application every 7 to 10 days, or as needed, for as long as conditions favor disease development. Lower rates (0.25 to 1 pound per acre) may be applied under light disease pressure, to smaller (e.g. newly-emerged) plants, or when Double Nickel 55 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (1 to 3 pounds per acre), apply more frequently (every 3 to 7 days), and mix or rotate Double Nickel 55 with other fungicides for improved performance.

Soil application: For control of soilborne diseases infecting seeds, seedlings, roots, crown, stems, or other plant parts below ground or in contact with soil: Apply Double Nickel 55 at 0.125 to 1 pound per acre. Mix the required amount in sufficient water to apply by one of the following methods:

- Soil drench applied to transplants in flats or pots in the greenhouse or nursery any time prior to transplanting (see additional drench instructions under "Nurseries, greenhouses, shade houses, and ornamental plants" below).
- Soil drench at transplanting, using a "water wheel" injector, spray nozzles/hoses, or other method to drench each root ball and/or planting hole.
- Soil or seedline drench, or banded spray (in-furrow) at planting. See the section on "Banded (in-furrow) application" below for additional instructions.

Follow-up (post-planting) preventative applications can be made every 2-4 weeks by one or more of the following methods, if needed:

- Drip (trickle) or any type of sprinkler irrigation, any time after planting or transplanting. See Chemigation Instructions for additional information.
- Spray directly onto the soil surface and/or lower plant parts. If targeting root disease, follow immediately with sufficient overhead sprinkler irrigation to move Double Nickel 55 to the root zone.
- Injection directly into the rooting zone using shanks or similar equipment.

Lower rates (0.125 to 0.5 pounds per acre) may be applied under light disease pressure, to smaller plants, or when Double Nickel 55 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when

environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (0.5 to 1 pound per acre), apply more frequently (every 2 weeks), and mix or rotate Double Nickel 55 with other fungicides for improved performance.

Banded (in-furrow) application: Use the table below to determine the correct application rate of Double Nickel 55 per 1,000 row feet, based on row spacing and desired rate per acre. Mix the required amount of Double Nickel 55 in water and apply as banded spray (4" to 6" wide) or seedline drench centered over the planting furrow. Apply directly over seeds in the furrow just before they are covered with soil. The volume of water required per acre or per 1,000 row feet will depend on the application equipment used. Consult your local cooperative extension service if you need assistance calibrating band spraying equipment.

Rates for banded (in-furrow) application: Find desired application rate in the left column. Read across that line to the correct row spacing indicated at the top to find the number of ounces (dry) per 1,000 row feet that will provide the desired application rate per acre. To convert to level teaspoons, multiply the number of ounces by 8.2. For level tablespoons, multiply the number of ounces by 2.75.

Rate/acre (pounds)	Space between rows (inches)														
	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
0.25	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3
0.5	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6
0.75	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9
1.0	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.2	1.2
1.25	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.4	1.5	1.5
1.5	0.6	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.7	1.8
1.75	0.6	0.7	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1
2.0	0.7	0.9	1.0	1.1	1.2	1.3	1.5	1.6	1.7	1.8	2.0	2.1	2.2	2.3	2.4
2.25	0.8	1.0	1.1	1.2	1.4	1.5	1.7	1.8	1.9	2.1	2.2	2.3	2.5	2.9	2.8
2.5	0.9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1
2.75	1.0	1.2	1.3	1.5	1.7	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.0	3.2	3.4
3.0	1.1	1.3	1.5	1.7	1.8	2.0	2.2	2.4	2.6	2.8	2.9	3.1	3.3	3.5	3.7

Nurseries, greenhouses, shadehouses, and ornamental plants

Spray application: Mix 0.25 to 3 pounds of Double Nickel 55 per 100 gallons of water and apply as a foliar spray of sufficient volume to wet the entire plant with minimal runoff. Begin preventative applications at plant emergence and repeat every 3-28 days as needed (every 3-7 days if disease pressure is high or environmental conditions are highly favorable to disease outbreak, 10-26 days under low pressure or less conducive conditions).

Drench application: Mix 0.125 to 2 pounds of Double Nickel 55 per 100 gallons of water and apply as a drench or coarse spray to soil or other growing media in pots, flats, plugs, trays, or planting beds, for control or suppression of soilborne diseases of seedlings, cuttings, bedding plants, and transplants (including vegetables and other transplanted food crops). Make first application at or immediately before seeding, sticking, germination, or transplanting. Repeat applications every 14-28 days as needed. Transplants can be treated immediately before transplanting into field soils to protect against damping-off and other diseases that reduce plant establishment.

Cutting or root dip: Dip basal end of cuttings or bare roots (individually or in bunches) in a suspension of 1 to 2 pounds of Double Nickel 55 per gallon of water. Immerse for 5-10 seconds immediately before planting.

Chemigation: Mix 0.125 to 2 pounds of Double Nickel 55 per 100 gallons of water and apply via drip, handheld, or sprinkler irrigation systems. Refer to "Chemigation Instructions" for more details.

CROPS/USE SITES	DISEASES/PATHOGENS
Indoor, outdoor, and shade- or other cover-grown ornamental trees and shrubs, flowering plants, foliage plants, tropical plants, potted plants, potted or cut flowers, bedding plants, forestry seedlings, conifer production for reforestation, fruit trees, vegetables and other crops grown in greenhouses or nurseries.	Powdery mildews caused by *Erisyphe, Podosphaera, Sphaerotheca, Oidium,* and *Golovinomyces* spp.) Anthracnose (*Colletotrichum* spp.) Bacterial leaf spots caused by *Erwinia, Pseudomonas,* and *Xanthomonas* spp. Damping-off disease (*Rhizoctonia, Pythium, Fusarium* spp.) Late blight, blackeye, and root rots caused by *Phytophthora* spp. Gray mold and blight caused by *Botrytis cinerea* Black root rot (*Aspergillus* spp.) Black spot of roses (*Diplocarpon rosea*) Downy mildew (*Peronospora* spp.) Leaf spots caused by *Alternaria, Septoria, Cercospora, Entomosporium, Helminthosporium,* and *Myrothecium* spp.) Rust (*Puccinia* spp.) Scab (*Venturia* spp.) Root rot, bottom rot, or stem rot caused by *Rhizoctonia solani* Sclerotinia blight Fusarium wilts

Turfgrass application: For control of foliar diseases, apply Double Nickel 55 at 0.5 to 1 ounce per 1,000 square feet as a ground-directed spray in sufficient water to provide thorough coverage. To control root and crown diseases in or on the soil, immediately follow the spray with sufficient overhead sprinkler irrigation to move the product into the root zone.

USE SITES/CROPS	DISEASES/PATHOGENS
Turf, sod, lawns, golf course (fairways, roughs, greens, tees), grass seed production including but not limited to: Bluegrass, Bentgrass, Bermudagrass (common & hybrid), Dichondra, Fescue, Orchardgrass, *Poa annua*, St. Augustine grass, Ryegrass, *Zoysia*, mixtures, and other grasses or ornamental turf	Anthracnose *(Colletotrichum graminicola)* Brown patch *(Rhizoctonia solani)* Dollar spot *(Lanzia and Moellerodiscus spp., formerly Sclerotinia homeocarpa)* Powdery mildew *(Erisyphe graminis)* Rust *(Puccinia spp.)* Gray leaf spot *(Pyricularia grisea)* "Damping off" or seedling blights caused by *Pythium*

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a dry area inaccessible to children. Store in original containers only. Keep container closed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CHEMIGATION INSTRUCTIONS

General Information:

Apply this product only through drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (including impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

Drip (trickle) and micro-irrigation chemigation

1. The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.

Sprinkler chemigation:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.

5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
8. Do not apply when wind speed favors drift beyond the area intended for treatment.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purpose referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the disease problem, condition of the crop, incompatibility with other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

LABELING ACCEPTABLE
STATE OF CALIFORNIA
DEPARTMENT OF PESTICIDE REGULATION
PESTICIDE REGISTRATION
Date 7/9/12 Reviewer Rhodes
Reg. No. 70051-108-AA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JUL 27 2012

Christine A Dively
Certis USA
9145 Guiford Road
Suite 175
Columbia, MD 21046

RE: Product Name: Double Nickel 55
EPA Reg. No: 70051-108
Application for Notification request dated June 7, 2012 for Revision to add text "Not Approved for use in California" and "Hawaii only" for Specific Use sites

Dear Ms. Dively:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticides Registration Notice (PRN) 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the letter submitted with this application has been stamped "Notification, received and accepted" and will be placed accordingly in our records.

Questions concerning this action should be directed to Susanne Cerrelli (703) 308-8077 or email at cerrelli.susanne@epa.gov.

Sincerely,

Alan Reynolds,
Acting Branch Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)

CONCURRENCES

SYMBOL ►	7511P	7511P						
SURNAME ►	Cerrelli	Reynolds						
DATE ►	7/26/12	7/26/12						

EPA Form 1320-1A (1/90)

OFFICIAL FILE COPY

Double Nickel 55™

BIOFUNGICIDE

Water Dispersible Granular Biofungicide

FOR ORGANIC PRODUCTION

OMRI Listed

Active Ingredient:

Bacillus amyloliquefaciens strain D747* 25.0%

Other Ingredients 75.0%

Total 100.0%

*Contains a minimum of 5×10^{10} colony-forming units (cfu) per gram

EPA Reg. No. 70051-108
EPA Est. No. 70051-CA-001

Manufactured by: Certis USA, L.L.C.
9145 Guilford Rd., Suite. 175
Columbia, MD 21046

NET WEIGHT: 5 LBS Lot No:

Notification Accepted
Date: JUL 19 2012
Reviewer: Susanne Cerulli

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID - Agricultural Use

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product label with you when calling a poison control center or doctor.
Hot Line No.:1-800-255-3924 for additional information

PRECAUTIONARY STATEMENTS - Agricultural Use

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow manufacturer's instructions for cleaning and maintaining PPE. If no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. AS soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS- Agricultural Use

Do not apply directly to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply when weather conditions favor drift or runoff from treated areas.

GENERAL INFORMATION

DOUBLE NICKEL 55™ is a broad-spectrum preventative biofungicide for control or suppression of fungal and bacterial plant diseases. The active ingredient of DOUBLE NICKEL 55™ is a naturally occurring strain (D747) of the beneficial rhizobacterium *Bacillus amyloliquefaciens*, which colonizes roots, leaves, and other plant surfaces. D747 rapidly colonizes plant root hairs, leaves, and other surfaces, preventing establishment of disease-causing fungi and bacteria.

DOUBLE NICKEL 55™ can be applied alone or in combination and/or rotation with chemical fungicides as a tool for integrated disease management in agricultural crops, ornamental and nursery plants, and turfgrass, in accordance with the most restrictive of those label limitations and precautions. DOUBLE NICKEL 55™ offers a valuable tool for management of resistance to chemical fungicides through its multiple and unique modes of action.

DOUBLE NICKEL 55™ can be applied up to and including the day of harvest.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the State or Tribal Agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: cover-alls, waterproof gloves, shoes plus socks.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses. Keep unprotected persons out of treated areas until sprays have dried.

MIXING AND HANDLING INSTRUCTIONS

Mix the required amount of DOUBLE NICKEL 55™ in cool water with sufficient agitation to maintain a uniform suspension in the spray or mixing tank. Tank should be cleaned prior to use. Do not use highly alkaline or highly acidic water to mix sprays. Use a buffering agent if necessary to maintain neutrality (pH 6 to 8) of water in the tank. Maintain agitation during application. Apply immediately after mixing; do not allow spray mix to stand overnight.

APPLICATION METHODS

Ground: DOUBLE NICKEL 55™ can be applied in most commonly-used ground application equipment, such as tractor-mounted boom, airblast, high clearance, hose-end, backpack, and other pressurized sprayers; hose-end or hand-held sprayers; foggers or mist blowers; water wheel and other drench applicators; and shank or other soil injection method.

Aerial: DOUBLE NICKEL 55™ can be applied by fixed or rotary winged aircraft in a minimum of 3 gallons of water per acre. Standard precautions should be taken to minimize spray drift.

Chemigation: DOUBLE NICKEL 55™ can be applied through drip (trickle) and sprinkler type irrigation equipment. Refer to the section entitled "Chemigation Instructions" for detailed instructions.

Agricultural crops

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons	
Brassica vegetables such as broccoli, cabbage, cauliflower, Brussels sprouts, kohlrabi, and other cole crops.	Pin rot complex (*Alternaria/Xanthomonas*)* Leaf spots (*Alternaria* spp., *Xanthomonas* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe polygoni*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Bulb vegetables such as onions, garlic, shallots, and others.	*Botrytis* spp. (neck rot, leaf blight) Purple blotch (*Alternaria* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Rust (*Puccinia pori*)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Cucurbits such as cucumbers, squash (all types), cantaloupes, muskmelons, watermelons, and other melons.	Powdery mildew (*Erisyphe* and *Sphaerotheca* spp.) Downy mildew (*Pseudoperonospora* spp.) Gummy stem blight (*Didymella bryoniae* and *Phoma cucurbitacearum*) See instructions below for "Soil application" against the following diseases: Vine decline (*Monosporascus cannonballus*)** Charcoal rot (*Macrophomina phaseoli*)** "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp.
Fruiting vegetables such as tomatoes, peppers, eggplant, tomatillo, okra, and others.	Bacterial spot (*Xanthomonas* spp.)*[1] Bacterial speck (*Pseudomonas syringae* pv. *tomato*)*[1] Gray mold (*Botrytis cinerea*) Powdery mildew* (*Leveillula*, *Oidiopsis*, *Erisyphe*, and *Sphaerotheca* spp.) Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. Southern blight (*Sclerotium rolfsii*)* and**
Leafy vegetables such as head and leaf lettuce, celery, spinach, radicchio, arugula, watercress, and others (including leafy *Brassica* vegetables such as mustard and collard greens, kale, bok choi, and related crops).	Downy mildew (*Bremia lactucae*, *Peronospora* spp.)* Powdery mildew (*Golovinomyces (Erisyphe) cichoracearum*)* Bacterial blights Head and leaf drop (*Sclerotinia* spp.)[2] Pink rot (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* spp.) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. Bottom rot (*Rhizoctonia solani*)
Legume vegetables succulent and dried beans and peas such as green, snap, shell, and Lima beans, garbanzo beans, chickpeas, soybeans, dry beans, peas, split peas, lentils, and other legumes.	White mold (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Microsphaera diffusa*) Rusts*, including *Uromyces appendiculatus*, *Puccinia* spp., and Asian soybean rust (*Phayosporo pachyrhizi*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Root, tuber, and corm vegetables such as potato, sweet potato, carrot, cassava, beets, ginger, radish, horseradish[22], ginseng, turnip, and other root, tuber and corm crops.	Black root/crown rot (*Alternaria* spp.) Bacterial leaf blight (*Xanthomonas campestris*) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Gray mold (*Botrytis* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Black leg /bacterial soft rot (*Erwinia carotovora*)**

	Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: Black scurf (*Rhizoctonia solani*) Cavity spot (*Pythium* spp.) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp.
Other vegetables such as sweet corn, popcorn, asparagus, peanut, and watercress	*Botrytis* spp. Rusts (*Puccinia* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* and *Cercosporidium* spp.)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Tree fruits and nuts	
Citrus such as orange, lemon, lime, grapefruit, tangerine (mandarin), tangelo, pummelo, and other citrus	*Alternaria* leaf spot (*Alternaria alternata*) Postbloom fruit drop (*Colletotrichum acutatum*)* Greasy spot (*Mycosphaerella citri*)*[3] Citrus canker (*Xanthomonas campestris* pv. *citri*)[1] Scab (*Elsinoe fawcetti*)*[4] Melanose (*Diaporthe citri*)*
Pome fruits such as apple, pear, crabapple, quince, and others	Powdery mildew (*Podosphaera leucotricha*)[5] Scab (*Venturia* spp.)* Flyspeck (*Zygophiala jamaicensis*)[6] ** Sooty blotch disease complex[6] ** Brooks spot (*Mycosphoerella pomi*)[6] ** Bot rot/white rot (*Botryosphaeria dothideo*)[6] ** Bitter rot (*Colletotrichum* spp.)[6] Cedar apple rust (*Gymnosporangium juniperi-virginianae*)[6] ** Fire blight (*Erwinia amylovora*)*[7]
Stone fruits such as apricot, cherry, nectarine, peach, plum, prune, pluot, and others	Powdery mildew (*Sphaerotheca* and *Podosphaera* spp.)*[8] Bacterial canker (*Pseudomonas* spp.) Brown rot blossom blight (*Monilinia laxa*)[9] Brown rot (*Monilinia fructicola*)*[10] Gray mold (*Botrytis cinerea*)[10] Peach leaf curl (*Taphrina deformans*) Bacterial leaf spot (*Xanthomonas arbicola* pv. *pruni*)[1] Rusty spot (*Podosphaera leucotricha*)[1]
Tree nuts such as almond, pistachio, pecan, walnut, filbert, hazelnut, chestnut, macadamia, and other tree nuts.	Walnut blight (*Xonthomonas campestris*)[11] Anthracnose (*Colletotrichum acutatum*)* Bacterial canker (*Pseudomonas syringae*) Shot hole (*Wilsonomyces carpophilus*)* Brown rot (*Monilinia* spp.)* Pecan scab (*Cladosprium caryigenum*)*[1] and **
Pomegranates	Leaf and fruit spots (*Cercospora*, *Gloeosporium* and *Pestalotia* spp.)[1] Fruit rots (*Alternaria*, *Botrytis*, and other spp.)[10] Powdery mildew (*Sphaerotheca pannosa*)
Other fruits	
Strawberry	Powdery mildew (*Sphaerotheca macularis*, *Erisyphe* spp.)*[12] Gray mold (*Botrytis cinerea*)*[11] Anthracnose (*Colletotrichum acutatum*) Angular leaf spot (*Xanthomonas fragariae*)[1] For the following diseases, see instructions below for "Soil application" (and also root dip instructions[22]): "Damping off" and root or crown diseases caused by *Rhizoctonia*, *Fusarium*, *Pythium*, *Plytophthora*, and/or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*)**

Berries, including blueberry, blackberry, raspberry, loganberry, huckleberry, gooseberry, elderberry, cranberry (non-flooded fields), currant, and other berries	Mummy berry (*Monilinia vaccinii-corymbosi*)* Botrytis blight (*Botrytis cinerea*) Bacterial canker (*Pseudomonos* spp.)[13] Anthracnose fruit rot (*Colletotrichum acutotum*)[10]
Grapes including wine grapes, table grapes, and raisins	Powdery mildew (*Erisyphe* (formerly *Uncinula*) *necator*)[14] Gray mold (*Botrytis cinerea*)[15] Sour rot complex[15] Downy mildew (*Plasmoparo viticola*)* Phomopsis (*Phamopsis viticola*)[16] Eutypa (*Eutypa lata*)[17]
Tropical fruits such as avocado[18], mango[18], papaya[19], pineapple[19], banana, plantain, and others.	Anthracnose (*Colletotrichum* spp.) Scab (*Sphaceloma perseoe*) Bacterial canker (*Xanthomonas campestris*) Sigatoka (*Mycosphaerella fijiensis*)[20]
Other Crops	
Herbs and spiecs such as basil, thyme, coriander, dill, cilantro, parsley, mint, and others.	Powdery mildews (*Oidium* spp. and others) Downy mildews (*Peronospora* spp. and others)* Damping off diseases (*Rhizoctonio, Pythium, Alternario*, and *Fusorium* spp.) Leaf spots (*Alternaria, Septoria, Colletotrichum*, and *Cercospora* spp.)* Bacterial diseases (*Erwinio, Xanthomonas*, and *Pseudomonos* spp.) Rusts (*Puccinia* spp. and others) "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Coffee (Hawaii only)	Coffee berry disease (*Colletotrichum coffeanum*)[1] Coffee rust (*Hemileio vastotrix*)[1] Anthracnose (*Colletotrichum* spp.) *Botrytis* flower blight *Cercospora* leaf spot and berry blotch "Damping off" and root or crown diseases caused by *Rhizoctonio, Fusorium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Tobacco	Angular leaf spot (*Pseudomonas* spp.) Anthracnose (*Colletotrichum* and *Glomerella* spp.) Blue mold or downy mildew (*Peronospora* spp.)* Brown spot (*Alternoria*) Barn spot/ frogeye leaf spot (*Cerrcospora nicotianae*)[10] Collar rot (*Sclerotinia slcerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Erysiphe cichoracearum*) Target spot (*Rhizoctonia solani*) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Olpidium, Phytophthoro*, or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*) Black root rot (*Thielaviopsis basicola*) Black shank (*Phytophthora* spp.)* Southern blight/southern stem rot (*Sclerotium rolfsii*)*
Mint	Rust (*Puccinia* spp.)
Hops	Powdery mildew (*Sphaerotheco macularis*)[21]

Footnotes:

*Suppression only; for improved control mix or rotate with chemical fungicide approved for such use. **NOT FOR USE IN CALIFORNIA

[1] Tank mix or rotate with copper-based fungicides at label rates for improved control.

[2] Apply at or immediately following planting (but before plant emergence) as a banded seedline treatment 4 to 6 inches wide. Make second application at thinning or cultivation in sufficient water and multiple nozzles to ensure thorough coverage of lower leaves and surrounding soil surface. Incorporation with light irrigation after application may improve disease control. Repeat at 10-14 day intervals if conditions promoting disease persist.

[3] For greasy spot suppression, apply at first new foliar flush and repeat with each new flush. Tank mix with spray oil or copper based fungicide at labeled rates.

[4] For suppression of citrus scab, start applications at first new foliage flush and repeat at petal fall and when fruit are ½ inch in diameter.

[5] Make first application at or before tight cluster if conditions favor disease development. Repeat at 7-10 day intervals through the second cover spray or longer on susceptible varieties or if environmental conditions favor rapid disease development.

[6] Begin applications before bloom when environmental conditions favor disease development, repeating at 7 to 14 day intervals or as needed. Control may be enhanced by addition of a surfactant to improve spray coverage. Use only surfactants known to be safe for use on the crop and for which such use is allowed.

[7] Rotate with antibiotics registered for fire blight control for improved performance. Begin applications at 1-5% open blossoms and repeat every 3-7 days as necessary until petal fall, when intervals can be increased to 7 days. Double Nickel 55™ can also be used in summer "cover spray" applications to control the shoot blight phase of fire blight and summer diseases. Can be mixed with copper fungicides to improve control.

[8] Make first application at popcorn stage and repeat every 7 days.

[9] Start applying at early bloom stage and repeat every 7 days through petal fall.

[10] Pre-harvest applications in sufficient water to cover fruit or other harvested plant parts may improve control of postharvest infections.

[11] Begin applications at or before pistillate bloom, repeating every 7-10 days. Apply before rainfall if possible, and tank mix or rotate with a copper-based bactericide registered for such use for improved control.

[12] Start applications at or just before flowering and repeat every 7-10 days as needed through harvest.

[13] Apply before fall rains and again during dormancy before spring growth.

[14] Start applications when new shoots are ½ to 1½ inches long. Repeat at 3-5 inches, 8-10 inches, and then at 7-10 day intervals until disease conditions no longer exist.

[15] Apply at bloom, before bunch closure, at veraison, and before harvest.

[16] Apply when shoots are ½ to 1 inch long and again when 6-8 inches long.

[17] Mix 2 fluid ounces Double Nickel 55™ per gallon of water and apply to pruning wounds.

[18] Apply at budbreak and repeat on 14-21 day interval as needed through harvest.

[19] Apply at flowering and repeat on 14-21 day interval as needed through harvest

[20] Apply at first appearance of leaves and repeat at 7-21 day intervals as needed, in sufficient water to obtain thorough coverage of foliage. Tank mix with spray oil or other registered fungicides for improved control.

[21] Mix 6 to10 fluid ounces Double Nickel 55™ per 100 gallons of water and apply in minimum of 20 gallons per acre form emergence to training, 50 gallons per acre from training to wire, and 100 gallons per acre from wire touch through harvest.

[22] For treatment of horseradish or strawberry roots immediately before transplanting: immerse bare roots (individually or in bunches) for 10 seconds in a suspension of 1 to 2 pints Double Nickel 55™ per gallon of water.

Foliar application: For control of diseases on foliage, flowers, fruit, or other above-ground parts of plants: Mix DOUBLE NICKEL 55™ in water and apply as a spray at a rate of **0.25 to 3 pounds per acre** in sufficient water to achieve thorough coverage of the crop canopy with minimal runoff. Begin applications at crop emergence, transplanting, or when conditions are conducive to development of disease. Repeat application every 7 to 10 days, or as needed, for as long as conditions favor disease development. Lower rates (0.25 to 1 pound per acre) may be applied under light disease pressure, to smaller (e.g. newly-emerged) plants, or when DOUBLE NICKEL 55™ is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (1 to 3 pounds per acre), apply more frequently (every 3 to 7 days), and mix or rotate DOUBLE NICKEL 55™ with other fungicides for improved performance.

Soil application: For control of soilborne diseases infecting seeds, seedlings, roots, crown, stems, or other plant parts below ground or in contact with soil: Apply DOUBLE NICKEL 55™ at **0.125 to 1 pound per acre**. Mix the required amount in sufficient water to apply by one of the following methods:

- Soil drench applied to transplants in flats or pots in the greenhouse or nursery any time prior to transplanting (see additional drench instructions under "Nurseries, greenhouses, shade houses, and ornamental plants" below).
- Soil drench at transplanting, using a "water wheel" injector, spray nozzles/hoses, or other method to drench each root ball and/or planting hole.
- Soil or seedline drench, or banded spray (in-furrow) at planting. See the section on "Banded (in-furrow) application" below for additional instructions.

Follow-up (post-planting) preventative applications can be made every 2-4 weeks by one or more of the following methods, if needed:

- Drip (trickle) or any type of sprinkler irrigation, any time after planting or transplanting. See Chemigation Instructions for additional information.
- Spray directly onto the soil surface and/or lower plant parts. If targeting root disease, follow immediately with sufficient overhead sprinkler irrigation to move DOUBLE NICKEL 55™ to the root zone.
- Injection directly into the rooting zone using shanks or similar equipment.

Lower rates (0.125 to 0.5 pounds per acre) may be applied under light disease pressure, to smaller plants, or when DOUBLE NICKEL 55™ is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (0.5 to 1 pound per acre), apply more frequently (every 2 weeks), and mix or rotate DOUBLE NICKEL 55™ with other fungicides for improved performance.

Banded (in-furrow) application: Use the table below to determine the correct application rate of DOUBLE NICKEL 55™ per 1,000 row feet, based on row spacing and desired rate per acre. Mix the required amount of DOUBLE NICKEL 55™ in water and apply as banded spray (4" to 6" wide) or seedline drench centered over the planting furrow. Apply directly over seeds in the furrow just before they are covered with soil. The volume of water required per acre or per 1,000 row feet will depend on the application equipment used. Consult your local cooperative extension service if you need assistance calibrating band spraying equipment.

Rates for banded (in-furrow) application: Find desired application rate in the left column. Read across that line to the correct row spacing indicated at the top to find the number of ounces (dry) per 1,000 row feet that will provide the desired application rate per acre. To convert to **level teaspoons**, multiply the number of ounces by 8.2. For **level tablespoons**, multiply the number of ounces by 2.75.

Rate/acre	Space between rows (inches)														
(pounds)	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
0.25	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3
0.5	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6
0.75	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9
1.0	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.2	1.2
1.25	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.4	1.5	1.5
1.5	0.6	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.7	1.8
1.75	0.6	0.7	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1
2.0	0.7	0.9	1.0	1.1	1.2	1.3	1.5	1.6	1.7	1.8	2.0	2.1	2.2	2.3	2.4
2.25	0.8	1.0	1.1	1.2	1.4	1.5	1.7	1.8	1.9	2.1	2.2	2.3	2.5	2.6	2.8
2.5	0.9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1
2.75	1.0	1.2	1.3	1.5	1.7	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.0	3.2	3.4
3.0	1.1	1.3	1.5	1.7	1.8	2.0	2.2	2.4	2.6	2.8	2.9	3.1	3.3	3.5	3.7

Nurseries, greenhouses, shadehouses, and ornamental plants:

Spray application: Mix **0.25 to 3 pounds of DOUBLE NICKEL 55™ per 100 gallons of water** and apply as a foliar spray of sufficient volume to wet the entire plant with minimal runoff. Begin preventative applications at plant emergence and repeat every 3-28 days as needed (every 3-7 days if disease pressure is high or environmental conditions are highly favorable to disease outbreak, 10-28 days under low pressure or less conducive conditions).

Drench application: Mix **0.125 to 2 pounds of DOUBLE NICKEL 55™ per 100 gallons of water** and apply as a drench or coarse spray to soil or other growing media in pots, flats, plugs, trays, or planting beds, for control or suppression of soilborne diseases of seedlings, cuttings, bedding plants, and transplants (including vegetables and other transplanted food crops). Make first application at or immediately before seeding, sticking, germination, or transplanting. Repeat applications every 14-28 days as needed. Transplants can be treated immediately before transplanting into field soils to protect against damping-off and other diseases that reduce plant establishment.

Cutting or root dip: Dip basal end of cuttings or bare roots (individually or in bunches) in a suspension of **1 to 2 pounds of DOUBLE NICKEL 55™ per gallon of water**. Immerse for 5-10 seconds immediately before planting.

Chemigation: Mix **0.125 to 2 pounds of DOUBLE NICKEL 55™ per 100 gallons of water** and apply via drip, handheld, or sprinkler irrigation systems. Refer to "Chemigation Instructions" for more details.

CROPS/USE SITES	DISEASES/PATHOGENS
Indoor, outdoor, and shade- or other cover-grown ornamental trees and shrubs, flowering plants, foliage plants, tropical plants, potted plants, potted or cut flowers, bedding plants, forestry seedlings, conifer production for reforestation, fruit trees, vegetables and other crops grown in greenhouses or nurseries.	Powdery mildews caused by *Erisyphe, Podosphaera, Sphaerotheca, Oidium,* and *Golovinomyces* spp.) Anthracnose (*Colletotrichum* spp.) Bacterial leaf spots caused by *Erwinia, Pseudomonas,* and *Xanthomonas* spp. Damping-off disease (*Rhizoctonia, Pythium, Fusarium* spp.) Late blight, blackeye, and root rots caused by *Phytophthora* spp. Gray mold and blight caused by *Botrytis cinerea* Black root rot (*Aspergillus* spp.) Black spot of roses (*Diplocarpon rosae*) Downy mildew (*Peronospora* spp.) Leaf spots caused by *Alternaria, Septoria, Cercospora, Entomosporium, Helminthosporium,* and *Myrothecium* spp.) Rust (*Puccinia* spp.) Scab (*Venturia* spp.) Root rot, bottom rot, or stem rot caused by *Rhizoctonia solani* *Sclerotinio* blight *Fusarium* wilts

Turfgrass application: For control of foliar diseases, apply DOUBLE NICKEL 55™ at **0.5 to 1 ounce per 1,000 square feet** as a ground-directed spray in sufficient water to provide thorough coverage. To control root and crown diseases in or on the soil, immediately follow the spray with sufficient overhead sprinkler irrigation to move the product into the root zone.

USE SITES/CROPS	DISEASES/PATHOGENS
Turf, sod, lawns, golf course (fairways, roughs, greens, tees), grass seed production Including but not limited to: Bluegrass, Bentgrass, Bermudagrass (common & hybrid), Dichondra, Fescue, Orchardgrass, *Poa annuo*, St. Augustine grass, Ryegrass, *Zoysia*, mixtures, and other grasses or ornamental turf	Anthracnose (*Colletotrichum graminicola*) Brown patch (*Rhizoctonia solani*) Dollar spot (*Lanzia* and *Moellerodiscus* spp., formerly *Sclerotinia homeocarpa*) Powdery mildew (*Erisyphe graminis*) Rust (*Puccinia* spp.) Gray leaf spot (*Pyriculario griseo*) "Damping off" or seedling blights caused by *Pythium*

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a dry area inaccessible to children. Store in original containers only. Keep container closed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CHEMIGATION INSTRUCTIONS

General information:

Apply this product only through drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (including impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

Drip (trickle) and micro-irrigation chemigation:

1. The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.

Sprinkler chemigation:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
8. Do not apply when wind speed favors drift beyond the area intended for treatment.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purpose referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the disease problem, condition of the crop, incompatibility with other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046

(301) 604-7340

Fax: 301-604-7015
www.certisusa.com

Courier

June 7, 2012

Mr. Alan Reynolds
Team Leader
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division
U.S. Environmental Protection Agency

Re: Certis USA, L.L.C.
Double Nickel 55 (EPA Registration No. 70051-108)
Notification of Revised Pests Not Approved for Use in California
(per PR Notice 98-10)

On behalf of Certis USA, L.L.C. (9145 Guilford Rd, Suite 175, Columbia, MD 21046), I am respectfully submitting the following documents to support a Notification to add asterisks to several pests, as requested by California DPR. These asterisks indicate that Double Nickel 55 (EPA Reg. No. 70051-108) is not approved for use on these pests in the state of California. In addition, the text "Hawaii only" has been added after the crop coffee. Please note that no other changes have been made to this label.

The following documents are enclosed:

- EPA Form 8570-1; Application for Pesticide
- Certification Statement per PF Notice 98-10
- Copy of the EPA Stamped label
- Marked version of the amended label
- Clean copy of the amended label
- Self-addressed, stamped postcard to be returned upon Notification acceptance

Please do not hesitate to contact me if you have any questions about this submission. I can be reached by telephone at 301-483-3806, or by email at cdively@certisusa.com.

Sincerely,

Christine A. Dively

Christine A. Dively
Director of Regulatory Affairs
Certis USA, L.L.C.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70051-108	2. EPA Product Manager A. Reynolds	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) Double Nickel 55	PM# Microbial Pesticides Branch	
5. Name and Address of Applicant *(Include ZIP Code)* Certis USA, L.L.C. 9145 Guilford Road, Suite 175, Columbia MD 21046 [ ] *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification to revise certain pests with asterisks that indicate "Not for Use in California" per PR Notice 98-10
See attached certification statement

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes*	[ ] Yes	[ ] Yes	[ ] Metal
[X] No	[X] No	[X] No	[X] Plastic
			[ ] Glass
			[ ] Paper
			[ ] Other (Specify) _____
	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

* ***Certification must be submitted***

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	5 lbs	[X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [X] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Christine A. Dively	Director of Reg. Affairs	301-483-3806

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Christine A. Dively	3. Title: Director of Regulatory Affairs
4. Typed Name: Christine A. Dively	5. Date: June 7, 2012

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

NOTIFICATION STATEMENT

CX-9030 EPA Reg. No. 70051-108-- in compliance with PR Notice 98-10

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Double Nickel 55™

BIOFUNGICIDE

Water Dispersible Granular Biofungicide

FOR ORGANIC PRODUCTION

OMRI Listed

Active Ingredient:

Bacillus amyloliquefaciens strain D747* 25.0%

Other Ingredients 75.0%

Total 100.0%

*Contains a minimum of 5×10^{10} colony-forming units (cfu) per gram

EPA Reg. No. 70051-108
EPA Est. No. 70051-CA-001

Manufactured by: Certis USA, L.L.C.
9145 Guilford Rd., Suite. 175
Columbia, MD 21046

NET WEIGHT: 5 LBS Lot No:

Notification Accepted
Date: JUL 19 2012
Reviewer: Suzanne Cerrelli

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID - Agricultural Use

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product label with you when calling a poison control center or doctor.
Hot Line No.:1-800-255-3924 for additional information

PRECAUTIONARY STATEMENTS - Agricultural Use

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow manufacturer's instructions for cleaning and maintaining PPE. If no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. AS soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS- Agricultural Use

Do not apply directly to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply when weather conditions favor drift or runoff from treated areas.

GENERAL INFORMATION

DOUBLE NICKEL 55™ is a broad-spectrum preventative biofungicide for control or suppression of fungal and bacterial plant diseases. The active ingredient of DOUBLE NICKEL 55™ is a naturally occurring strain (D747) of the beneficial rhizobacterium *Bacillus amyloliquefaciens*, which colonizes roots, leaves, and other plant surfaces. D747 rapidly colonizes plant root hairs, leaves, and other surfaces, preventing establishment of disease-causing fungi and bacteria.

DOUBLE NICKEL 55™ can be applied alone or in combination and/or rotation with chemical fungicides as a tool for integrated disease management in agricultural crops, ornamental and nursery plants, and turfgrass, in accordance with the most restrictive of those label limitations and precautions. DOUBLE NICKEL 55™ offers a valuable tool for management of resistance to chemical fungicides through its multiple and unique modes of action.

DOUBLE NICKEL 55™ can be applied up to and including the day of harvest.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the State or Tribal Agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: cover-alls, waterproof gloves, shoes plus socks.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses. Keep unprotected persons out of treated areas until sprays have dried.

MIXING AND HANDLING INSTRUCTIONS

Mix the required amount of DOUBLE NICKEL 55™ in cool water with sufficient agitation to maintain a uniform suspension in the spray or mixing tank. Tank should be cleaned prior to use. Do not use highly alkaline or highly acidic water to mix sprays. Use a buffering agent if necessary to maintain neutrality (pH 6 to 8) of water in the tank. Maintain agitation during application. Apply immediately after mixing; do not allow spray mix to stand overnight.

APPLICATION METHODS

Ground: DOUBLE NICKEL 55™ can be applied in most commonly-used ground application equipment, such as tractor-mounted boom, airblast, high clearance, hose-end, backpack, and other pressurized sprayers; hose-end or hand-held sprayers; foggers or mist blowers; water wheel and other drench applicators; and shank or other soil injection method.

Aerial: DOUBLE NICKEL 55™ can be applied by fixed or rotary winged aircraft in a minimum of 3 gallons of water per acre. Standard precautions should be taken to minimize spray drift.

Chemigation: DOUBLE NICKEL 55™ can be applied through drip (trickle) and sprinkler type irrigation equipment. Refer to the section entitled "Chemigation Instructions" for detailed instructions.

Agricultural crops

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons	
Brassica vegetables such as broccoli, cabbage, cauliflower, Brussels sprouts, kohlrabi, and other cole crops.	Pin rot complex (*Alternaria/Xanthomonas*)* Leaf spots (*Alternaria* spp., *Xonthomonas* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe polygoni*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Bulb vegetables such as onions, garlic, shallots, and others.	*Botrytis* spp. (neck rot, leaf blight) Purple blotch (*Alternaria* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Rust (*Puccinia pori*)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil applicatioa").
Cucurbits such as cucumbers, squash (all types), cantaloupes, muskmelons, watermelons, and other melons.	Powdery mildew (*Erisyphe* and *Sphaerotheca* spp.) Downy mildew (*Pseudoperonospora* spp.) Gummy stem blight (*Didymella bryoniae* and *Phoma cucurbitaceorum*) See instructions below for "Soil application" against the following diseases: Vine decline (*Monosporascus cannonballus*)** Charcoal rot (*Macrophomina phaseoli*)** "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp.
Fruiting vegetables such as tomatoes, peppers, eggplant, tomatillo, okra, and others.	Bacterial spot (*Xanthomonas* spp.)*[1] Bacterial speck (*Pseudomonas syringae* pv. *tomato*)*[1] Gray mold (*Botrytis cinerea*) Powdery mildew* (*Leveillula, Oidiopsis, Erisyphe*, and *Sphaerotheca* spp.) Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. Southern blight (*Sclerotium rolfsii*)* and**
Leafy vegetables such as head and leaf lettuce, celery, spinach, radicchio, arugula, watercress, and others (including leafy *Brassica* vegetables such as mustard and collard greens, kale, bok choi, and related crops).	Downy mildew (*Bremia lactucae*, *Peronospora* spp.)* Powdery mildew (*Golovinomyces (Erisyphe) cichoracearum*)* Bacterial blights Head and leaf drop (*Sclerotinia* spp.)[2] Pink rot (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* spp.) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. Bottom rot (*Rhizoctonia solani*)
Legume vegetables succulent and dried beans and peas such as green, snap, shell, and Lima beans, garbanzo beans, chickpeas, soybeans, dry beans, peas, split peas, lentils, and other legumes.	White mold (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Microsphaera diffusa*) Rusts*, including *Uromyces appendiculatus*, *Puccinia* spp., and Asian soybean rust (*Phayosporo pachyrhizi*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Root, tuber, and corm vegetables such as potato, sweet potato, carrot, cassava, beets, ginger, radish, horseradish[22], ginseng, turnip, and other root, tuber and corm crops.	Black root/crown rot (*Alternaria* spp.) Bacterial leaf blight (*Xanthomonas campestris*) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Gray mold (*Botrytis* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Black leg /bacterial soft rot (*Erwinia carotovora*)**

	Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: Black scurf (*Rhizoctonia solani*) Cavity spot (*Pythium* spp.) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp.
Other vegetables such as sweet corn, popcorn, asparagus, peanut, and watercress	*Botrytis* spp. Rusts (*Puccinia* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* and *Cercosporidium* spp.)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Tree fruits and nuts	
Citrus such as orange, lemon, lime, grapefruit, tangerine (mandarin), tangelo, pummelo, and other citrus	*Alternaria* leaf spot (*Alternaria alternata*) Postbloom fruit drop (*Colletotrichum acutatum*)* Greasy spot (*Mycosphaerella citri*)*[3] Citrus canker (*Xanthomonas campestris* pv. *citri*)[1] Scab (*Elsinoe fawcetti*)*[4] Melanose (*Diaporthe citri*)*
Pome fruits such as apple, pear, crabapple, quince, and others	Powdery mildew (*Podosphaera leucotricha*)[5] Scab (*Venturia* spp.)* Flyspeck (*Zygophiala jamaicensis*)[6] ** Sooty blotch disease complex[6] ** Brooks spot (*Mycosphaerella pomi*)[6] ** Bot rot/white rot (*Botryosphaeria dothidea*)[6] ** Bitter rot (*Colletotrichum* spp.)[6] Cedar apple rust (*Gymnosporangium juniperi-virginianae*)[6] ** Fire blight (*Erwinia amylovora*)*[7]
Stone fruits such as apricot, cherry, nectarine, peach, plum, prune, pluot, and others	Powdery mildew (*Sphaerotheca* and *Podosphaera* spp.)*[8] Bacterial canker (*Pseudomonas* spp.) Brown rot blossom blight (*Monilinia laxa*)[9] Brown rot (*Monilinia fructicola*)*[10] Gray mold (*Botrytis cinerea*)[10] Peach leaf curl (*Taphrina deformans*) Bacterial leaf spot (*Xanthomonas arbicola* pv. *pruni*)[1] Rusty spot (*Podosphaera leucotricha*)[1]
Tree nuts such as almond, pistachio, pecan, walnut, filbert, hazelnut, chestnut, macadamia, and other tree nuts.	Walnut blight (*Xanthomonas campestris*)[11] Anthracnose (*Colletotrichum acutatum*)* Bacterial canker (*Pseudomonas syringae*) Shot hole (*Wilsonomyces carpophilus*)* Brown rot (*Monilinia* spp.)* Pecan scab (*Cladosprium caryigenum*)*[1] and **
Pomegranates	Leaf and fruit spots (*Cercospora*, *Gloeosporium* and *Pestalotia* spp.)[1] Fruit rots (*Alternaria*, *Botrytis*, and other spp.)[10] Powdery mildew (*Sphaerotheca pannosa*)
Other fruits	
Strawberry	Powdery mildew (*Sphaerotheca macularis*, *Erisyphe* spp.)*[12] Gray mold (*Botrytis cinerea*)*[11] Anthracnose (*Calletotrichum acutatum*) Angular leaf spot (*Xanthomonas frogariae*)[1] For the following diseases, see instructions below for "Soil application" (and also root dip instructions[22]): "Damping off" and root or crown diseases caused by *Rhizoctonia*, *Fusarium*, *Pythium*, *Phytophthora*, and/or *Verticillium** spp. Charcoal rot (*Macrophamina phaseolina*)**

Berries, including blueberry, blackberry, raspberry, loganberry, huckleberry, gooseberry, elderberry, cranberry (non-flooded fields), currant, and other berries	Mummy berry (*Monilinia vaccinii-corymbosi*)* Botrytis blight (*Botrytis cinerea*) Bacterial canker (*Pseudomonas* spp.)[13] Anthracnose fruit rot (*Colletotrichum acutatum*)[10]
Grapes including wine grapes, table grapes, and raisins	Powdery mildew (*Erisyphe* (formerly *Uncinulo*) *necator*)[14] Gray mold (*Botrytis cinerea*)[15] Sour rot complex[15] Downy mildew (*Plasmopara viticola*)* Phomopsis (*Phomopsis viticola*)[16] Eutypa (*Eutypa lata*)[17]
Tropical fruits such as avocado[18], mango[18], papaya[19], pineapple[19], banana, plantain, and others.	Anthracnose (*Colletotrichum* spp.) Scab (*Sphaceloma perseae*) Bacterial canker (*Xanthomonas campestris*) Sigatoka (*Mycosphaerella fijiensis*)[20]
Other Crops	
Herbs and spices such as basil, thyme, coriander, dill, cilantro, parsley, mint, and others.	Powdery mildews (*Oidium* spp. and others) Downy mildews (*Peronospora* spp. and others)* Damping off diseases (*Rhizoctonia, Pythium, Alternaria*, and *Fusarium* spp.) Leaf spots (*Alternaria, Septoria, Colletotrichum*, and *Cercospora* spp.)* Bacterial diseases (*Erwinia, Xanthomonas*, and *Pseudomonas* spp.) Rusts (*Puccinia* spp. and others) "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Coffee (Hawaii only)	Coffee berry disease (*Colletotrichum coffeanum*)[1] Coffee rust (*Hemileia vastatrix*)[1] Anthracnose (*Colletotrichum* spp.) *Botrytis* flower blight *Cercospora* leaf spot and berry blotch "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Tobacco	Angular leaf spot (*Pseudomonas* spp.) Anthracnose (*Colletotrichum* and *Glomerella* spp.) Blue mold or downy mildew (*Peronospora* spp.)* Brown spot (*Alternaria*) Barn spot/ frogeye leaf spot (*Cercosporo nicotianae*)[10] Collar rot (*Sclerotinia sicerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Erysiphe cichoracearum*) Target spot (*Rhizoctonia solani*) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizactonia, Fusarium, Olpidium, Phytophthora*, or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*) Black root rot (*Thielaviopsis basicola*) Black shank (*Phytophthora* spp.)* Southern blight/southern stem rot (*Sclerotium rolfsii*)*
Mint	Rust (*Puccinia* spp.)
Hops	Powdery mildew (*Sphaerotheca macularis*)[21]

Footnotes:

*Suppression only; for improved control mix or rotate with chemical fungicide approved for such use. **NOT FOR USE IN CALIFORNIA

[1] Tank mix or rotate with copper-based fungicides at label rates for improved control.

[2] Apply at or immediately following planting (but before plant emergence) as a banded seedline treatment 4 to 6 inches wide. Make second application at thinning or cultivation in sufficient water and multiple nozzles to ensure thorough coverage of lower leaves and surrounding soil surface. Incorporation with light irrigation after application may improve disease control. Repeat at 10-14 day intervals if conditions promoting disease persist.

[3] For greasy spot suppression, apply at first new foliar flush and repeat with each new flush. Tank mix with spray oil or copper based fungicide at labeled rates.

[4] For suppression of citrus scab, start applications at first new foliage flush and repeat at petal fall and when fruit are ½ inch in diameter.

[5] Make first application at or before tight cluster if conditions favor disease development. Repeat at 7-10 day intervals through the second cover spray or longer on susceptible varieties or if environmental conditions favor rapid disease development.

[6] Begin applications before bloom when environmental conditions favor disease development, repeating at 7 to 14 day intervals or as needed. Control may be enhanced by addition of a surfactant to improve spray coverage. Use only surfactants known to be safe for use on the crop and for which such use is allowed.

[7] Rotate with antibiotics registered for fire blight control for improved performance. Begin applications at 1-5% open blossoms and repeat every 3-7 days as necessary until petal fall, when intervals can be increased to 7 days. Double Nickel 55™ can also be used in summer "cover spray" applications to control the shoot blight phase of fire blight and summer diseases. Can be mixed with copper fungicides to improve control.

[8] Make first application at popcorn stage and repeat every 7 days.

[9] Start applying at early bloom stage and repeat every 7 days through petal fall.

[10] Pre-harvest applications in sufficient water to cover fruit or other harvested plant parts may improve control of postharvest infections.

[11] Begin applications at or before pistillate bloom, repeating every 7-10 days. Apply before rainfall if possible, and tank mix or rotate with a copper-based bactericide registered for such use for improved control.

[12] Start applications at or just before flowering and repeat every 7-10 days as needed through harvest.

[13] Apply before fall rains and again during dormancy before spring growth.

[14] Start applications when new shoots are ½ to 1½ inches long. Repeat at 3-5 inches, 8-10 inches, and then at 7-10 day intervals until disease conditions no longer exist.

[15] Apply at bloom, before bunch closure, at veraison, and before harvest.

[16] Apply when shoots are ½ to 1 inch long and again when 6-8 inches long.

[17] Mix 2 fluid ounces Double Nickel 55™ per gallon of water and apply to pruning wounds.

[18] Apply at budbreak and repeat on 14-21 day interval as needed through harvest.

[19] Apply at flowering and repeat on 14-21 day interval as needed through harvest

[40] Apply at first appearance of leaves and repeat at 7-21 day intervals as needed, in sufficient water to obtain thorough coverage of foliage. Tank mix with spray oil or other registered fungicides for improved control.

[21] Mix 6 to10 fluid ounces Double Nickel 55™ per 100 gallons of water and apply in minimum of 20 gallons per acre form emergence to training, 50 gallons per acre from training to wire, and 100 gallons per acre from wire touch through harvest.

[12] For treatment of horseradish or strawberry roots immediately before transplanting: immerse bare roots (individually or in bunches) for 10 seconds in a suspension of 1 to 2 pints Double Nickel 55™ per gallon of water.

Foliar application: For control of diseases on foliage, flowers, fruit, or other above-ground parts of plants: Mix DOUBLE NICKEL 55™ in water and apply as a spray at a rate of **0.25 to 3** pounds **per acre** in sufficient water to achieve thorough coverage of the crop canopy with minimal runoff. Begin applications at crop emergence, transplanting, or when conditions are conducive to development of disease. Repeat application every 7 to 10 days, or as needed, for as long as conditions favor disease development. Lower rates (0.25 to 1 pound per acre) may be applied under light disease pressure, to smaller (e.g. newly-emerged) plants, or when DOUBLE NICKEL 55™ is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (1 to 3 pounds per acre), apply more frequently (every 3 to 7 days), and mix or rotate DOUBLE NICKEL 55™ with other fungicides for improved performance.

Soil application: For control of soilborne diseases infecting seeds, seedlings, roots, crown, stems, or other plant parts below ground or in contact with soil: Apply DOUBLE NICKEL 55™ at **0.125 to 1 pound per acre**. Mix the required amount in sufficient water to apply by one of the following methods:

- Soil drench applied to transplants in flats or pots in the greenhouse or nursery any time prior to transplanting (see additional drench instructions under "Nurseries, greenhouses, shade houses, and ornamental plants" below).
- Soil drench at transplanting, using a "water wheel" injector, spray nozzles/hoses, or other method to drench each root ball and/or planting hole.
- Soil or seedline drench, or banded spray (in-furrow) at planting. See the section on "Banded (in-furrow) application" below for additional instructions.

Follow-up (post-planting) preventative applications can be made every 2-4 weeks by one or more of the following methods, if needed:

- Drip (trickle) or any type of sprinkler irrigation, any time after planting or transplanting. See Chemigation Instructions for additional information.
- Spray directly onto the soil surface and/or lower plant parts. If targeting root disease, follow immediately with sufficient overhead sprinkler irrigation to move DOUBLE NICKEL 55™ to the root zone.
- Injection directly into the rooting zone using shanks or similar equipment.

Lower rates (0.125 to 0.5 pounds per acre) may be applied under light disease pressure, to smaller plants, or when DOUBLE NICKEL 55™ is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (0.5 to 1 pound per acre), apply more frequently (every 2 weeks), and mix or rotate DOUBLE NICKEL 55™ with other fungicides for improved performance.

Banded (in-furrow) application: Use the table below to determine the correct application rate of DOUBLE NICKEL 55™ per 1,000 row feet, based on row spacing and desired rate per acre. Mix the required amount of DOUBLE NICKEL 55™ in water and apply as banded spray (4" to 6" wide) or seedline drench centered over the planting furrow. Apply directly over seeds in the furrow just before they are covered with soil. The volume of water required per acre or per 1,000 row feet will depend on the application equipment used. Consult your local cooperative extension service if you need assistance calibrating band spraying equipment.

Rates for banded (in-furrow) application: Find desired application rate in the left column. Read across that line to the correct row spacing indicated at the top to find the number of ounces (dry) per 1,000 row feet that will provide the desired application rate per acre. To convert to **level teaspoons**, multiply the number of ounces by 8.2. For **level tablespoons**, multiply the number of ounces by 2.75.

Rate/acre	Space between rows (inches)														
(pounds)	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
0.25	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3
0.5	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6
0.75	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9
1.0	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.2	1.2
1.25	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.4	1.5	1.5
1.5	0.6	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.7	1.8
1.75	0.6	0.7	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1
2.0	0.7	0.9	1.0	1.1	1.2	1.3	1.5	1.6	1.7	1.8	2.0	2.1	2.2	2.3	2.4
2.25	0.8	1.0	1.1	1.2	1.4	1.5	1.7	1.8	1.9	2.1	2.2	2.3	2.5	2.6	2.8
2.5	0.9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1
2.75	1.0	1.2	1.3	1.5	1.7	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.0	3.2	3.4
3.0	1.1	1.3	1.5	1.7	1.8	2.0	2.2	2.4	2.6	2.8	2.9	3.1	3.3	3.5	3.7

Nurseries, greenhouses, shadehouses, and ornamental plants:

Spray application: Mix **0.25 to 3 pounds of DOUBLE NICKEL 55™ per 100 gallons of water** and apply as a foliar spray of sufficient volume to wet the entire plant with minimal runoff. Begin preventative applications at plant emergence and repeat every 3-28 days as needed (every 3-7 days if disease pressure is high or environmental conditions are highly favorable to disease outbreak, 10-28 days under low pressure or less conducive conditions).

Drench application: Mix **0.125 to 2 pounds of DOUBLE NICKEL 55™ per 100 gallons of water** and apply as a drench or coarse spray to soil or other growing media in pots, flats, plugs, trays, or planting beds, for control or suppression of soilborne diseases of seedlings, cuttings, bedding plants, and transplants (including vegetables and other transplanted food crops). Make first application at or immediately before seeding, sticking, germination, or transplanting. Repeat applications every 14-28 days as needed. Transplants can be treated immediately before transplanting into field soils to protect against damping-off and other diseases that reduce plant establishment.

Cutting or root dip: Dip basal end of cuttings or bare roots (individually or in bunches) in a suspension of **1 to 2 pounds of DOUBLE NICKEL 55™ per gallon of water**. Immerse for 5-10 seconds immediately before planting.

Chemigation: Mix **0.125 to 2 pounds of DOUBLE NICKEL 55™ per 100 gallons of water** and apply via drip, handheld, or sprinkler irrigation systems. Refer to "Chemigation Instructions" for more details.

CROPS/USE SITES	DISEASES/PATHOGENS
Indoor, outdoor, and shade- or other cover-grown ornamental trees and shrubs, flowering plants, foliage plants, tropical plants, potted plants, potted or cut flowers, bedding plants, forestry seedlings, conifer production for reforestation, fruit trees, vegetables and other crops grown in greenhouses or nurseries.	Powdery mildews caused by *Erisyphe, Podosphoera, Sphaerotheca, Oidium,* and *Golovinomyces* spp.) Anthracnose (*Colletotrichum* spp.) Bacterial leaf spots caused by *Erwinia, Pseudomonas,* and *Xanthomonas* spp. Damping-off disease (*Rhizoctonia, Pythium, Fusarium* spp.) Late blight, blackeye, and root rots caused by *Phytophthoro* spp. Gray mold and blight caused by *Botrytis cinerea* Black root rot (*Aspergillus* spp.) Black spot of roses (*Diplocarpon rosae*) Downy mildew (*Peronosporo* spp.) Leaf spots caused by *Alternaria, Septoria, Cercospora, Entomosporium, Helminthosporium,* and *Myrothecium* spp.) Rust (*Puccinia* spp.) Scab (*Venturia* spp.) Root rot, bottom rot, or stem rot caused by *Rhizoctonia soloni* *Sclerotinia* blight *Fusarium* wilts

Turfgrass application: For control of foliar diseases, apply DOUBLE NICKEL 55™ at **0.5 to 1 ounce per 1,000 square feet** as a ground-directed spray in sufficient water to provide thorough coverage. To control root and crown diseases in or on the soil, immediately follow the spray with sufficient overhead sprinkler irrigation to move the product into the root zone.

USE SITES/CROPS	DISEASES/PATHOGENS
Turf, sod, lawns, golf course (fairways, roughs, greens, tees), grass seed production Including but not limited to: Bluegrass, Bentgrass, Bermudagrass (common & hybrid), Dichondra, Fescue, Orchardgrass, *Poa annua*, St. Augustine grass, Ryegrass, *Zoysia*, mixtures, and other grasses or ornamental turf	Anthracnose (*Colletotrichum graminicola*) Brown patch (*Rhizoctonia solani*) Dollar spot (*Lanzia* and *Moellerodiscus* spp., formerly *Sclerotinia homeocarpa*) Powdery mildew (*Erisyphe graminis*) Rust (*Puccinia* spp.) Gray leaf spot (*Pyricularia grisea*) "Damping off" or seedling blights caused by *Pythium*

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a dry area inaccessible to children. Store in original containers only. Keep container closed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CHEMIGATION INSTRUCTIONS

General information:

Apply this product only through drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (including impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

Drip (trickle) and micro-irrigation chemigation:

1. The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.

Sprinkler chemigation:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
8. Do not apply when wind speed favors drift beyond the area intended for treatment.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purpose referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the disease problem, condition of the crop, incompatibility with other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046

(301) 604-7340

Fax: 301-604-7015
www.certisusa.com

Hand-Delivered

March 22, 2012

Sheryl Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division (7504P)
Office of Pesticide Programs
US Environmental Protection Agency

Re: Certis U.S.A., L.L.C.
Submission of Final Printed Labels

Dear Dr. Reilly;

On behalf of Certis U.S.A., L.L.C. (9145 Guilford Road, Suite 175, Columbia, Maryland 21046), I respectfully submit final printed labels for the following products:

- PFR-97 20% WDG EPA Registration No. 70051-19
- Double Nickel LC EPA Registration No. 70051-107
- Double Nickel 55 EPA Registration No. 70051-108

Enclosed are EPA Form 8570-1 and two copies of the final printed label for each product.

Please do not hesitate to contact me if you have any questions about this submission. I can be reached by telephone at 301-483-3806 or by email at cdively@certisusa.com.

Sincerely,

Christine A. Dively
Director of Regulatory Affairs
Certis USA

Enclosure

Please read instructions on reverse before co... sting form. Form Approved. OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
70051-108	Reynolds	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Double Nickel 55	Microbial Pesticides Branch	

5. Name and Address of Applicant *(Include ZIP Code)*

Certis USA, L.L.C.
9145 Guilford Road, Suite 175
Columbia, Maryland 21046

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[X] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of final printed labels per PR Notice 98-10.
"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. sec. 1001 to wilfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes*	[ ] Yes	[ ] Yes	[ ] Metal
[X] No	[X] No	[X] No	[X] Plastic
			[ ] Glass
			[ ] Paper
			[ ] Other (Specify) _____
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	5 lbs	[X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [X] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Christine A. Dively	Director of Reg. Affairs	301-483-3806

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Christine A. Dively	Director of Regulatory Affairs
4. Typed Name	**5. Date**
Christine A. Dively	March 22, 2012

DoubleNickel55™

BIOFUNGICIDE

NOT REVIEWED
in accordance with PR Notice 82-2
based on draft labeling dated

Water Dispersible Granular Biofungicide

FOR ORGANIC PRODUCTION

Active Ingredient:
Bacillus amyloliquefaciens strain D747* 25.0%
Other Ingredients: 75.0%
Total 100.0%
Contains a minimum of 5×10^{10} colony-forming units (cfu) per gram

Net Contents: 5 Pounds
EPA Reg. No. 70051-108
EPA Est. No. 70051-CA-001

Lot No:

Manufactured by:
Certis USA, L.L.C.
9145 Guilford Rd, Suite 175
Columbia, MD 21046

CERTIS

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID - Agricultural Use
If in eyes: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product label with you when calling a poison control center or doctor.

Hot Line No.:1-800-255-3924 for additional information

PRECAUTIONARY STATEMENTS - Agricultural Use
HAZARDS TO HUMANS & DOMESTIC ANIMALS
CAUTION: Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)
Applicators and other handlers must wear:
- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow manufacturer's instructions for cleaning and maintaining PPE. If no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS
Users should:
- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS- Agricultural Use
Do not apply directly to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply when weather conditions favor drift or runoff from treated areas.

GENERAL INFORMATION
Double Nickel 55 is a broad-spectrum preventative biofungicide for control or suppression of fungal and bacterial plant diseases. The active ingredient of Double Nickel 55 is a naturally occurring strain (D747) of the beneficial rhizobacterium *Bacillus amyloliquefaciens*, which colonizes roots, leaves, and other plant surfaces. D747 rapidly colonizes plant root hairs, leaves, and other surfaces, preventing establishment of disease-causing fungi and bacteria.

Double Nickel 55 can be applied alone or in combination and/or rotation with chemical fungicides as a tool for integrated disease management in agricultural crops, ornamental and nursery plants, and turfgrass, in accordance with the most restrictive of those label limitations and precautions. Double Nickel 55 offers a valuable tool for management of resistance to chemical fungicides through its multiple and unique modes of action.

Double Nickel 55 can be applied up to and including the day of harvest.

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the State or Tribal Agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Material Sent for Data Extraction

Reg. # 70051-108

Description: New AI + New Product

☐ Material(s) Sent to Data Extraction Contractors:

- ☑ New Stamped Label Dated 12-16-11
- ☐ Notification Dated _____
- ☒ 3 New CSF(s) Dated Basic 10-18-11; Alternate #1 10-18-11; 11-18-12 Alternate #2
- ☐ Other: _____

☑ Decision #: 437753

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Susanne Cerrelli

Phone: 703-308-8077 Division: BPPD

Date: 3-14-12

EPA Reg. Number:	Date of Issuance:
70051-108	DEC 16 2011

Term of Issuance: Unconditional

Name of Pesticide Product: **CX-9030**

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

NOTICE OF PESTICIDE REGISTRATION

X Registration
___ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Certis U.S.A., L.L.C.
9145 Guilford Road, Suite 175
Columbia, MD 21046

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms and conditions:

1. Revise the EPA Registration number on the label to read, "EPA Reg. No. **70051-108**."
2. Submit two (2) copies of the revised final printed labeling before you release the product for shipment.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:	Date:
W. Michael McDavit W. Michael McDavit, Associate Director Biopesticides and Pollution Prevention Division (7511P)	DEC 16 2011

EPA Form 8570-6

CONCURRENCES

SYMBOL ►	7511P							
SURNAME ►	[illegible]							
DATE ►	12-16-11							

EPA Form 1320-1A (1/90)

OFFICIAL FILE COPY

AGRICULTURAL USE REQUIREMENTS
Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: cover-alls, waterproof gloves, shoes plus socks.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

NON-AGRICULTURAL USE REQUIREMENTS
The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses. Keep unprotected persons out of treated areas until sprays have dried.

MIXING AND HANDLING INSTRUCTIONS
Mix the required amount of Double Nickel 55 in cool water with sufficient agitation to maintain a uniform suspension in the spray or mixing tank. Tank should be cleaned prior to use. Do not use highly alkaline or highly acidic water to mix sprays. Use a buffering agent if necessary to maintain neutrality (pH 6 to 8) of water in the tank. Maintain agitation during application. Apply immediately after mixing; do not allow spray mix to stand overnight.

APPLICATION METHODS
Ground: Double Nickel 55 can be applied in most commonly-used ground application equipment, such as tractor-mounted boom, airblast, high clearance, hose-end, backpack, and other pressurized sprayers; hose-end or hand-held sprayers; foggers or mist blowers; water wheel and other drench applicators; and shank or other soil injection method.

Aerial: Double Nickel 55 can be applied by fixed or rotary winged aircraft in a minimum of 3 gallons of water per acre. Standard precautions should be taken to minimize spray drift.

Chemigation: Double Nickel 55 can be applied through drip (trickle) and sprinkler type irrigation equipment. Refer to the section entitled "Chemigation Instructions" for detailed instructions.

Agricultural crops

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons	
Brassica vegetables such as broccoli, cabbage, cauliflower, Brussels sprouts, kohlrabi, and other cole crops.	Pin rot complex (*Alternaria/Xanthomonas*)* Leaf spots (*Alternaria* spp., *Xanthomonas* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe polygoni*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").

(continued)

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons *(continued)*	
Bulb vegetables such as onions, garlic, shallots, and others.	*Botrytis* spp. (neck rot, leaf blight) Purple blotch (*Alternaria* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Rust *(Puccinia pori)** "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").
Cucurbits such as cucumbers, squash (all types), cantaloupes, muskmelons, watermelons, and other melons.	Powdery mildew (*Erisyphe* and *Sphaerotheca* spp.) Downy mildew (*Pseudoperonospora* spp.) Gummy stem blight (*Didymella bryoniae* and *Phoma cucurbitacearum*) See instructions below for "Soil application" against the following diseases: Vine decline *(Monosporascus cannonballus)* Charcoal rot *(Macrophomina phaseoli)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp.
Fruiting vegetables such as tomatoes, peppers, eggplant, tomatillo, okra, and others.	Bacterial spot (*Xanthomonas* spp.)*[1] Bacterial speck (*Pseudomonas syringae* pv. *tomato*)*[1] Gray mold *(Botrytis cinerea)* Powdery mildew* (*Leveillula, Oidiopsis, Erisyphe,* and *Sphaerotheca* spp.) Early blight *(Alternaria solani)** Late blight *(Phytophthora infestans)** See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. Southern blight *(Sclerotium rolfsii)**
Leafy vegetables such as head and leaf lettuce, celery, spinach, radicchio, arugula, watercress, and others (including leafy Brassica vegetables such as mustard and collard greens, kale, bok choi, and related crops).	Downy mildew (*Bremia lactucae, Peronospora* spp.)* Powdery mildew *(Golovinomyces (Erisyphe) cichoracearum)** Bacterial blights Head and leaf drop (*Sclerotinia* spp.)[2] Pink rot *(Sclerotinia sclerotiorum)*[2] Leaf spots (*Cercospora* spp.) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. Bottom rot (*Rhizoctonia solani*)
Legume vegetables succulent and dried beans and peas such as green, snap, shell, and Lima beans, garbanzo beans, chickpeas, soybeans, dry beans, peas, split peas, lentils, and other legumes.	White mold *(Sclerotinia sclerotiorum)*[2] Gray mold *(Botrytis cinerea)* Powdery mildew *(Microsphaera diffusa)* Rusts*, including *Uromyces appendiculatus, Puccinia* spp., and Asian soybean rust *(Phayospora pachyrhizi)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").

(continued)

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons *(continued)*	
Root, tuber, and corm vegetables such as potato, sweet potato, carrot, cassava, beets, ginger, radish, horseradish[22], ginseng, turnip, and other root, tuber and corm crops.	Black root/crown rot (*Alternaria* spp.) Bacterial leaf blight (*Xanthomonas campestris*) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Gray mold (*Botrytis* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Black leg /bacterial soft rot (*Erwinia carotovora*) Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: Black scurf (*Rhizoctonia solani*) Cavity spot (*Pythium* spp.) "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora*, or *Verticillium** spp.
Other vegetables such as sweet corn, popcorn, asparagus, peanut, and watercress	*Botrytis* spp. Rusts (*Puccinia* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* and *Cercosporidium* spp.)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Tree fruits and nuts	
Citrus such as orange, lemon, lime, grapefruit, tangerine (mandarin), tangelo, pummelo, and other citrus	*Alternaria* leaf spot (*Alternaria alternata*) Postbloom fruit drop (*Colletotrichum acutatum*)* Greasy spot (*Mycosphaerella citri*)*[3] Citrus canker (*Xanthomonas campestris* pv. *citri*)* Scab (*Elsinoe fawcetti*)*[4] Melanose (*Diaporthe citri*)*
Pome fruits such as apple, pear, crabapple, quince, and others	Powdery mildew (*Podosphaera leucotricha*)[5] Scab (*Venturia* spp.)* Flyspeck (*Zygophiala jamaicensis*)[6] Sooty blotch disease complex[6] Brooks spot (*Mycosphaerella pomi*)[6] Bot rot/white rot (*Botryosphaeria dothidea*)[6] Bitter rot (*Colletotrichum* spp.)[6] Cedar apple rust (*Gymnosporangium juniperi-virginianae*)[5] Fire blight (*Erwinia amylovora*)*[7]
Stone fruits such as apricot, cherry, nectarine, peach, plum, prune, pluot, and others	Powdery mildew (*Sphaerotheca and Podosphaera* spp.)*[8] Bacterial canker (*Pseudomonas* spp.) Brown rot blossom blight (*Monilinia* taxa)[9] Brown rot (*Monilinia fructicola*)*[10] Gray mold (*Botrytis cinerea*)*[9] Peach leaf curl (*Taphrina deformans*) Bacterial leaf spot (*Xanthomonas arboricola* pv. *pruni*)* Rusty spot (*Podosphaera leucotricha*)[1]
Tree nuts such as almond, pistachio, pecan, walnut, filbert, hazelnut, chestnut, macadamia, and other tree nuts.	Walnut blight (*Xanthomonas campestris*)[11] Anthracnose (*Colletotrichum acutatum*)* Bacterial canker (*Pseudomonas syringae*) Shot hole (*Wilsonomyces carpophilus*)* Brown rot (*Monilinia* spp.)* Pecan scab (*Cladosprium caryigenum*)*[1]
Pomegranates	Leaf and fruit spots (*Cercospora, Gloeosporium* and *Pestalotia* spp.)[1] Fruit rots (*Alternaria, Botrytis*, and other spp.)[10] Powdery mildew (*Sphaerothaca pannosa*)

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Other fruits	
Strawberry	Powdery mildew (*Sphaerotheca macularis, Erisyphe spp.*)*[12] Gray mold (*Botrytis cinerea*)*[11] Anthracnose (*Colletotrichum acutatum*) Angular leaf spot (*Xanthomonas fragariae*)[1] For the following diseases, see instructions below for "Soil application" (and also root dip instructions[22]): "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*)
Berries, including blueberry, blackberry, raspberry, loganberry, huckleberry, gooseberry, elderberry, cranberry (non-flooded fields), current, and other berries	Mummy berry (*Monilinia vaccinii-corymbosi*)* Botrytis blight (*Botrytis cinerea*) Bacterial canker (*Pseudomonas* spp.)[13] Anthracnose fruit rot (*Colletotrichum acutatum*)[10]
Grapes including wine grapes, table grapes, and raisins	Powdery mildew (*Erisyphe* (formerly *Uncinuta*) *necator*)[14] Gray mold (*Botrytis cinerea*)[15] Sour rot complex[15] Downy mildew (*Plasmopara viticola*)* *Phomopsis* (*Phomopsis viticola*)[16] Eutypa (*Eutypa lata*)[17]
Tropical fruits such as avocado[18], mango[18], papaya[19], pineapple[19], banana, plantain, and others.	Anthracnose (*Colletotrichum* spp.) Scab (*Sphaceloma perseae*) Bacterial canker (*Xanthomonas campestris*) Sigatoka (*Mycosphaerella fijiensis*)[20]
Other Crops	
Herbs and spices such as basil, thyme, coriander, dill, cilantro, parsley, mint, and others.	Powdery mildews (*Didium* spp. and others) Downy mildews (*Peronospora* spp. and others)* Damping off diseases (*Rhizoctonia, Pythium, Alternaria*, and *Fusarium* spp.) Leaf spots (*Alternaria, Septoria, Colletotrichum*, and *Cercospora* spp.)* Bacterial diseases (*Erwinia, Xanthomonas*, and *Pseudomonas* spp.) Rusts (*Puccinia* spp. and others) "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Coffee	Coffee berry disease (*Colletotrichum coffeanum*) Coffee rust (*Hemileia vastatrix*)[1] Anthracnose (*Colletotrichum* spp.) *Botrytis* flower blight *Cercospora* leaf spot and berry blotch "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").

(continued)

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Other fruits *(continued)*	
Tobacco	Angular leaf spot (*Pseudomonas* spp.) Anthracnose (*Colletotrichum* and *Glomerella* spp.) Blue mold or downy mildew (*Peronospora* spp.)* Brown spot (*Alternaria*) Barn spot/ frogeye leaf spot (*Cercospora nicotianae*)[12] Collar rot (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Erysiphe cichoracearum*) Target spot (*Rhizoctonia solani*) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Olpidium, Phytophthora*, or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*) Black root rot (*Thielaviopsis basicola*) Black shank (*Phytophthora* spp.)* Southern blight/southern stem rot (*Sclerotium rolfsii*)*
Mint	Rust (*Puccinia* spp.)
Hops	Powdery mildew (*Sphaerotheca macularis*)[21]

Footnotes:

*Suppression only; for improved control mix or rotate with chemical fungicide approved for such use.

1 Tank mix or rotate with copper-based fungicides at label rates for improved control.

2 Apply at or immediately following planting (but before plant emergence) as a banded seedline treatment 4 to 6 inches wide. Make second application at thinning or cultivation in sufficient water and multiple nozzles to ensure thorough coverage of lower leaves and surrounding soil surface. Incorporation with light irrigation after application may improve disease control. Repeat at 10-14 day intervals if conditions promoting disease persist.

3 For greasy spot suppression, apply at first new foliar flush and repeat with each new flush. Tank mix with spray oil or copper based fungicide at labeled rates.

4 For suppression of citrus scab, start applications at first new foliage flush and repeat at petal fall and when fruit are ½ inch in diameter.

5 Make first application at or before tight cluster if conditions favor disease development. Repeat at 7-10 day intervals through the second cover spray or longer on susceptible varieties or if environmental conditions favor rapid disease development.

6 Begin applications before bloom when environmental conditions favor disease development, repeating at 7 to 14 day intervals or as needed. Control may be enhanced by addition of a surfactant to improve spray coverage. Use only surfactants known to be safe for use on the crop and for which such use is allowed.

7 Rotate with antibiotics registered for fire blight control for improved performance. Begin applications at 1-5% open blossoms and repeat every 3-7 days as necessary until petal fall, when intervals can be increased to 7 days. Double Nickel 55 can also be used in summer "cover spray" applications to control the shoot blight phase of fire blight and summer diseases. Can be mixed with copper fungicides to improve control.

8 Make first application at popcorn stage and repeat every 7 days.

9 Start applying at early bloom stage and repeat every 7 days through petal fall.

10 Pre-harvest applications in sufficient water to cover fruit or other harvested plant parts may improve control of postharvest infections.

11 Begin applications at or before pistillate bloom, repeating every 7-10 days. Apply before rainfall if possible, and tank mix or rotate with a copper-based bactericide registered for such use for improved control.

12 Start applications at or just before flowering and repeat every 7-10 days as needed through harvest.

(continued)

Footnotes: *(continued)*

13 Apply before fall rains and again during dormancy before spring growth.

14 Start applications when new shoots are ½ to 1½ inches long. Repeat at 3-5 inches, 8-10 inches, and then at 7-10 day intervals until disease conditions no longer exist.

15 Apply at bloom, before bunch closure, at veraison, and before harvest.

16 Apply when shoots are ½ to 1 inch long and again when 6-8 inches long.

17 Mix 2 fluid ounces Double Nickel 55 per gallon of water and apply to pruning wounds.

18 Apply at budbreak and repeat on 14-21 day interval as needed through harvest.

19 Apply at flowering and repeat on 14-21 day interval as needed through harvest.

20 Apply at first appearance of leaves and repeat at 7-21 day intervals as needed, in sufficient water to obtain thorough coverage of foliage. Tank mix with spray oil or other registered fungicides for improved control.

21 Mix 6 to10 fluid ounces Double Nickel 55 per 100 gallons of water and apply in minimum of 20 gallons per acre from emergence to training, 50 gallons per acre from training to wire, and 100 gallons per acre from wire touch through harvest.

22 For treatment of horseradish or strawberry roots immediately before transplanting: immerse bare roots (individually or in bunches) for 10 seconds in a suspension of 1 to 2 pints Double Nickel 55 per gallon of water.

Foliar application: For control of diseases on foliage, flowers, fruit, or other above-ground parts of plants: Mix Double Nickel 55 in water and apply as a spray at a rate of **0.25 to 3 pounds per acre** in sufficient water to achieve thorough coverage of the crop canopy with minimal runoff. Begin applications at crop emergence, transplanting, or when conditions are conducive to development of disease. Repeat application every 7 to 10 days, or as needed, for as long as conditions favor disease development. Lower rates (0.25 to 1 pound per acre) may be applied under light disease pressure, to smaller (e.g. newly-emerged) plants, or when Double Nickel 55 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (1 to 3 pounds per acre), apply more frequently (every 3 to 7 days), and mix or rotate Double Nickel 55 with other fungicides for improved performance.

Soil application: For control of soilborne diseases infecting seeds, seedlings, roots, crown, stems, or other plant parts below ground or in contact with soil: Apply Double Nickel 55 at **0.125 to 1 pound per acre**. Mix the required amount in sufficient water to apply by one of the following methods:

- Soil drench applied to transplants in flats or pots in the greenhouse or nursery any time prior to transplanting (see additional drench instructions under "Nurseries, greenhouses, shade houses, and ornamental plants" below).
- Soil drench at transplanting, using a "water wheel" injector, spray nozzles/hoses, or other method to drench each root ball and/or planting hole.
- Soil or seedline drench, or banded spray (in-furrow) at planting. See the section on "Banded (in-furrow) application" below for additional instructions.

Follow-up (post-planting) preventative applications can be made every 2-4 weeks by one or more of the following methods, if needed:

- Drip (trickle) or any type of sprinkler irrigation, any time after planting or transplanting. See Chemigation Instructions for additional information.
- Spray directly onto the soil surface and/or lower plant parts. If targeting root disease, follow immediately with sufficient overhead sprinkler irrigation to move Double Nickel 55 to the root zone.
- Injection directly into the rooting zone using shanks or similar equipment.

Lower rates (0.125 to 0.5 pounds per acre) may be applied under light disease pressure, to smaller plants, or when Double Nickel 55 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when

environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (0.5 to 1 pound per acre), apply more frequently (every 2 weeks), and mix or rotate Double Nickel 55 with other fungicides for improved performance.

Banded (in-furrow) application: Use the table below to determine the correct application rate of Double Nickel 55 per 1,000 row feet, based on row spacing and desired rate per acre. Mix the required amount of Double Nickel 55 in water and apply as banded spray (4" to 6" wide) or seedline drench centered over the planting furrow. Apply directly over seeds in the furrow just before they are covered with soil. The volume of water required per acre or per 1,000 row feet will depend on the application equipment used. Consult your local cooperative extension service if you need assistance calibrating band spraying equipment.

Rates for banded (in-furrow) application: Find desired application rate in the left column. Read across that line to the correct row spacing indicated at the top to find the number of ounces (dry) per 1,000 row feet that will provide the desired application rate per acre. To convert to level **teaspoons**, multiply the number of ounces by 8.2. For **level tablespoons**, multiply the number of ounces by 2.75.

Rate/acre (pounds)	Space between rows (inches)														
	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
0.25	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3
0.5	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6
0.75	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9
1.0	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.2	1.2
1.25	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.4	1.5	1.5
1.5	0.6	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.7	1.8
1.75	0.6	0.7	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1
2.0	0.7	0.9	1.0	1.1	1.2	1.3	1.5	1.6	1.7	1.8	2.0	2.1	2.2	2.3	2.4
2.25	0.8	1.0	1.1	1.2	1.4	1.5	1.7	1.8	1.9	2.1	2.2	2.3	2.5	2.6	2.8
2.5	0.9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1
2.75	1.0	1.2	1.3	1.5	1.7	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.0	3.2	3.4
3.0	1.1	1.3	1.5	1.7	1.8	2.0	2.2	2.4	2.6	2.8	2.9	3.1	3.3	3.5	3.7

Nurseries, greenhouses, shadehouses, and ornamental plants

Spray application: Mix **0.25 to 3 pounds of Double Nickel 55 per 100 gallons of water** and apply as a foliar spray of sufficient volume to wet the entire plant with minimal runoff. Begin preventative applications at plant emergence and repeat every 3-28 days as needed (every 3-7 days if disease pressure is high or environmental conditions are highly favorable to disease outbreak, 10-28 days under low pressure or less conducive conditions).

Drench application: Mix **0.125 to 2 pounds of Double Nickel 55 per 100 gallons of water** and apply as a drench or coarse spray to soil or other growing media in pots, flats, plugs, trays, or planting beds, for control or suppression of soilborne diseases of seedlings, cuttings, bedding plants, and transplants (including vegetables and other transplanted food crops). Make first application at or immediately before seeding, sticking, germination, or transplanting. Repeat applications every 14-28 days as needed. Transplants can be treated immediately before transplanting into field soils to protect against damping-off and other diseases that reduce plant establishment.

Cutting or root dip: Dip basal end of cuttings or bare roots (individually or in bunches) in a suspension of **1 to 2 pounds of Double Nickel 55 per gallon of water**. Immerse for 5-10 seconds immediately before planting.

Chemigation: Mix **0.125 to 2 pounds of Double Nickel 55 per 100 gallons of water** and apply via drip, handheld, or sprinkler irrigation systems. Refer to "Chemigation Instructions" for more details.

CROPS/USE SITES	DISEASES/PATHOGENS
Indoor, outdoor, and shade- or other cover-grown ornamental trees and shrubs, flowering plants, foliage plants, tropical plants, potted plants, potted or cut flowers, bedding plants, forestry seedlings, conifer production for reforestation, fruit trees, vegetables and other crops grown in greenhouses or nurseries.	Powdery mildews caused by *Erisyphe, Podosphaera, Sphaerotheca, Oidium,* and *Golovinomyces* spp.) Anthracnose (*Colletotrichum* spp.) Bacterial leaf spots caused by *Erwinia, Pseudomonas,* and *Xanthomonas* spp. Damping-off disease (*Rhizoctonia, Pythium, Fusarium* spp.) Late blight, blackeye, and root rots caused by *Phytophthora* spp. Gray mold and blight caused by *Botrytis cinerea* Black root rot (*Aspergillus* spp.) Black spot of roses (*Diplocarpon rosae*) Downy mildew (*Peronospora* spp.) Leaf spots caused by *Alternaria, Septoria, Cercospora, Entomosporium, Helminthosporium,* and *Myrothecium* spp.) Rust (*Puccinia* spp.) Scab (*Venturia* spp.) Root rot, bottom rot, or stem rot caused by *Rhizoctonia solani* *Sclerotinia* blight *Fusarium* wilts

Turfgrass application: For control of foliar diseases, apply Double Nickel 55 at **0.5 to 1 ounce per 1,000 square feet** as a ground-directed spray in sufficient water to provide thorough coverage. To control root and crown diseases in or on the soil, immediately follow the spray with sufficient overhead sprinkler irrigation to move the product into the root zone.

USE SITES/CROPS	DISEASES/PATHOGENS
Turf, sod, lawns, golf course (fairways, roughs, greens, tees), grass seed production Including but not limited to: Bluegrass, Bentgrass, Bermudagrass (common & hybrid), Dichondra, Fescue, Orchardgrass, *Poa annua*, St. Augustine grass, Ryegrass, *Zoysia*, mixtures, and other grasses or ornamental turf	Anthracnose *(Colletotrichum graminicola)* Brown patch *(Rhizoctonia solani)* Dollar spot *(Lanzia and Moellerodiscus* spp., formerly *Sclerotinia homeocarpa)* Powdery mildew *(Erisyphe graminis)* Rust (*Puccinia* spp.) Gray leaf spot *(Pyricularia grisea)* "Damping off" or seedling blights caused by *Pythium*

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a dry area inaccessible to children. Store in original containers only. Keep container closed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CHEMIGATION INSTRUCTIONS

General Information:

Apply this product only through drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (including impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

Drip (trickle) and micro-irrigation chemigation

1. The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.

Sprinkler chemigation:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.

5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
8. Do not apply when wind speed favors drift beyond the area intended for treatment.

WARRANTY

Cerfis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purpose referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the disease problem, condition of the crop, incompatibility with other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

DoubleNickel55™

BIOFUNGICIDE

Water Dispersible Granular Biofungicide

FOR ORGANIC PRODUCTION

Active Ingredient:
Bacillus amyloliquefaciens strain D747* 25.0%
Other Ingredients: 75.0%
Total 100.0%
Contains a minimum of 5×10^{10} colony-forming units (cfu) per gram

KEEP OUT OF REACH OF CHILDREN
CAUTION

Net Contents: 5 Pounds
EPA Reg. No. 70051-108
EPA Est. No. 70051-CA-001

Lot No:

Manufactured by:
Certis USA, L.L.C.
9145 Guilford Rd, Suite 175
Columbia, MD 21046

CERTIS

FIRST AID - Agricultural Use

If in eyes: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product label with you when calling a poison control center or doctor.

Hot Line No.:1-800-255-3924 for additional information

PRECAUTIONARY STATEMENTS - Agricultural Use
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:
- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow manufacturer's instructions for cleaning and maintaining PPE. If no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:
- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS- Agricultural Use

Do not apply directly to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply when weather conditions favor drift or runoff from treated areas.

GENERAL INFORMATION

Double Nickel 55 is a broad-spectrum preventative biofungicide for control or suppression of fungal and bacterial plant diseases. The active ingredient of Double Nickel 55 is a naturally occurring strain (D747) of the beneficial rhizobacterium *Bacillus amyloliquefaciens*, which colonizes roots, leaves, and other plant surfaces. D747 rapidly colonizes plant root hairs, leaves, and other surfaces, preventing establishment of disease-causing fungi and bacteria.

Double Nickel 55 can be applied alone or in combination and/or rotation with chemical fungicides as a tool for integrated disease management in agricultural crops, ornamentals and nursery plants, and turfgrass, in accordance with the most restrictive of those label limitations and precautions. Double Nickel 55 offers a valuable tool for management of resistance to chemical fungicides through its multiple and unique modes of action.

Double Nickel 55 can be applied up to and including the day of harvest.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the State or Tribal Agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

AGRICULTURAL USE REQUIREMENTS
Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: cover-alls, waterproof gloves, shoes plus socks.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

NON-AGRICULTURAL USE REQUIREMENTS
The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses. Keep unprotected persons out of treated areas until sprays have dried.

MIXING AND HANDLING INSTRUCTIONS
Mix the required amount of Double Nickel 55 in cool water with sufficient agitation to maintain a uniform suspension in the spray or mixing tank. Tank should be cleaned prior to use. Do not use highly alkaline or highly acidic water to mix sprays. Use a buffering agent if necessary to maintain neutrality (pH 6 to 8) of water in the tank. Maintain agitation during application. Apply immediately after mixing; do not allow spray mix to stand overnight.

APPLICATION METHODS
Ground: Double Nickel 55 can be applied in most commonly-used ground application equipment, such as tractor-mounted boom, airblast, high clearance, hose-end, backpack, and other pressurized sprayers; hose-end or hand-held sprayers; foggers or mist blowers; water wheel and other drench applicators; and shank or other soil injection method.

Aerial: Double Nickel 55 can be applied by fixed or rotary winged aircraft in a minimum of 3 gallons of water per acre. Standard precautions should be taken to minimize spray drift.

Chemigation: Double Nickel 55 can be applied through drip (trickle) and sprinkler type irrigation equipment. Refer to the section entitled "Chemigation Instructions" for detailed instructions.

Agricultural crops

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons	
Brassica vegetables such as broccoli, cabbage, cauliflower, Brussels sprouts, kohlrabi, and other cole crops.	Pin rot complex *(Alternaria/Xanthomonas)** Leaf spots (*Alternaria* spp., *Xanthomonas* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe polygoni*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").

(continued)

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons *(continued)*	
Bulb vegetables such as onions, garlic, shallots, and others.	*Botrytis* spp. (neck rot, leaf blight) Purple blotch (*Alternaria* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Rust *(Puccinia poni)** "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").
Cucurbits such as cucumbers, squash (all types), cantaloupes, muskmelons, watermelons, and other melons.	Powdery mildew (*Erisyphe and Sphaerotheca* spp.) Downy mildew (*Pseudoperonospora* spp.) Gummy stem blight (*Didymella bryoniae* and *Phoma cucurbitacearum*) See instructions below for "Soil application" against the following diseases: Vine decline (*Monosporascus cannonballus*) Charcoal rot *(Macrophomina phaseoli)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp.
Fruiting vegetables such as tomatoes, peppers, eggplant, tomatillo, okra, and others.	Bacterial spot (*Xanthomonas* spp.)*[1] Bacterial speck (*Pseudomonas syringae pv. tomato*)*[1] Gray mold (*Botrytis cinerea*) Powdery mildew* (*Leveillula, Didiopsis, Erisyphe,* and *Sphaerotheca* spp.) Early blight *(Alternaria solani)** Late blight *(Phytophthora infestans)** See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. Southern blight *(Sclerotium rolfsii)**
Leafy vegetables such as head and leaf lettuce, celery, spinach, radicchio, arugula, watercress, and others (including leafy Brassica vegetables such as mustard and collard greens, kale, bok choi, and related crops).	Downy mildew (*Bremia lactucae, Peronospora* spp.)* Powdery mildew *(Golovinomyces (Erisyphe) cichoracearum)** Bacterial blights Head and leaf drop (*Sclerotinia* spp.)[2] Pink rot *(Sclerotinia sclerotiorum)*[2] Leaf spots (*Cercospora* spp.) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. Bottom rot (*Rhizoctonia solani*)
Legume vegetables succulent and dried beans and peas such as green, snap, shell, and Lima beans, garbanzo beans, chickpeas, soybeans, dry beans, peas, split peas, lentils, and other legumes.	White mold *(Sclerotinia sclerotiorum)*[2] Gray mold *(Botrytis cinerea)* Powdery mildew *(Microsphaera diffusa)* Rusts*, including *Uromyces appendiculatus, Puccinia* spp., and Asian soybean rust *(Phayospora pachyrhizi)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").

(continued)

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons *(continued)*	
Root, tuber, and corm vegetables such as potato, sweet potato, carrot, cassava, beets, ginger, radish, horse-radish[22], ginseng, turnip, and other root, tuber and corm crops.	Black root/crown rot (*Alternaria* spp.) Bacterial leaf blight *(Xanthomonas campestris)* Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Gray mold (*Botrytis* spp.) White mold *(Sclerotinia sclerotiorum)*[2] Black leg /bacterial soft rot *(Erwinia cerotovora)* Early blight *(Alternaria solani)** Late blight *(Phytophthora infestans)** See instructions below for "Soil application" against the following diseases: Black scurf *(Rhizoctonia solani)* Cavity spot (*Pythium* spp.) "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora*, or *Verticillium** spp.
Other vegetables such as sweet corn, popcorn, asparagus, peanut, and watercress	*Botrytis* spp. Rusts (*Puccinia* spp.) White mold *(Sclerotinia sclerotiorum)*[2] Leaf spots (*Cercospora* and *Cercosporidium* spp.)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Tree fruits and nuts	
Citrus such as orange, lemon, lime, grapefruit, tangerine (mandarin), tangelo, pummelo, and other citrus	*Alternaria* leaf spot *(Alternaria alternata)* Postbloom fruit drop *(Colletotrichum acutatum)** Greasy spot *(Mycosphaeretta citri)**[3] Citrus canker (*Xanthomonas campestris* pv. *citri*)[3] Scab *(Elsinoe fawcettii)**[4] Melanose *(Diaporthe citri)**
Pome fruits such as apple, pear, crabapple, quince, and others	Powdery mildew *(Podosphaera leucotricha)*[5] Scab (*Venturia* spp.)* Flyspeck (*Zygophiala jamaicensis*)[5] Sooty blotch disease complex[5] Brooks spot *(Mycosphaeretta pomi)*[6] Bot rot/white rot *(Botryosphaeria dothidea)*[6] Bitter rot (*Colletotrichum* spp.)[6] Cedar apple rust *(Gymnosporangium juniperi-virginianae)*[6] Fire blight *(Erwinia amylovora)*[47]
Stone fruits such as apricot, cherry, nectarine, peach, plum, prune, pluot, and others	Powdery mildew (*Sphaerotheca* and *Podosphaera* spp.)*[8] Bacterial canker (*Pseudomonas* spp.) Brown rot blossom blight *(Monitinia taxa)*[9] Brown rot *(Monitinia fructicola)**[10] Gray mold *(Botrytis cinerea)*[10] Peach leaf curl *(Taphrina deformans)* Bacterial leaf spot *(Xanthomonas arbicola* pv. *pruni)*[1] Rusty spot *(Podosphaera leucotricha)*[4]
Tree nuts such as almond, pistachio, pecan, walnut, filbert, hazelnut, chestnut, macadamia, and other tree nuts.	Walnut blight *(Xanthomonas campestris)*[11] Anthracnose *(Colletotrichum acutatum)** Bacterial canker *(Pseudomonas syringae)* Shot hole *(Wilsonomyces carpophilus)** Brown rot (*Monilinia* spp.)* Pecan scab *(Cladosprium caryigenum)**[1]
Pomegranates	Leaf and fruit spots (*Cercospora, Gloeosporium* and *Pestalotia* spp.)[1] Fruit rots (*Alternaria, Botrytis*, and other spp.)[10] Powdery mildew *(Sphaerotheca pannosa)*

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Other fruits	
Strawberry	Powdery mildew *(Sphaerotheca macularis, Erisyphe spp.)**[12] Gray mold *(Botrytis cinerea)**[11] Anthracnose *(Colletotrichum acutatum)* Angular leaf spot *(Xanthomonas fragariae)*[7] For the following diseases, see instructions below for "Soil application" (and also root dip instructions[22]): "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. Charcoal rot *(Macrophomina phaseolina)*
Berries, including blueberry, blackberry, raspberry, loganberry, huckleberry, gooseberry, elderberry, cranberry (non-flooded fields), current, and other berries	Mummy berry *(Monitinia vaccinii-corymbosi)** Botrytis blight *(Botrytis cinerea)* Bacterial canker (*Pseudomonas* spp.)[13] Anthracnose fruit rot *(Colletotrichum acutatum)*[10]
Grapes including wine grapes, table grapes, and raisins	Powdery mildew *(Erisyphe* (formerly *Uncinula*) *necator)*[14] Gray mold *(Botrytis cinerea)*[15] Sour rot complex[15] Downy mildew *(Plasmopara viticola)** Phomopsis *(Phomopsis viticola)*[16] Eutypa *(Eutypa lata)*[17]
Tropical fruits such as avocado[18], mango[18], papaya[19], pineapple[19], banana, plantain, and others.	Anthracnose (*Colletotrichum* spp.) Scab *(Sphaceloma perseae)* Bacterial canker *(Xanthomonas campestris)* Sigatoka *(Mycosphaeretta fijiensis)*[20]
Other Crops	
Herbs and spices such as basil, thyme, coriander, dill, cilantro, parsley, mint, and others.	Powdery mildews (*Oidium* spp. and others) Downy mildews (*Peronospora* spp. and others)* Damping off diseases (*Rhizoctonia, Pythium, Alternaria*, and *Fusarium* spp.) Leaf spots (*Alternaria, Septoria, Colletotrichum*, and *Cercospora* spp.)* Bacterial diseases (*Erwinia, Xanthomonas*, and *Pseudomonas* spp.) Rusts (*Puccinia* spp. and others) "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Coffee	Coffee berry disease *(Colletotrichum coffeanum)*[1] Coffee rust *(Hemileia vastatrix)*[1] Anthracnose (*Colletotrichum* spp.) *Botrytis* flower blight *Cercospora* leaf spot and berry blotch "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").

(continued)

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Other fruits *(continued)*	
Tobacco	Angular leaf spot (*Pseudomonas* spp.) Anthracnose (*Colletotrichum* and *Glomerella* spp.) Blue mold or downy mildew (*Peronospora* spp.)* Brown spot (*Alternaria*) Barn spot/ frogeye leaf spot (*Cercospora nicotianae*)[10] Collar rot (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Erysiphe cichoracearum*) Target spot (*Rhizoctonia solani*) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Olpidium, Phytophthora*, or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*) Black root rot (*Thielaviopsis basicola*) Black shank (*Phytophthora* spp.)* Southern blight/southern stem rot (*Sclerotium rolfsii*)*
Mint	Rust (*Puccinia* spp.)
Hops	Powdery mildew (*Sphaerotheca macularis*)[21]

Footnotes:

*Suppression only; for improved control mix or rotate with chemical fungicide approved for such use.

1 Tank mix or rotate with copper-based fungicides at label rates for improved control.

2 Apply at or immediately following planting (but before plant emergence) as a banded seedline treatment 4 to 6 inches wide. Make second application at thinning or cultivation in sufficient water and multiple nozzles to ensure thorough coverage of lower leaves and surrounding soil surface. Incorporation with light irrigation after application may improve disease control. Repeat at 10-14 day intervals if conditions promoting disease persist.

3 For greasy spot suppression, apply at first new foliar flush and repeat with each new flush. Tank mix with spray oil or copper based fungicide at labeled rates.

4 For suppression of citrus scab, start applications at first new foliage flush and repeat at petal fall and when fruit are ½ inch in diameter.

5 Make first application at or before tight cluster if conditions favor disease development. Repeat at 7-10 day intervals through the second cover spray or longer on susceptible varieties or if environmental conditions favor rapid disease development.

6 Begin applications before bloom when environmental conditions favor disease development, repeating at 7 to 14 day intervals or as needed. Control may be enhanced by addition of a surfactant to improve spray coverage. Use only surfactants known to be safe for use on the crop and for which such use is allowed.

7 Rotate with antibiotics registered for fire blight control for improved performance. Begin applications at 1-5% open blossoms and repeat every 3-7 days as necessary until petal fall, when intervals can be increased to 7 days. Double Nickel 55 can also be used in summer "cover spray" applications to control the shoot blight phase of fire blight and summer diseases. Can be mixed with copper fungicides to improve control.

8 Make first application at popcorn stage and repeat every 7 days.

9 Start applying at early bloom stage and repeat every 7 days through petal fall.

10 Pre-harvest applications in sufficient water to cover fruit or other harvested plant parts may improve control of postharvest infections.

11 Begin applications at or before pistillate bloom, repeating every 7-10 days. Apply before rainfall if possible, and tank mix or rotate with a copper-based bactericide registered for such use for improved control.

12 Start applications at or just before flowering and repeat every 7-10 days as needed through harvest.

(continued)

Footnotes: *(continued)*

13 Apply before fall rains and again during dormancy before spring growth.

14 Start applications when new shoots are ½ to 1½ inches long. Repeat at 3-5 inches, 8-10 inches, and then at 7-10 day intervals until disease conditions no longer exist.

15 Apply at bloom, before bunch closure, at veraison, and before harvest.

16 Apply when shoots are ½ to 1 inch long and again when 6-8 inches long.

17 Mix 2 fluid ounces Double Nickel 55 per gallon of water and apply to pruning wounds.

18 Apply at budbreak and repeat on 14-21 day interval as needed through harvest.

19 Apply at flowering and repeat on 14-21 day interval as needed through harvest.

20 Apply at first appearance of leaves and repeat at 7-21 day intervals as needed, in sufficient water to obtain thorough coverage of foliage. Tank mix with spray oil or other registered fungicides for improved control.

21 Mix 6 to10 fluid ounces Double Nickel 55 per 100 gallons of water and apply in minimum of 20 gallons per acre from emergence to training, 50 gallons per acre from training to wire, and 100 gallons per acre from wire touch through harvest.

22 For treatment of horseradish or strawberry roots immediately before transplanting: immerse bare roots (individually or in bunches) for 10 seconds in a suspension of 1 to 2 pints Double Nickel 55 per gallon of water.

Foliar application: For control of diseases on foliage, flowers, fruit, or other above-ground parts of plants: Mix Double Nickel 55 in water and apply as a spray at a rate of **0.25 to 3 pounds** per acre in sufficient water to achieve thorough coverage of the crop canopy with minimal runoff. Begin applications at crop emergence, transplanting, or when conditions are conducive to development of disease. Repeat application every 7 to 10 days, or as needed, for as long as conditions favor disease development. Lower rates (0.25 to 1 pound per acre) may be applied under light disease pressure, to smaller (e.g. newly-emerged) plants, or when Double Nickel 55 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (1 to 3 pounds per acre), apply more frequently (every 3 to 7 days), and mix or rotate Double Nickel 55 with other fungicides for improved performance.

Soil application: For control of soilborne diseases infecting seeds, seedlings, roots, crown, stems, or other plant parts below ground or in contact with soil: Apply Double Nickel 55 at **0.125 to 1** pound per acre. Mix the required amount in sufficient water to apply by one of the following methods:

- Soil drench applied to transplants in flats or pots in the greenhouse or nursery any time prior to transplanting (see additional drench instructions under "Nurseries, greenhouses, shade houses, and ornamental plants" below).
- Soil drench at transplanting, using a "water wheel" injector, spray nozzles/hoses, or other method to drench each root ball and/or planting hole.
- Soil or seedline drench, or banded spray (in-furrow) at planting. See the section on "Banded (in-furrow) application" below for additional instructions.

Follow-up (post-planting) preventative applications can be made every 2-4 weeks by one or more of the following methods, if needed:

- Drip (trickle) or any type of sprinkler irrigation, any time after planting or transplanting. See Chemigation Instructions for additional information.
- Spray directly onto the soil surface and/or lower plant parts. If targeting root disease, follow immediately with sufficient overhead sprinkler irrigation to move Double Nickel 55 to the root zone.
- Injection directly into the rooting zone using shanks or similar equipment.

Lower rates (0.125 to 0.5 pounds per acre) may be applied under light disease pressure, to smaller plants, or when Double Nickel 55 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when

environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (0.5 to 1 pound per acre), apply more frequently (every 2 weeks), and mix or rotate Double Nickel 55 with other fungicides for improved performance.

Banded (in-furrow) application: Use the table below to determine the correct application rate of Double Nickel 55 per 1,000 row feet, based on row spacing and desired rate per acre. Mix the required amount of Double Nickel 55 in water and apply as banded spray (4" to 6" wide) or seedline drench centered over the planting furrow. Apply directly over seeds in the furrow just before they are covered with soil. The volume of water required per acre or per 1,000 row feet will depend on the application equipment used. Consult your local cooperative extension service if you need assistance calibrating band spraying equipment.

Rates for banded (in-furrow) application: Find desired application rate in the left column. Read across that line to the correct row spacing indicated at the top to find the number of ounces (dry) per 1,000 row feet that will provide the desired application rate per acre. To convert to level **teaspoons**, multiply the number of ounces by 8.2. For **level tablespoons**, multiply the number of ounces by 2.75.

Ratefacre (pounds)	Space between rows (inches)														
	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
0.25	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3
0.5	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6
0.75	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9
1.0	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.2	1.2
1.25	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.4	1.5	1.5
1.5	0.6	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.7	1.8
1.75	0.6	0.7	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1
2.0	0.7	0.9	1.0	1.1	1.2	1.3	1.5	1.6	1.7	1.8	2.0	2.1	2.2	2.3	2.4
2.25	0.8	1.0	1.1	1.2	1.4	1.5	1.7	1.8	1.9	2.1	2.2	2.3	2.5	2.6	2.8
2.5	0.9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1
2.75	1.0	1.2	1.3	1.5	1.7	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.0	3.2	3.4
3.0	1.1	1.3	1.5	1.7	1.8	2.0	2.2	2.4	2.6	2.8	2.9	3.1	3.3	3.5	3.7

Nurseries, greenhouses, shadehouses, and ornamental plants

Spray application: Mix **0.25 to 3 pounds of Double Nickel 55 per 100 gallons of water** and apply as a foliar spray of sufficient volume to wet the entire plant with minimal runoff. Begin preventative applications at plant emergence and repeat every 3-28 days as needed (every 3-7 days if disease pressure is high or environmental conditions are highly favorable to disease outbreak, 10-28 days under low pressure or less conducive conditions).

Drench application: Mix **0.125 to 2 pounds of Double Nickel 55 per 100 gallons of water** and apply as a drench or coarse spray to soil or other growing media in pots, flats, plugs, trays, or planting beds, for control or suppression of soilborne diseases of seedlings, cuttings, bedding plants, and transplants (including vegetables and other transplanted food crops). Make first application at or immediately before seeding, sticking, germination, or transplanting. Repeat applications every 14-28 days as needed. Transplants can be treated immediately before transplanting into field soils to protect against damping-off and other diseases that reduce plant establishment.

Cutting or root dip: Dip basal end of cuttings or bare roots (individually or in bunches) in a suspension of **1 to 2 pounds of Double Nickel 55 per gallon of water**. Immerse for 5-10 seconds immediately before planting.

Chemigation: Mix **0.125 to 2 pounds of Double Nickel 55 per 100 gallons of water** and apply via drip, handheld, or sprinkler irrigation systems. Refer to "Chemigation Instructions" for more details.

CROPS/USE SITES	DISEASES/PATHOGENS
Indoor, outdoor, and shade- or other cover-grown ornamental trees and shrubs, flowering plants, foliage plants, tropical plants, potted plants, potted or cut flowers, bedding plants, forestry seedlings, conifer production for reforestation, fruit trees, vegetables and other crops grown in greenhouses or nurseries.	Powdery mildews caused by *Erisyphe, Podosphaera, Sphaerotheca, Oidium*, and *Golovinomyces* spp.) Anthracnose (*Coffetotrichum* spp.) Bacterial leaf spots caused by *Erwinia, Pseudomonas*, and *Xanthomonas* spp. Damping-off disease (*Rhizoctonia, Pythium, Fusarium* spp.) Late blight, blackeye, and root rots caused by *Phytophthora* spp. Gray mold and blight caused by *Botrytis cinerea* Black root rot (*Aspergillus* spp.) Black spot of roses (*Diplocarpon rosae*) Downy mildew (*Peronospora* spp.) Leaf spots caused by *Alternaria, Septoria, Cercospora, Entomosporium, Helminthosporium*, and *Myrothecium* spp.) Rust (*Puccinia* spp.) Scab (*Venturia* spp.) Root rot, bottom rot, or stem rot caused by *Rhizoctonia solani* *Sclerotinia* blight *Fusarium* wilts

Turfgrass application: For control of foliar diseases, apply Double Nickel 55 at **0.5 to 1 ounce per 1,000 square feet** as a ground-directed spray in sufficient water to provide thorough coverage. To control root and crown diseases in or on the soil, immediately follow the spray with sufficient overhead sprinkler irrigation to move the product into the root zone.

USE SITES/CROPS	DISEASES/PATHOGENS
Turf, sod, lawns, golf course (fairways, roughs, greens, tees), grass seed production Including but not limited to: Bluegrass, Bentgrass, Bermudagrass (common & hybrid), Dichondra, Fescue, Orchardgrass, *Poa annua*, St. Augustine grass, Ryegrass, *Zoysia*, mixtures, and other grasses or ornamental turf	Anthracnose *(Colletotrichum graminicola)* Brown patch *(Rhizoctonia solani)* Dollar spot (*Lanzia and Moellerodiscus* spp., formerly *Sclerotinia homeocarpa*) Powdery mildew *(Erisyphe graminis)* Rust (*Puccinia* spp.) Gray leaf spot *(Pyricularia grisea)* "Damping off" or seedling blights caused by *Pythium*

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a dry area inaccessible to children. Store in original containers only. Keep container closed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CHEMIGATION INSTRUCTIONS

General information:

Apply this product only through drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (including impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

Drip (trickle) and micro-irrigation chemigation

1. The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.

Sprinkler chemigation:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.

5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
8. Do not apply when wind speed favors drift beyond the area intended for treatment.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purpose referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the disease problem, condition of the crop, incompatibility with other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

OMRI Listed®

The following product is OMRI Listed. It may be used in certified organic production or food processing and handling according to the USDA National Organic Program Rule.

Product
DoubleNickel 55™ Biofungicide

Company
Certis USA
Ms. Christine Dively
9145 Guilford Rd, Suite 175
Columbia, MD 21046-1952

Status	Category	Issue Date
Allowed with Restrictions	Microbial Pesticides	20-Mar-12

Product number	Class	Expiration Date
ttc-29D1	Crop Pest, Weed, and Disease Control	01-Jun-2013

Restrictions
May be used for pesticidal purposes only if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

Peggy Miars
Executive Director

Product review is conducted according to the policies in the current OMRI Policy Manual and based on the standards in the current OMRI Standards Manual.
To verify the current status of this or any OMRI Listed product, view the most current version of the OMRI Products List at www.omri.org.
OMRI listing is not equivalent to organic certification and is not a product endorsement. It cannot be construed as such.
Final decisions on the acceptability of a product for use in a certified organic system are the responsibility of a USDA accredited certification agent.
It is the operator's responsibility to properly use the product, including following any restrictions.

OMRI® Listed

Organic Materials Review Institute
P.O. Box 11558, Eugene, OR 97440-3758, USA
541.343.7600 · fax 541.343.8971 · info@omri.org · www.omri.org

Receipt for Section 3

S: 813868 Resubmission: Yes No

Regulatory Type: Product Registration - Section 3 Fee For Service: Yes No

Application Type: Notification

Company: 70051 CERTIS USA, LLC

Print Letter
Enter More Information
Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92

Product #: 70051-108 Product Name: CX-9030

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 22-Mar-2012 OPP Rec'vd Date: 23-Mar-2012

Front End Date: 23-Mar-2012 Risk Manager Send Date: 23-Mar-2012

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: New Ingredient:

Receipt Content | Des
Paper Label

View/Edit

Receipt Description:

Notification of additional Brand Name

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date: Form B: Signature Date:

332: Notification

Susanne,

Since you have the jacket, you get this notification. Please let me know when it is completed.

-Mike

Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046

(301) 604-7340

Fax: 301-604-7015
www.certisusa.com

Hand-Delivered

March 22, 2012

Sheryl Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division (7504P)
Office of Pesticide Programs
US Environmental Protection Agency

Re: Certis U.S.A., L.L.C.
Notification of Additional Brand Name
CX-9030; EPA Registration Number 70051-108; Amylo-X

Dear Dr. Reilly;

On behalf of Certis U.S.A., L.L.C. (9145 Guilford Road, Suite 175, Columbia, Maryland 21046), I respectfully submit a *Notification for CX-9030*, to provide the additional brand name, Amylo-X. Please note that we are dropping the WG from the approved brand name Amylo-X WG. No other changes have been made to the EPA stamped label, dated December 16, 2011.

Please do not hesitate to contact me if you have any questions about this submission. I can be reached by telephone at 301-483-3806 or by email at cdively@certisusa.com.

Sincerely,

Christine A. Dively

Christine A. Dively
Director of Regulatory Affairs
Certis USA

Enclosure

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70051-108	2. EPA Product Manager Reynolds	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) CX-9030	PM# Microbial Pesticide Branch	
5. Name and Address of Applicant *(Include ZIP Code)* Certis USA, L.L.C. 9145 Guilford Road, Suite 175 Columbia Maryland 21046 [ ] *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional pages if necessary. (For section I and Section II.)

Submission of an Alternate Brand Name (Amylo-X), dropping the WG from the approved ABN Amylo-X WG.
See attached certification statement.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes*	[ ] Yes	[ ] Yes	[ ] Metal
[X] No	[X] No	[X] No	[X] Plastic
			[ ] Glass
			[ ] Paper
			[ ] Other (Specify) _____
	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

** Certification must be submitted*

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	5 lbs	[X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [X] Lithograph [X] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Christine A. Dively	Director of Reg. Affairs	301-483-3806

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature Christine A. Dively	3. Title Director of Regulatory Affairs
4. Typed Name Christine A. Dively	5. Date March 22, 2012

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

NOTIFICATION STATEMENT

CX-9030 EPA Reg. No. 70051-108-- in compliance with PR Notice 98-10

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

CX-9030

OMRI Seal placeholder

Water Dispersible Granular Biofungicide

(Alternate brand names: Double Nickel 55; Amylo-X) Alternate Brand Name

For Organic Production

Active Ingredient:

Bacillus amyloliquefaciens strain D747* 25.0%

Other Ingredients 75.0%

Total 100.0%

Contains a minimum of 5×10^{10} colony-forming units (cfu) per gram

EPA Reg. No. 70051-

EPA Est. No. 70051-CA-001

Notification Accepted

Date: JUN 13 2012

Reviewer: Susanne Cerceli

Manufactured by: Certis USA, L.L.C.
9145 Guilford Rd., Suite. 175
Columbia, MD 21046

NET WEIGHT: 5 LBS Lot No:

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID - Agricultural Use

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product label with you when calling a poison control center or doctor.
Hot Line No.: 1-800-255-3924 for additional information

PRECAUTIONARY STATEMENTS - Agricultural Use

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants

- Waterproof gloves
- Shoes plus socks

Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow manufacturer's instructions for cleaning and maintaining PPE. In no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. AS soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS- Agricultural Use

Do not apply directly to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply when weather conditions favor drift or runoff from treated areas.

GENERAL INFORMATION

CX-9030 is a broad-spectrum preventative biofungicide for control or suppression of fungal and bacterial plant diseases. The active ingredient of CX-9030 is a naturally occurring strain (D747) of the beneficial rhizobacterium *Bacillus amyloliquefaciens*, which colonizes roots, leaves, and other plant surfaces. D747 rapidly colonizes plant root hairs, leaves, and other surfaces, preventing establishment of disease-causing fungi and bacteria.

CX-9030 can be applied alone or in combination and/or rotation with chemical fungicides as a tool for integrated disease management in agricultural crops, ornamental and nursery plants, and turfgrass, in accordance with the most restrictive of those label limitations and precautions. CX-9030 offers a valuable tool for management of resistance to chemical fungicides through its multiple and unique modes of action.

CX-9030 can be applied up to and including the day of harvest.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the State or Tribal Agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: cover-alls, waterproof gloves, shoes plus socks.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses. Keep unprotected persons out of treated areas until sprays have dried.

MIXING AND HANDLING INSTRUCTIONS

Mix the required amount of CX-9030 in cool water with sufficient agitation to maintain a uniform suspension in the spray or mixing tank. Tank should be cleaned prior to use. Do not use highly alkaline or highly acidic water to mix sprays. Use a buffering agent if necessary to maintain neutrality (pH 6 to 8) of water in the tank. Maintain agitation during application. Apply immediately after mixing; do not allow spray mix to stand overnight.

APPLICATION METHODS

Ground: CX-9030 can be applied in most commonly-used ground application equipment, such as tractor-mounted boom, airblast, high clearance, hose-end, backpack, and other pressurized sprayers; hose-end or hand-held sprayers; foggers or mist blowers; water wheel and other drench applicators; and shank or other soil injection method.

Aerial: CX-9030 can be applied by fixed or rotary winged aircraft in a minimum of 3 gallons of water per acre. Standard precautions should be taken to minimize spray drift.

Chemigation: CX-9030 can be applied through drip (trickle) and sprinkler type irrigation equipment. Refer to the section entitled "Chemigation Instructions" for detailed instructions.

Agricultural crops

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons	
Brassica vegetables such as broccoli, cabbage, cauliflower, Brussels sprouts, kohlrabi, and other cole crops.	Pin rot complex (*Alternaria/Xanthomonas*)* Leaf spots (*Alternaria* spp., *Xanthomonas* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe polygoni*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Bulb vegetables such as onions, garlic, shallots, and others.	*Botrytis* spp. (neck rot, leaf blight) Purple blotch (*Alternaria* spp.) Downy mildew (*Peronaspora* spp.) Powdery mildew (*Erisyphe* spp.) Rust (*Puccinia pori*)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Cucurbits such as cucumbers, squash (all types), cantaloupes, muskmelons, watermelons, and other melons.	Powdery mildew (*Erisyphe* and *Sphaeratheca* spp.) Downy mildew (*Pseudoperonospara* spp.) Gummy stem blight (*Didymella bryonioe* and *Phoma cucurbitacearum*) See instructions below for "Soil application" against the following diseases: Vine decline (*Monosparoscus cannonballus*) Charcoal rot (*Macrophomina phaseali*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp.
Fruiting vegetables such as tomatoes, peppers, eggplant, tomatillo, okra, and others.	Bacterial spot (*Xanthamonas* spp.)*[1] Bacterial speck (*Pseudomonas syringae* pv. *tamato*)*[1] Gray mold (*Botrytis cinerea*) Powdery mildew* (*Leveillula*, *Oidiopsis*, *Erisyphe*, and *Sphaerotheca* spp.) Early blight (*Alternaria saloni*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. Southern blight (*Sclerotium rolfsii*)*
Leafy vegetables such as head and leaf lettuce, celery, spinach, radicchio, arugula, watercress, and others (including leafy *Brassica* vegetables such as mustard and collard greens, kale, bok choi, and related crops).	Downy mildew (*Bremia loctucoe*, *Peronaspora* spp.)* Powdery mildew (*Golovinomyces (Erisyphe) cichoracearum*)* Bacterial blights Head and leaf drop (*Sclerotinia* spp.)[2] Pink rot (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* spp.) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp Bottom rot (*Rhizoctonia solani*)
Legume vegetables succulent and dried beans and peas such as green, snap, shell, and Lima beans, garbanzo beans, chickpeas, soybeans, dry beans, peas, split peas, lentils, and other legumes.	White mold (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Microsphaera diffusa*) Rusts*, including *Uromyces appendiculatus*, *Puccinia* spp., and Asian soybean rust (*Phoyospora paclyrhizi*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Root, tuber, and corm vegetables such as potato, sweet potato, carrot,	Black root/crown rot (*Alternaria* spp.) Bacterial leaf blight (*Xanthomonas campestris*)

cassava, beets, ginger, radish, horseradish[22], ginseng, turnip, and other root, tuber and corm crops.	Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Gray mold (*Botrytis* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Black leg /bacterial soft rot (*Erwinia carotovora*) Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: Black scurf (*Rhizoctonia solani*) Cavity spot (*Pythium* spp.) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp.
Other vegetables such as sweet corn, popcorn, asparagus, peanut, and watercress	*Botrytis* spp. Rusts (*Puccinia* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* and *Cercosporidium* spp.)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Tree fruits and nuts	
Citrus such as orange, lemon, lime, grapefruit, tangerine (mandarin), tangelo, pummelo, and other citrus	*Alternoria* leaf spot (*Alternaria alternata*) Postbloom fruit drop (*Colletotrichum acutatum*)* Greasy spot (*Mycosphaerella citri*)*[3] Citrus canker (*Xanthomonas campestris* pv. *citri*)[1] Scab (*Elsinoe fawcetti*)*[4] Melanose (*Diaporthe citri*)*
Pome fruits such as apple, pear, crabapple, quince, and others	Powdery mildew (*Podosphaera leucotricha*)[5] Scab (*Venturia* spp.)* Flyspeck (*Zygophiala jamaicensis*)[6] Sooty blotch disease complex[6] Brooks spot (*Mycosphaerella pomi*)[6] Bot rot/white rot (*Botryosphaeria dothidea*)[6] Bitter rot (*Colletotrichum* spp.)[6] Cedar apple rust (*Gymnosporangium juniperi-virginianae*)[6] Fire blight (*Erwinia amylavora*)*[7]
Stone fruits such as apricot, cherry, nectarine, peach, plum, prune, pluot, and others	Powdery mildew (*Sphaerotheca* and *Podosphaera* spp.)*[8] Bacterial canker (*Pseudomonas* spp.) Brown rot blossom blight (*Monilinia laxa*)[9] Brown rot (*Monilinia fructicola*)*[10] Gray mold (*Botrytis cinerea*)[10] Peach leaf curl (*Taphrina deformans*) Bacterial leaf spot (*Xanthomonas orbicola* pv. *pruni*)[1] Rusty spot (*Podosphaera leucotricha*)[1]
Tree nuts such as almond, pistachio, pecan, walnut, filbert, hazelnut, chestnut, macadamia, and other tree nuts.	Walnut blight (*Xanthomonas campestris*)[11] Anthracnose (*Colletotrichum acutatum*)* Bacterial canker (*Pseudamonas syringoe*) Shot hole (*Wilsonomyces carpophilus*)* Brown rot (*Monilinia* spp.)* Pecan scab (*Cladosprium caryigenum*)*[1]
Pomegranates	Leaf and fruit spots (*Cercosporo*, *Gloeosporium* and *Pestalotia* spp.)[1] Fruit rots (*Alternaria*, *Botrytis*, and other spp.)[10] Powdery mildew (*Sphaerotheca pannosa*)
Other fruits	
Strawberry	Powdery mildew (*Sphaerotheca macularis*, *Erisyphe* spp.)*[12] Gray mold (*Botrytis cinerea*)*[11] Anthracnose (*Colletotrichum acutatum*) Angular leaf spot (*Xanthomonas fragariae*)[1] For the following diseases, see instructions below for "Soil application" (and also root

	dip instructions[22]): "Damping off" and root or crown diseases caused by *Rhizoctonia*, *Fusarium*, *Pythium*, *Phytophthora*, and/or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*)
Berries, including blueberry, blackberry, raspberry, loganberry, huckleberry, gooseberry, elderberry, cranberry (non-flooded fields), current, and other berries	Mummy berry (*Monilinia vaccinii-carymbosi*)* Botrytis blight (*Botrytis cinerea*) Bacterial canker (*Pseudomonas* spp.)[13] Anthracnose fruit rot (*Colletotrichum acutatum*)[10]
Grapes including wine grapes, table grapes, and raisins	Powdery mildew (*Erisyphe* (formerly *Uncinula*) *necatar*)[14] Gray mold (*Botrytis cinerea*)[15] Sour rot complex[15] Downy mildew (*Plasmopara viticola*)* Phomopsis (*Phomopsis viticola*)[16] Eutypa (*Eutypa lata*)[17]
Tropical fruits such as avocado[18], mango[18], papaya[19], pineapple[19], banana, plantain, and others.	Anthracnose (*Colletotrichum* spp.) Scab (*Sphaceloma perseae*) Bacterial canker (*Xanthamonas campestris*) Sigatoka (*Mycosphaerella fijiensis*)[20]
Other Crops	
Herbs and spices such as basil, thyme, coriander, dill, cilantro, parsley, mint, and others.	Powdery mildews (*Oidium* spp. and others) Downy mildews (*Peronospora* spp. and others)* Damping off diseases (*Rhizactania*, *Pythium*, *Alternaria*, and *Fusarium* spp.) Leaf spots (*Alternaria*, *Septoria*, *Colletotrichum*, and *Cercospora* spp.)* Bacterial diseases (*Erwinia*, *Xanthomonas*, and *Pseudomonas* spp.) Rusts (*Puccinia* spp. and others) "Damping off" and root or crown diseases caused by *Rhizactania*, *Fusarium*, *Pythium*, *Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Coffee	Coffee berry disease (*Colletotrichum coffeanum*)[1] Coffee rust (*Hemileia vastatrix*)[1] Anthracnose (*Colletotrichum* spp.) *Botrytis* flower blight *Cercospora* leaf spot and berry blotch "Damping off" and root or crown diseases caused by *Rhizoctonia*, *Fusarium*, *Pythium*, *Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Tobacco	Angular leaf spot (*Pseudomonas* spp.) Anthracnose (*Colletotrichum* and *Glomerella* spp.) Blue mold or downy mildew (*Peronospora* spp.)* Brown spot (*Alternaria*) Barn spot/ frogeye leaf spot (*Cercospora nicotianae*)[10] Collar rot (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Erysiphe cichoracearum*) Target spot (*Rhizactania solani*) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Olpidium*, *Phytophthora*, or *Verticillium** spp. Charcoal rot (*Macraphomina phaseolina*) Black root rot (*Thielaviopsis basicola*) Black shank (*Phytophthora* spp.)* Southern blight/southern stem rot (*Sclerotium rolfsii*)*
Mint	Rust (*Puccinia* spp.)
Hops	Powdery mildew (*Sphaerotheca macularis*)[21]
Footnotes: *Suppression only; for improved control mix or rotate with chemical fungicide approved for such use.	

[1] Tank mix or rotate with copper-based fungicides at label rates for improved control.

[1] Apply at or immediately following planting (but before plant emergence) as a banded seedline treatment 4 to 6 inches wide. Make second application at thinning or cultivation in sufficient water and multiple nozzles to ensure thorough coverage of lower leaves and surrounding soil surface. Incorporation with light irrigation after application may improve disease control. Repeat at 10-14 day intervals if conditions promoting disease persist.

[3] For greasy spot suppression, apply at first new foliar flush and repeat with each new flush. Tank mix with spray oil or copper based fungicide at labeled rates.

[4] For suppression of citrus scab, start applications at first new foliage flush and repeat at petal fall and when fruit are ½ inch in diameter.

[5] Make first application at or before tight cluster if conditions favor disease development. Repeat at 7-10 day intervals through the second cover spray or longer on susceptible varieties or if environmental conditions favor rapid disease development.

[6] Begin applications before bloom when environmental conditions favor disease development, repeating at 7 to 14 day intervals or as needed. Control may be enhanced by addition of a surfactant to improve spray coverage. Use only surfactants known to be safe for use on the crop and for which such use is allowed.

[7] Rotate with antibiotics registered for fire blight control for improved performance. Begin applications at 1-5% open blossoms and repeat every 3-7 days as necessary until petal fall, when intervals can be increased to 7 days. CX-9032 can also be used in summer "cover spray" applications to control the shoot blight phase of fire blight and summer diseases. Can be mixed with copper fungicides to improve control.

[8] Make first application at popcorn stage and repeat every 7 days.

[9] Start applying at early bloom stage and repeat every 7 days through petal fall.

[10] Pre-harvest applications in sufficient water to cover fruit or other harvested plant parts may improve control of postharvest infections.

[11] Begin applications at or before pistillate bloom, repeating every 7-10 days. Apply before rainfall if possible, and tank mix or rotate with a copper-based bactericide registered for such use for improved control.

[12] Start applications at or just before flowering and repeat every 7-10 days as needed through harvest.

[13] Apply before fall rains and again during dormancy before spring growth.

[14] Start applications when new shoots are ½ to 1½ inches long. Repeat at 3-5 inches, 8-10 inches, and then at 7-10 day intervals until disease conditions no longer exist.

[15] Apply at bloom, before bunch closure, at veraison, and before harvest.

[16] Apply when shoots are ½ to 1 inch long and again when 6-8 inches long.

[17] Mix 2 fluid ounces CX-9032 per gallon of water and apply to pruning wounds.

[18] Apply at budbreak and repeat on 14-21 day interval as needed through harvest.

[19] Apply at flowering and repeat on 14-21 day interval as needed through harvest

[20] Apply at first appearance of leaves and repeat at 7-21 day intervals as needed, in sufficient water to obtain thorough coverage of foliage. Tank mix with spray oil or other registered fungicides for improved control.

[21] Mix 6 to10 fluid ounces CX-9032 per 100 gallons of water and apply in minimum of 20 gallons per acre from emergence to training, 50 gallons per acre from training to wire, and 100 gallons per acre from wire touch through harvest.

[22] For treatment of horseradish or strawberry roots immediately before transplanting: immerse bare roots (individually or in bunches) for 10 seconds in a suspension of 1 to 2 pints CX-9032 per gallon of water.

Foliar application: For control of diseases on foliage, flowers, fruit, or other above-ground parts of plants: Mix CX-9030 in water and apply as a spray at a rate of **0.25 to 3 pounds per acre** in sufficient water to achieve thorough coverage of the crop canopy with minimal runoff. Begin applications at crop emergence, transplanting, or when conditions are conducive to development of disease. Repeat application every 7 to 10 days, or as needed, for as long as conditions favor disease development. Lower rates (0.25 to 1 pound per acre) may be applied under light disease pressure, to smaller (e.g. newly-emerged) plants, or when CX-9030 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (1 to 3 pounds per acre), apply more frequently (every 3 to 7 days), and mix or rotate CX-9030 with other fungicides for improved performance.

Soil application: For control of soilborne diseases infecting seeds, seedlings, roots, crown, stems, or other plant parts below ground or in contact with soil: Apply CX-9030 at **0.125 to 1 pound per acre**. Mix the required amount in sufficient water to apply by one of the following methods:

- Soil drench applied to transplants in flats or pots in the greenhouse or nursery any time prior to transplanting (see additional drench instructions under "Nurseries, greenhouses, shade houses, and ornamental plants[12] below).

- Soil drench at transplanting, using a "water wheel" injector, spray nozzles/hoses, or other method to drench each root ball and/or planting hole.
- Soil or seedline drench, or banded spray (in-furrow) at planting. See the section on "Banded (in-furrow) application" below for additional instructions.

Follow-up (post-planting) preventative applications can be made every 2-4 weeks by one or more of the following methods, if needed:

- Drip (trickle) or any type of sprinkler irrigation, any time after planting or transplanting. See Chemigation Instructions for additional information.
- Spray directly onto the soil surface and/or lower plant parts. If targeting root disease, follow immediately with sufficient overhead sprinkler irrigation to move CX-9030 to the root zone.
- Injection directly into the rooting zone using shanks or similar equipment.

Lower rates (0.125 to 0.5 pounds per acre) may be applied under light disease pressure, to smaller plants, or when CX-9030 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (0.5 to 1 pound per acre), apply more frequently (every 2 weeks), and mix or rotate CX-9030 with other fungicides for improved performance.

Banded (in-furrow) application: Use the table below to determine the correct application rate of CX-9030 per 1,000 row feet, based on row spacing and desired rate per acre. Mix the required amount of CX-9030 in water and apply as banded spray (4" to 6" wide) or seedline drench centered over the planting furrow. Apply directly over seeds in the furrow just before they are covered with soil. The volume of water required per acre or per 1,000 row feet will depend on the application equipment used. Consult your local cooperative extension service if you need assistance calibrating band spraying equipment.

Rates for banded (in-furrow) application: Find desired application rate in the left column. Read across that line to the correct row spacing indicated at the top to find the number of ounces (dry) per 1,000 row feet that will provide the desired application rate per acre. To convert to **level teaspoons**, multiply the number of ounces by 8.2. For **level tablespoons**, multiply the number of ounces by 2.75.

Rate/acre	Space between rows (inches)														
(pounds)	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
0.25	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3
0.5	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6
0.75	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9
1.0	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.2	1.2
1.25	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.4	1.5	1.5
1.5	0.6	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.7	1.8
1.75	0.6	0.7	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1
2.0	0.7	0.9	1.0	1.1	1.2	1.3	1.5	1.6	1.7	1.8	2.0	2.1	2.2	2.3	2.4
2.25	0.8	1.0	1.1	1.2	1.4	1.5	1.7	1.8	1.9	2.1	2.2	2.3	2.5	2.6	2.8
2.5	0.9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1
2.75	1.0	1.2	1.3	1.5	1.7	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.0	3.2	3.4
3.0	1.1	1.3	1.5	1.7	1.8	2.0	2.2	2.4	2.6	2.8	2.9	3.1	3.3	3.5	3.7

Nurseries, greenhouses, shadehouses, and ornamental plants

Spray application: Mix **0.25 to 3 pounds of CX-9030** per **100 gallons of water** and apply as a foliar spray of sufficient volume to wet the entire plant with minimal runoff. Begin preventative applications at plant emergence and repeat every 3-28 days as needed (every 3-7 days if disease

pressure is high or environmental conditions are highly favorable to disease outbreak, 10-28 days under low pressure or less conducive conditions).

Drench application: Mix **0.125 to 2 pounds of CX-9030 per 100 gallons of water** and apply as a drench or coarse spray to soil or other growing media in pots, flats, plugs, trays, or planting beds, for control or suppression of soilborne diseases of seedlings, cuttings, bedding plants, and transplants (including vegetables and other transplanted food crops). Make first application at or immediately before seeding, sticking, germination, or transplanting. Repeat applications every 14-28 days as needed. Transplants can be treated immediately before transplanting into field soils to protect against damping-off and other diseases that reduce plant establishment.

Cutting or root dip: Dip basal end of cuttings or bare roots (individually or in bunches) in a suspension of **1 to 2 pounds of CX-9030 per gallon of water**. Immerse for 5-10 seconds immediately before planting.

Chemigation: Mix **0.125 to 2 pounds of CX-9030 per 100 gallons of water** and apply via drip, handheld, or sprinkler irrigation systems. Refer to "Chemigation Instructions" for more details.

CROPS/USE SITES	DISEASES/PATHOGENS
Indoor, outdoor, and shade- or other cover-grown ornamental trees and shrubs, flowering plants, foliage plants, tropical plants, potted plants, potted or cut flowers, bedding plants, forestry seedlings, conifer production for reforestation, fruit trees, vegetables and other crops grown in greenhouses or nurseries.	Powdery mildews caused by *Erisyphe, Podosphoera, Sphaerotheca, Oidium,* and *Golovinomyces* spp.) Anthracnose (*Colletotrichum* spp.) Bacterial leaf spots caused by *Erwinia, Pseudomonas,* and *Xanthomonas* spp. Damping-off disease (*Rhizoctonia, Pythium, Fusarium* spp.) Late blight, blackeye, and root rots caused by *Phytophthora* spp. Gray mold and blight caused by *Botrytis cinereo* Black root rot (*Aspergillus* spp.) Black spot of roses (*Diplocarpon rosae*) Downy mildew (*Peronospora* spp.) Leaf spots caused by *Alternoria, Septoria, Cercospora, Entomosporium, Helminthosporium,* and *Myrothecium* spp.) Rust (*Puccinia* spp.) Scab (*Venturia* spp.) Root rot, bottom rot, or stem rot caused by *Rhizoctonia solani* *Sclerotinia* blight *Fusarium* wilts

Turfgrass application: For control of foliar diseases, apply CX-9030 at **0.5 to 1 ounce per 1,000 square feet** as a ground-directed spray in sufficient water to provide thorough coverage. To control root and crown diseases in or on the soil, immediately follow the spray with sufficient overhead sprinkler irrigation to move the product into the root zone.

USE SITES/CROPS	DISEASES/PATHOGENS
Turf, sod, lawns, golf course (fairways, roughs, greens, tees), grass seed production Including but not limited to: Bluegrass, Bentgrass, Bermudagrass (common & hybrid), Dichondra, Fescue, Orchardgrass, *Poa annua*, St. Augustine grass, Ryegrass, *Zoysia*, mixtures, and other grasses or ornamental turf	Anthracnose (*Colletotrichum grominicola*) Brown patch (*Rhizoctonia solani*) Dollar spot (*Lonzia* and *Moellerodiscus* spp., formerly *Sclerotinia homoeocarpa*) Powdery mildew (*Erisyphe graminis*) Rust (*Puccinia* spp.) Gray leaf spot (*Pyriculario grisea*) "Damping off" or seedling blights caused by *Pythium*

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a dry area inaccessible to children. Store in original containers only. Keep container closed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CHEMIGATION INSTRUCTIONS

General information:

Apply this product only through drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (including impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

Drip (trickle) and micro-irrigation chemigation

1. The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.

Sprinkler chemigation:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
8. Do not apply when wind speed favors drift beyond the area intended for treatment.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purpose referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the disease problem, condition of the crop, incompatibility with other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Bacillus amyloliquefaciens strain D747

Pesticide Chemical (PC) Code: 016482

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

December 8, 2011 version

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BIOPESTICIDES REGISTRATION ACTION DOCUMENT TEAM

Office of Pesticide Programs (OPP)
Biopesticides and Pollution Prevention Division
Microbial Pesticides Branch

Science Reviews

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John L. Kough, Ph.D.	Product Analysis, Human Health
Gail Tomimatsu, Ph.D.	Environmental Effects
Shannon Borges	Environmental Effects

Regulations

Sheryl K. Reilly, Ph.D.	Chief, Microbial Pesticides Branch
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I. EXECUTIVE SUMMARY

Certis USA, LLC, ("Certis" or "applicant) submitted data to support the registration of *Bacillus amyloliquefaciens* strain D747 is the active ingredient in two end-use pesticide products, CX-9030 (EPA File Symbol 70051-107) and CX-9032 (EPA File Symbol 70051-108). The products are intended for use to control fungi and bacteria in outdoor agricultural crops, greenhouses, nurseries, shadehouses, ornamentals, and turfgrass. *B. amyloliquefaciens* strain D747 was initially identified by Certis as "*Bacillus subtilis* variant *amyloliquefaciens strain D747,*" since *B. subtilis* and *B. amyloliquefaciens* were originally classified as subtypes or variants of the same species. *B. amyloliquefaciens* is now considered a separate species, and the correct taxonomic designation is used in this Biopesticides Registration Action Document ("BRAD") (Priest et. al., 1987; Logan and de Vos, 2009; and Murray et. al., 2007).

EPA scientists reviewed product analysis, mammalian and nontarget organism toxicity data, and other information submitted by Certis to support the registration of the two aforementioned product registrations. The product analysis data requirements for *B. amyloliquefaciens* strain D747, including product chemistry and composition, analysis of samples, and physical and chemical characteristics, were fulfilled by acceptable studies conducted in accordance with Agency guidelines. Mammalian toxicity data (acute oral, injection, and pulmonary toxicity/pathogenicity) and information from peer-reviewed scientific literature demonstrated that *B. amyloliquefaciens* strain D747 is not toxic, infective or pathogenic in laboratory rats. Acceptable nontarget organism data also demonstrated that *B. amyloliquefaciens* strain D747 is not toxic to estuarine and marine fish and invertebrates, nontarget insects (including honey bees), and nontarget plants.

We have assessed human health and environmental risks of *B. amyloliquefaciens* strain D747, and determined that the pesticide would not cause unreasonable adverse effects to nontarget organisms when used in accordance with the directions on the labels, and in accordance with good agricultural practices. Additional mammalian and nontarget organism toxicity data are not required for the registered uses and application methods.

Bacillus species, including *B. amyloliquefaciens*, are commonly found in soils, including agricultural settings, and are naturally present on fresh produce. The Manual of Clinical Microbiology (9th Edition) states that dried foods, such as spices, milk powder and grains, often contain large amounts of *Bacillus* spores. *B. amyloliquefaciens* is not known to produce any mammalian toxins, and no food-borne disease outbreaks associated with *B. amyloliquefaciens* have been reported. Given that the microorganism occurs naturally in soils, exposure to *B. amyloliquefaciens* from surface and groundwater may occur. No adverse effects have been reported, and none are expected from exposure to *B. amyloliquefaciens* through drinking water.

Despite the low toxicological profile of *B. amyloliquefaciens* strain D747, personal protective equipment (PPE) is required for pesticide handlers that are frequently exposed to the active ingredient for prolonged periods. Handlers will be directed to wear a long-sleeved shirt, long pants, socks, shoes, waterproof gloves, and a dust/mist filtering respirator meeting National Institute for Occupational Safety and Health (NIOSH) standards of at least N-95, R-95, or P-95. EPA may require additional PPE, other than the standard described above, if additional pesticide uses resulting in increased exposures are proposed in the future.

EPA has concluded that, based upon the results of the toxicity tests and lack of adverse incidents,

there is a reasonable certainty that no harm will result to the United States population, including infants and children, from aggregate exposure to residues of *B. amyloliquefaciens* strain D747. No dietary risks (including drinking water) are expected from use of *B. amyloliquefaciens* strain D747 as an active ingredient in pesticide products. The two end-use pesticide products, CX-9030 and CX-9032 meet the standards for registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

On October 1, 2009, EPA announced a new policy to provide a more meaningful opportunity for the public to participate in major registration decisions before they occur. According to this policy, EPA intends to provide a public comment period prior to making a registration decision for, at minimum, the following types of applications: new active ingredients; first food uses; first outdoor uses; first residential uses; or any other registration actions for which EPA believes there may be significant public interest.

Consistent with the policy of making registration actions more transparent, the pesticide products containing *B. amyloliquefaciens* strain D747, a new active ingredient, were subject to a 30-day comment period. . During this comment period, no comments were received on EPA's preliminary decision to register the two end-use pesticide products containing *B. amyloliquefaciens* strain D747, CX-9030 and CX-9032. Therefore, EPA maintained that, based upon the risk assessment and information submitted in support of registration of such pesticide products, it was in the best interest of the public and the environment to issue the end-use pesticide product registrations for *B. amyloliquefaciens* strain D747, CX-9030 and CX-9032. The basis for this preliminary decision can be found in the risk assessment for *B. amyloliquefaciens* strain D747, which is presented in this document.

II. ACTIVE INGREDIENT OVERVIEW

Biological Name:	*Bacillus amyloliquefaciens* strain D747
Culture Deposit:	Agricultural Research Service Culture Collection (also known as the Northern Regional Research Laboratory (NRRL) Collection) in Peoria, Illinois, under Accession Number NRRL B-50405.
OPP Chemical Code:	016482
Type of Pesticide:	Microbial Pesticide – Insecticide See Appendix B for specific information (e.g., use sites, application rates, methods of application, formulation types, and target pests) regarding the registered pesticide products containing this active ingredient.

III. REGULATORY BACKGROUND

A. Applications for Pesticide Product Registration

Certis USA, LLC (address: 9145 Guilford Road, Suite 175, Columbia, MD, 21046), submitted applications to register two end-use pesticide product, CX-9032 and CX-9030, under FIFRA section 3(c)(5) on July 26, 2010. EPA announced receipt of these applications to register pesticide products containing a new active ingredient on February 2, 2011 (76 Federal Register (FR) 5805), and opened a 30-day public comment period, pursuant to the provisions of FIFRA section 3(c)(4). No comments were received following this publication.

B. Food Tolerance Exemption

Concurrent with its registration applications, and under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(d), Certis USA, LLC, submitted a petition to establish an exemption from the requirement of a tolerance for *Bacillus subtilis* variant *amyloliquefaciens* strain D747 (Pesticide Petition (PP) 0F7760). In the Federal Register of February 4, 2011 (76 FR 6465), EPA announced that Certis USA, LLC, proposed to establish an exemption from the requirement of a tolerance for residues of the insecticide, *Bacillus subtilis* variant *amyloliquefaciens* strain D747, in or on all food commodities, and opened a 30-day comment period. No comments were received following this publication. The correct taxonomic designation of the microorganism is *Bacillus amyloliquefaciens* strain D747; therefore, the tolerance exemption, when established, will reflect the correct name of the active ingredient.

IV. RISK ASSESSMENT

In the Federal Register of October 26, 2007, EPA issued a Final Rule establishing changes to the data requirements that support the registration of microbial pesticides. The rule also updated the definition for microbial pesticides (72 FR 61002), and became effective on December 26, 2007. The data and information evaluated for this BRAD were considered in accordance with these requirements.

The classifications or ratings that are given for each data requirement in this BRAD were assigned by the EPA scientists who reviewed the data, and convey the usefulness of the information for the human health and nontarget risk assessment purposes. "Acceptable" indicates that a study is scientifically sound and is useful for risk assessment. A "supplemental" classification indicates the studies provided some information that can be useful for risk assessment. "Supplemental" ratings are given to studies that are not required for registration, as well as those that are required. In the latter case, the study lacks information that should have been obtained if it was conducted according to the guideline associated with the data requirement. Sometimes the missing information would not add anything necessary to inform a risk assessment, and the study classification remains "supplemental." A classification of "supplemental:upgradable" indicates the study lacks necessary information, but if it is made available by the applicant, the study may be upgraded to "acceptable." An "unacceptable" rating indicates that new data must be submitted.

Toxicity categories are assigned to acute toxicity studies, based upon any signs of toxicity (hazards) observed in the test animals during the course of the study, whether the study was

conducted in accordance with test guidelines or comes from other sources, such as peer-reviewed, scientific literature. The active ingredient or particular product is classified into Toxicity Category I, II, III, or IV, where Toxicity Category I indicates the highest toxicity, and Toxicity Category IV indicates the lowest toxicity (see 40 CFR § 156.62).

A. Product Analysis Assessment (40 CFR § 158.2120)

All product analysis data requirements for *B. amyloliquefaciens* strain D747 have been fulfilled for the current product registrations. Refer to Tables 1, 2, 3, and 4 in Appendix A for a brief summary of the data requirements, including both generic and product-specific information.

B. Human Health Assessment (40 CFR § 158.2140)

1. Toxicity

All Tier I mammalian toxicity data requirements for *B. amyloliquefaciens* strain D747 have been fulfilled for the current product registrations. Refer to Tables 5, 6 and 7. Based on the lack of acute toxicity/pathogenicity, Tier II and Tier III studies were not required.

For a comprehensive summary of the generic and product-specific toxicity data requirements described below, refer to Tables 5, 6 and 7 in Appendix A.

a. Acute Toxicity/Pathogenicity – Tier I

Acute Oral Toxicity/Pathogenicity (Office of Chemical Safety and Pollution Prevention (OCSPP) Guideline 885.3050; Master Record Identification Number (MRID No. 481657-04):
B. amyloliquefaciens strain D747 was administered once orally to 14 rats of both sexes (5-weeks old) at a single dosage of 10^8 colony-forming units (CFU) per animals. No deaths occurred, and no abnormalities (clinical signs, body weight) were observed, during the study or at necropsy. The test microbe was detected at $10^3 - 10^5$ CFU/g in feces 1 day after administration of the test material, but was not detected on day14. The examination for internal persistence did not detect the test microbe in any organs or tissues, such as the kidney, brain, liver, lung, spleen, stomach, small intestine (duodenum), large intestine (cecum), mesenteric lymph nodes, or blood, throughout the experimental period. Fecal clearance occurred by day 14, and no viable organisms were recovered from blood or other organs or tissues. The results of this acceptable study demonstrated that *B. amyloliquefaciens* strain D747 was not infective, pathogenic, or toxic to rats when orally dosed with 1.0×10^8 CFU / animal.

Acute Pulmonary Toxicity/Pathogenicity (OCSPP Guideline 885.3150; MRID No.481657-06):
B. amyloliquefaciens strain D747 was administered once intratracheally to 20 male and female Sprague-Dawley rats (5-week old) at a dosage of 10^7 CFU per animal. No deaths occurred, and no abnormalities (clinical signs, body weight) were observed during the study or at necropsy. The examination for internal persistence showed that the test microbe was detected shortly after administration in the lung, trachea, and nasal cavity. The test microbes were not detected in the nasal cavity on day 7, and almost completely cleared from the trachea by day 60, when the study ended. The presence of the test microbes decreased in the lungs by approximately 10^2-10^3 CFU/g from day 0 to day 60. The test microbes were detected in the bronchial lymph nodes on day 3. Since many test microbes remained in the trachea on day 3, their presence in the bronchial lymph nodes on day 3 was attributed to transfer by macrophages from the respiratory tract to the lymph

nodes. This conclusion was supported by the observation that a particle larger than 1 μm in diameter administered into the trachea and bronchi was phagocytized by a macrophage and carried to a lymph node. The presence of the microbes in the lungs, though decreasing throughout the observation period, was attributed to the continuous transfer of viable test organisms to the bronchial lymph nodes. This result is not unusual for spore-forming bacteria, since bacterial spores are extremely tolerant of adverse conditions, and take a longer time for the immune system to clear than bacteria that do not form spores. Since a pattern of clearance was demonstrated, the remaining viable cells were considered to be spores, which take longer for a healthy immune system to clear. This acceptable study demonstrated that *B. amyloliquefaciens* strain D747 was not toxic or pathogenic to rats when dosed intratracheally at 1.0×10^7 CFU/ animal.

Acute Injection Toxicity/Pathogenicity (Intravenous) – Rat (OCSPP Guideline 885.3200; MRID No. 481657-05): In an acute intravenous injection toxicity and pathogenicity study, groups of 17 male and female Sprague-Dawley rats (5-weeks old) were injected with *B. amyloliquefaciens* strain D747 at a dosage of 10^7 CFU per animal, and the influence on the animals was investigated. No deaths occurred, and there were no observed abnormalities (clinical signs, body weight) during the study or at necropsy. The examination for internal persistence of the test microbe showed that the test microbes were mainly detected in the kidney, liver, spleen, and blood shortly after administration. The test microbe decreased after that and was not detected in the blood from day14; clearance from the kidney occurred by day 60. McClintock et al. previously reported that when *B. thuringiensis* and *B. subtilis*, which are both spore-forming bacteria, were administered intravenously to rats, clearance from the liver and spleen is difficult. In this study, the test microbe did not completely disappear from these organs by day 60. No test microbes were detected in the brain, and only a few viable microbes at the limit level were sporadically detected in the small and large intestines, and lymph nodes, but were cleared by day 60. This acceptable study demonstrated that *B. amyloliquefaciens* strain D747 was not toxic, infective, or pathogenic to rats when injected intravenously with 1.0×10^7 CFU/ animal.

Hypersensitivity Incidents (OCSPP Guideline 885.3400; MRID No. 481655-05): No hypersensitivity incidents in humans have been reported, and none occurred during research, development, or testing of *B. amyloliquefaciens* strain D747. Should hypersensitivity or other adverse incidents in humans occur in the future, Certis must report them to EPA, in accordance with FIFRA section 6(a)(2).

Cell Culture (OCSPP Guideline 885.3500): This study was not required because *B. amyloliquefaciens* strain D747 is not a virus (refer to test note #4 of 40 CFR § 158.2140(d)).

b. Acute Toxicity and Subchronic Toxicity/Pathogenicity – Tier II; Reproductive Fertility Effects, Carcinogenicity, Immunotoxicity, and Infectivity/Pathogenicity Analysis – Tier III

Tier II and Tier III studies were not required for *B. amyloliquefaciens* strain D747 based on the lack of acute toxicity/pathogenicity in the Tier I studies.

c. Endocrine Disruptors

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active

and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

B. amyloliquefaciens strain D747 is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA section 408(p), EPA must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP orders/data call-ins for all pesticide active ingredients.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: *http://www.epa.gov/endo/*.

2. Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." Additionally, section 408(b)(2)(D) of FFDCA requires that EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information, and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. All of the data requirements have been fulfilled, as described previously, and are presented in Table 5 in Appendix A. The following summarizes the results of EPA's dietary risk assessment for *B. amyloliquefaciens* strain D747.

a. Aggregate Exposure

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground or surface water, and through pesticide use in residential and other indoor uses.

Food Exposure and Risk Characterization: *Bacillus* species, including *B. amyloliquefaciens*, are commonly found in the soil in agricultural settings, and are present on fresh produce of all kinds with no known adverse effects. The Manual of Clinical Microbiology (9th edition) mentions that dried food such as spices, milk powder and grains often contain large amounts of *B.* spores. *B. amyloliquefaciens* is not known to produce any mammalian toxins, and no foodborne disease outbreaks associated with *B. amyloliquefaciens* have been reported.

Based on the data and other information submitted to satisfy the data requirements for registration of the manufacturing-use and end-use pesticide products containing the active ingredient, *B. amyloliquefaciens* strain D747, no toxicity, infectivity, pathogenicity or other adverse effects from dietary exposure to are expected (see section IV(B)(1)(a), above, and Table 5 in Appendix A).

Drinking Water Exposure and Risk Characterization: *B. amyloliquefaciens* is naturally present in soils (Logan and de Vos, 2009); therefore, *B. amyloliquefaciens* may occur in surface and possibly groundwater. According to the World Health Organization, *Bacillus* species are often detected in drinking water even after going through acceptable water treatment processes, largely because the spores are resistant to these disinfection processes (World Health Organization, 2011). Should this microbial pesticide be present, no adverse effects are expected from exposure to *B. amyloliquefaciens* through drinking water, based on the data and other information submitted to satisfy the data requirements for registration of the manufacturing-use and end-use pesticide products containing the active ingredient, *B. amyloliquefaciens* strain D747 (see section IV(B)(1)(a), above, and Table 5 in Appendix A).

Non-occupational, Residential Risk Characterization: The use sites for these products include residential garden sites and agricultural sites. As stated previously, *B. amyloliquefaciens* is naturally present in soil, and based on the data and other information submitted to satisfy the data requirements for registration of the manufacturing-use and end-use pesticide products containing the active ingredient, *B. amyloliquefaciens* strain D747, no toxicity, infectivity, pathogenicity or other adverse effects from non-occupational exposure are expected (see section IV(B)(1)(a), above, and Table 5 in Appendix A).

b. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance exemption, EPA consider "... available information concerning the cumulative effects of [a particular pesticide's] ... residues and other substances that have a common mechanism of toxicity."

EPA has found that *B. amyloliquefaciens* strain D747 does not share a common mechanism of toxicity with any other microorganism, pesticidal or toxic substance. EPA concludes that there are no cumulative effects associated with *B. amyloliquefaciens* strain D747 that need to be considered. For information regarding how EPA determines common mechanisms of toxicity and evaluates cumulative effects, see EPA's website at: http://www.epa.gov/pesticides/cumulative.

c. Determination of Safety for the United States (U.S.) Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

EPA concludes that, based upon the results of the toxicity data and other information considered and described in this document, there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of *B. amyloliquefaciens* strain D747. Such exposure includes all anticipated dietary and other exposures for which there is reliable information. With no threshold effects of concern, an additional margin of safety is not required for infants and children.

3. Occupational Exposure and Risk Characterization

Occupational exposure to *B. amyloliquefaciens* strain D747 is not expected to undue risks to pesticide handlers (mixer/loader/applicators), but EPA requires appropriate personal protective equipment and precautionary statements to mitigate any potential risks (e.g., respiratory allergenicity) to pesticide handlers from prolonged or repeated exposures. Handlers applying *B. amyloliquefaciens* strain D747 end-use products in agricultural settings must wear a long-sleeved shirt, long pants, socks, shoes, waterproof gloves, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95.

4. Human Health Risk Characterization

EPA considered human exposure to *B. amyloliquefaciens* strain D747 in light of the registration standards of FIFRA and the relevant FFDCA safety factors for allowable pesticide residues in

food and animal feed commodities. EPA has determined that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result when the pesticide products containing *B. amyloliquefaciens* strain D747 as the active ingredient are used in accordance with EPA-approved labeling.

C. Environmental Assessment (40 CFR § 158.2150)

The primary habitat of *Bacillus* species is soil, although they have also been isolated from a wide variety of other habitats. *B. amyloliquefaciens* has a wide-spread distribution, owed in part to its ability to form endospores that are resistant to greater variation in environmental conditions than the vegetative cells, should transfer to other climates occur. *B. amyloliquefaciens* has been isolated from internal tissues of healthy plants, and is known to promote plant growth. It is not recognized as a pathogen among *Bacillus* species (Logan and de Vos, 2009).

The data, literature citations, and data waiver rationale submitted by the applicant to support the pesticide products containing *B. amyloliquefaciens* strain D747 fulfilled the Tier I nontarget organism data requirements, and were sufficient for risk assessment purposes. Further testing of nontarget organisms at higher tier levels (i.e., Tiers II, III, and IV) is not required for the EPA-approved use sites. EPA performed an environmental risk assessment, and has determined that the use of *B. amyloliquefaciens* strain D747 is not expected to cause unreasonable adverse effects to nontarget organisms.

For a comprehensive summary of the generic data requirements described in sections IV(C)(1) of this BRAD, refer to Table 8 in Appendix A.

1. Ecological Exposure and Risk Characterization

a. Terrestrial Animals and Plants

The end-use products include a water-dispersible granular formulation and an aqueous suspension, for application to agricultural crops, nurseries, ornamental plants, turfgrass, greenhouses, and shadehouses. Applications can be made to both foliar surfaces and soil, so exposure to nontarget organisms is possible. The maximum application rates from the labels of registered products were used in the assessment of nontarget risk.

Data on the naturally occurring levels of *B. amyloliquefaciens* are not available. Many factors influence the environmental fate of microbial pesticides, and resulting population levels in the environment cannot be predicted. EPA expects that *B. amyloliquefaciens* strain D747 may survive after application if conditions are favorable, but the strain would not significantly add to the overall levels of *B. amyloliquefaciens* already present in the environment.

Birds (OCSPP Guideline 885.4050) and Mammals (OCSPP Guideline 885.4150):
A supplemental study showed that the acute oral LD_{50} for *B. amyloliquefaciens* strain D747 is > 4.5×10^{11} spores/kg BW or > 8×10^{9} spores/bird in Northern bobwhite (*Colinus virginianus*; MRID 48165712). Additionally, *B. amyloliquefaciens* is intentionally included in some domestic avian food diets as a nutritional additive (e.g., European Food Safety Authority, 2010; Wizna et al., 2009), and it is not known to be pathogenic to animals (Logan and de Vos, 2009). An extensive literature search in several databases returned no reports of toxicity or pathogenicity of *B. amyloliquefaciens* in birds. Based on these lines of evidence, *B.*

amyloliquefaciens strain D747 is not expected to pose risk of adverse effects in birds.

A study with laboratory rats (MRID 48165704) also showed that *B. amyloliquefaciens* strain D747 is not toxic, infective, or pathogenic at the maximum hazard dose of 1.0×10^8 CFU/animal. Therefore, adverse effects to wild mammals are also not expected as a result of the applications of *B. amyloliquefaciens* strain D747 in accordance with label instructions.

Nontarget Insects (OCSPP Guideline 885.4340) and Honey Bees (OCSPP Guideline 885.4380): Studies with *Orius stricollis*, *Crysoperla carnea*, and *Phytoseiulus persimilis* were submitted for the nontarget insect data requirement (MRID 48165716). While no effects of *B. amyloliquefaciens* strain D747 were observed in these studies, they were not acceptable for use in the ecological risk assessment. Two honey bee studies were also submitted that showed no adverse effects of *B. amyloliquefaciens* D747 after 48 hours (MRID 48165717) and 17 days (no MRID currently assigned). These studies were rated Supplemental because they were not of sufficient duration (30 days); however, except in rare cases, bacteria that are pathogenic to insects typically produce toxins that kill the insect within a few days (Tanada and Kaya, 1993). Adverse effects resulting from exposure to *B. amyloliquefaciens* strain D747, therefore, would likely have been evident in the bee studies, especially after 17 days. Scientific rationale was submitted to show that adverse effects are not expected to nontarget insects (MRIDs 48621502 and 48621503). Entomopathogenic *B.* species (e.g., *B. thuringiensis*, *B. sphaericus*) have been extensively studied, and their pathobiology is well-known. *B. amyloliquefaciens* is not among the *B.* species recognized as frank pathogens to insects or other animals (Logan and de Vos, 2009). There are some accounts in the literature of effects of *B. subtilis* on insects; however, none of these were associated with *B. amyloliquefaciens* or *B. subtilis* var. *amyloliquefaciens*. Therefore, based on the studies and other information provided, *B. amyloliquefaciens* strain D747 is not expected to pose risk to honey bees and other nontarget insects as a result when applied in accordance with label instructions..

Nontarget Plants (OCSPP Guideline 885.4300):
Studies with plants exposed to *B. amyloliquefaciens* strain D747 were unacceptable, based on several deficiencies (MRID 48165715). *B. amyloliquefaciens* is not taxonomically related to any known plant pathogens. As discussed previously, however, the microorganism has been isolated from tissues of healthy plants and is known as a plant growth-promoting rhizobacterium. It is, therefore, not expected to pose risk to nontarget plants as a result of t applications made in accordance with label instructions.

b. Aquatic Animals and Plants

B. amyloliquefaciens strain D747 is not intended to be applied directly to water, but some of the applied product may reach aquatic habitats through runoff or spray drift. Spray drift at application is the primary mechanism by which the pesticide is expected to reach water. A spray drift analysis was included in the aquatic risk assessment to determine exposure, and further detail is provided in the environmental risk assessment for *B. amyloliquefaciens* strain D747.

Freshwater Fish (OCSPP 885.4200) Guideline and Invertebrates (OCSPP Guideline 885.4240): In a 30-day study with rainbow trout (*Oncorhynchus mykiss*), the LC_{50} for *B. amyloliquefaciens* strain D747 was 8.1×10^{10} CFU/L, and the NOEC based on sub-lethal effects was 1.44×10^{10} CFU/L. If the maximum broadcast application rate (4 fluid ounces/1000 ft^2 or 2.55×10^6 CFU/cm^2) is applied directly to a 1-ha body of water 15 cm deep (the EPA Standard Wetland),

the resulting concentration would be 1.7 x 10^8 CFU/L. This would be the maximum possible aquatic concentration at this application rate, but this direct application to water is not on the EP labels. The NOEC and LC_{50} are approximately 85X and 476X higher than this concentration, respectively. Exposure in freshwater environments will be well below the concentrations that would produce adverse effects, and the applications of *B. amyloliquefaciens* strain D747 as presented on EPA- approved labels are not expected to pose risks to freshwater fish.

A study with *Daphnia magna* provided an EC_{50} based on mortality/immobility of 3.7 x 10^{10} CFU/L, and a NOEC for sub-lethal effects of 2.84 x 10^8 CFU/L. Based on the spray drift analysis, the NOEC would be approximately 20X the expected environmental concentration (EEC), and the EC_{50} would be 218X the EEC; therefore, the applications of *B. amyloliquefaciens* strain D747 D747 as presented on EPA- approved labels are not expected to result in adverse effects to freshwater invertebrates.

Marine/Estuarine Fish (OCSPP 885. 4280) and Invertebrates (OCSPP 885.4240):
Concentrations reaching marine or estuarine areas are expected to be less than those calculated above for freshwater animals, due to further dilution in deeper water. *B. amyloliquefaciens* strain D747 is not expected to reach marine or estuarine environments in significant concentrations, and risk to animals in these environments is not anticipated.

Aquatic Plants (OCSPP Guideline 885.4300):
B. amyloliquefaciens strain D747 is not related to known plant pathogens; therefore, adverse effects to aquatic plants are not anticipated.

2. Environmental Fate Data

The information provided to support uses and application methods that are presented on EPA-approved labels was sufficient to satisfy the Tier I nontarget organism data requirements and for nontarget organism risk assessment for *B. amyloliquefaciens* strain D747; further testing at higher tier levels (i.e., Tiers II, III, and IV) is not required.

3. Threatened and Endangered Species Assessment

Since EPA has determined that no effects are anticipated for any nontarget species exposed to *B. amyloliquefaciens* strain D747 as a result of applications made in accordance with EPA-approved labels, effects to federally listed threatened and endangered species and their designated critical habitats are also not expected. Therefore, a "No Effect" determination is made for direct and indirect effects to listed species and their designated critical habitats resulting from the approved uses of *B. amyloliquefaciens* strain D747.

V. ENVIRONMENTAL JUSTICE

EPA seeks to achieve environmental justice—the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income—with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. Fair treatment means that no group of people, including racial, ethnic, or socioeconomic groups, should bear a disproportionate share of the negative environmental consequences resulting from industrial, municipal, and commercial operations or the execution of federal, state, local, and tribal environmental programs and policies. Meaningful involvement means that (1) potentially

affected community residents have an appropriate opportunity to participate in decisions about a proposed activity that will affect their environment and/or health; (2) the public's contribution can influence the regulatory agency's decision; (3) the concerns of all participants involved will be considered in the decision-making process; and (4) the decision-makers seek out and facilitate the involvement of those potentially affected. EPA has this goal for all communities and persons across the United States.

EPA sought information on any groups or segments of the population who, as a result their location, cultural practices, or other factors, may have atypical, unusually high exposure to *B. amyloliquefaciens* strain D747, compared to the general population. No public comments were received on this particular matter.

For additional information regarding environmental justice issues, please visit EPA's web site at *http://www.epa.gov/compliance/environmentaljustice/index.html*.

VI. RISK MANAGEMENT DECISION

Section 3(c)(5) of FIFRA permits for the registration of a pesticide provided that all the following determinations are made:

(1) Its composition is such as to warrant the proposed claims for it;
(2) Its labeling and other material required to be submitted comply with the requirements of FIFRA;
(3) It will perform its intended function without unreasonable adverse effects on the environment; AND
(4) When used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

To satisfy criterion 1, the *B. amyloliquefaciens* strain D747 pesticide products have well-known properties. EPA has no knowledge that would contradict the claims made for these products, the CX-9030 and CX-9032 EP labels, and we have concluded that such products are not expected to cause unreasonable adverse effects on the environment when used according to the label instructions. Criterion 2 is satisfied by the current product labels, as well as the data and information presented in this document. It is believed that the *B. amyloliquefaciens* strain D747 pesticide products will not cause any unreasonable adverse effects on the environment, and CX-9030 and CX-9032 (end-use pesticide product), in particular, are likely to provide protection against fungal and bacterial pests as claimed, satisfying criterion 3. Criterion 4 is satisfied in that the *B. amyloliquefaciens* strain D747 pesticide products are not expected to cause unreasonable adverse effects when used according to label instructions. Therefore the end-use products, CX-9030 and CX-9032, containing *B. amyloliquefaciens* strain D747 as a new active ingredient, are eligible for registration under FIFRA section 3(c)(5) for the labeled uses. Should uses that are more extensive be proposed in the future (e.g., aquatic uses), EPA will likely require that additional data be submitted.

VII. ACTIONS REQUIRED BY THE REGISTRANT

A. Final Printed Labeling

Before releasing pesticide products containing *B. amyloliquefaciens* strain D747 for shipment, the registrant is required to provide appropriate final printed labeling to EPA prior to shipment of product.

B. Terms of Registration

As a term of the registration CX-9032 EP, the registrant must submit the following data within one year of this product's registration:

(1) Storage Stability (OCSPP Guideline 830.6317) and Corrosion Characteristics (OCSPP Guideline 830.6320): The results of a one-year storage stability and corrosion characteristics study.

C. Reporting of Adverse Effects and Hypersensitivity Incidents

Notwithstanding the information stated previously, it should be clearly understood that certain specific data are required to be reported to EPA as a requirement for maintaining the federal registration for a pesticide product. A brief summary of these types of data are described below.

Reports of all incidents of adverse effects to the environment must be submitted to EPA under the provisions stated in FIFRA section 6(a)(2). Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to EPA under the provisions of 40 CFR § 158.2140(d).

VIII. GLOSSARY OF ACRONYMS AND ABBREVIATIONS

ASAE	American Society of Agricultural Engineers
BPPD	Biopesticides and Pollution Prevention Division
BRAD	Biopesticides Registration Action Document
CFR	Code of Federal Regulations
CFU	colony-forming unit(s)
cfu/kg	colony-forming units per kilogram
cfu/mL	colony-forming units per milliliter
cP	centipoise
EDSP	Endocrine Disruptor Screening Program
EP	end-use product
EPA	Environmental Protection Agency (the "Agency")
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
g/mL	gram per milliliter
LC_{50}	median lethal concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is

	usually expressed as the weight of substance per weight or volume of water, air, or feed (e.g., mg/L, mg/kg, or ppm).
LD_{50}	median lethal dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, or inhalation). It is expressed as a weight of substance per unit weight of animal (e.g., mg/kg).
mg/kg	milligrams per kilogram
mg/L	milligrams per liter
MP	manufacturing-use product
mPa·s	milliPascal-second, term used as the unit of dynamic viscosity.
MRID No.	Master Record Identification Number
NIOSH	National Institute for Occupational Safety and Health
NRRL	Northern Regional Research Laboratory
OCSPP	Office of Chemical Safety and Pollution Prevention
OPP	Office of Pesticide Programs
PC Code	Pesticide Chemical Code
PP	Pesticide Petition
PPE	personal protective equipment
ppm	parts per million
TGAI	technical grade of the active ingredient
U.S.	United States

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APPENDIX A. MICROBIAL PESTICIDES DATA REQUIREMENTS (40 CFR PART 158 – SUBPART V)

TABLE 1. Product Analysis Data Requirements for the End-Use Product (EP), CX-9030 (40 CFR § 158.2120)

OCSPP Guideline Number	Data Requirement	Results	MRID No.
885.1100	Product Identity	Submitted data fulfill the requirement for product identity. CX-9030 contains 25.0% by weight *Bacillus amyloliquefaciens strain* strain D747 (minimum of 5x 10^{10} CFU/g)	481655-01 CSF dated 10/18/2011
885.1200	Manufacturing Process	Submitted data fulfill the requirement for manufacturing process.	481655-01
Not applicable	Deposition of a Sample in a Nationally Recognized Culture Collection	Submitted data fulfill the requirement for deposition. Culture on deposit under Accession Number NRRL B-50405.	481655-01
885.1300	Discussion of Formation of Unintentional Ingredients	Submitted data fulfill the requirement for discussion of formation of unintentional ingredients.	481655-01
885.1400	Analysis of Samples	Submitted date fulfill the requirement for analysis of samples.	481655-01
885.1500	Certification of Limits	Limits listed on the confidential statement of formula are adequate/acceptable	CSF dated 10/18/2011
Additional Studies			
830.1800	Enforcement Analytical Method	Submitted data fulfill the requirement for an enforcement analytical method	481655-01

TABLE 2. Product Analysis Data Requirements for the End-Use Product (EP), CX-9032 (40 CFR § 158.2120)

OCSPP Guideline Number	Data Requirement	Results	MRID No.
885.1100	Product Identity	Submitted data fulfill the requirement for product identity. CX-9030 contains 98.95% by weight *Bacillus amyloliquefaciens strain* strain D747 (minimum of 1x 10^{10} CFU/g)	481655-01 CSF dated 10/18/2011
885.1200	Manufacturing Process	Submitted data fulfill the requirement for manufacturing process.	481657-01 481655-01
Not applicable	Deposition of a Sample in a Nationally Recognized Culture Collection	Submitted data fulfill the requirement for deposition. Culture on deposit under Accession Number NRRL B-50405.	481657-01 481655-01
885.1300	Discussion of Formation of Unintentional Ingredients	Submitted data fulfill the requirement for discussion of formation of unintentional ingredients.	481657-01 481655-01
885.1400	Analysis of Samples	Submitted date fulfill the requirement for analysis of samples.	481655-01 481657-01
885.1500	Certification of Limits	Limits listed on the confidential statement of formula are adequate/acceptable	CSF dated 10/18/2011
Additional Studies			
830.1800	Enforcement Analytical Method	Submitted data fulfill the requirement for an enforcement analytical method	481655-01

TABLE 3. Physical and Chemical Characteristics for the Technical Grade of the Active Ingredient (TGAI) *Bacillus. amyloliquefaciens strain* strain D747 / CX-9030 (EP). (40 CFR § 158.2120)

OCSPP Guideline Number	Data Requirement	Results		MRID No.
		TGAI	CX-9030 (EP)	
830.6302	Color	Beige	Not Applicable	481657-02
830.6303	Physical State	Fine powder	Not applicable	481657-02
830.6304	Odor	Yeast odor	Not applicable	481657-02
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Spores inactivated at 54°C	Not applicable	481657-02
830.6314	Oxidation/Reduction: Chemical Incompatibility	Not applicable, the product does not contain oxidizing or reducing agents		481657-02
830.6315	Flammability	Not applicable, the product does not contain flammable ingredients		481657-02
830.6316	Explodability	Not applicable, the product does not contain explosive ingredients		481657-02
830.6317	Storage Stability	Stable up to one year at 25°C without loss of viability		481657-02 481657-03
830.6319	Miscibility	Not applicable, the product is not an emulsifiable liquid. (refer to test note #2 of 40 CFR § 158.2120(d)).		481657-02
830.6320	Corrosion Characteristics	Not applicable, the product is a powder.		481657-02
830.6321e	Dielectric Breakdown Voltage	Not applicable, the product is not for use around electrical equipment		481657-02
830.7000	pH	6.5 – 7.0 (1% w/w)	7.5- 8.0	481657-02
830.7100	Viscosity	Not applicable, the product is a powder.	Not Applicable.CX-9030 is not a liquid.	481657-02
830.7300	Density/Relative Density/Bulk Density (Specific Gravity)	0.307- 0.375 g/ml	0.60-.0.78 g/ cm^3	481657-02

TABLE 4. Physical and Chemical Characteristics for CX-9032 (EP). (40 CFR § 158.2120)

OCSPP Guideline Number	Data Requirement	Results		MRID No.
		TGAI	CX-9030 (EP)	
830.6302	Color	Beige	Light brown	481655-02
830.6303	Physical State	Fine powder	Liquid	481655-02
830.6304	Odor	Yeast odor	Yeast odor	481655-02
830.6313	Stability to Normal & Elevated Temperatures, Metals, & Metal Ions	Spores inactivated at 54°C..		481655-02
830.6317	Storage Stability	Stable up to one year at 25°C without loss of viability	Stable up to 78 days at 25°C without loss of viability. **As a term of the registration, EPA is requiring submission of the results of a one-year storage stability and corrosion characteristics study be submitted within one year.**	481655-02
830.6319	Miscibility	Not applicable; product is not an emulsifiable liquid. (refer to test note #2 of 40 CFR § 158.2120(d)).		481655-02
830.6320	Corrosion Characteristics	Not applicable; product is a powder.	None evident to polyethylene packaging after 78 days. **As a term of the CX-9032 (EP) registration, EPA is requiring submission of the results of a one-year storage stability & corrosion characteristics within one year.**	481655-02
830.7000	pH	6.5 – 7.0 (1% w/w)	4.2 - 4.3 (1% w/w).	481655-02
830.7100	Viscosity	Not applicable, the product is a powder.	4.6 - 16.0 milliPascal-second (mPa s) at 25°C	481655-02
830.7300	Density/Relative Density/Bulk Density (Specific Gravity)	0.307- 0.375 g/ml	1.02 – 1.03 g/mL	481655-02

TABLE 5. Toxicology Data Requirements for the Technical Grade of the Active Ingredient (TGAI) (40 CFR § 158.2140)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
		TGAI	
		Tier I	
885.3050	Acute Oral Toxicity/Pathogenicity	No evidence of infectivity, pathogenicity or toxicity was found from oral administration of 1.0×10^8 CFU *Bacillus amyloliquefaciens* strain D747 to rats. Clearance from fecal material occurred by day 14 and no viable organisms were recovered from blood or any other organ or tissue. **Classification: Acceptable**	481657-04
885.3150	Acute Pulmonary Toxicity/Pathogenicity	No evidence of infectivity, pathogenicity or toxicity was found from intratracheal administration of 1.0×10^7 spores *B. amyloliquefaciens* strain D747 to rats. **Classification: Acceptable**	481657-06
885.3200	Acute Injection Toxicity/Pathogenicity (Intravenous)	Not toxic, infective, and/or pathogenic to rats when dosed intravenously at 1.0×10^7 spores per animal. **Classification: Acceptable**	481657-05
885.3400	Hypersensitivity Incidents	No hypersensitivity incidents, including immediate-type or delayed-type reactions of humans and domestic animals that occurred during research, development, or testing of the TGAI/MP, were reported. Future hypersensitivity incidents must be reported (For reporting format: OCSPP Guideline 885.3400).	479450-23
885.3500	Cell Culture	Not required. *B. amyloliquefaciens* strain D747 is not a virus (Test note #4 of 40 CFR § 158.2140(d)).	
		Tiers II and III	
Not required for *Bacillus amyloliquefaciens* strain D747 based on the lack of acute toxicity/pathogenicity in the Tier I studies.			

TABLE 6. Toxicology Data Requirements for the End-Use Product (EP), CX-9030 (40 CFR § 158.2140)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
885.3400	Hypersensitivity Incidents	No hypersensitivity incidents, including immediate-type or delayed-type reactions of humans and domestic animals that occurred during research, development, or testing of the EP, were reported by the applicant. Any future hypersensitivity incidents must be reported per OCSPP Guideline 885.3400.	
870.1100	Acute Oral Toxicity	Oral LD_{50} > 5000 mg/Kg **Classification: Acceptable** **TOXICITY CATEGORY IV**	481657-07
870.1200	Acute Dermal Toxicity	Dermal LD_{50} > 5050 mg/Kg **Classification: Acceptable** **TOXICITY CATEGORY IV**	481657-08
870.1300	Acute Inhalation Toxicity	Inhalation LC_{50} > 2.18 mg/L **Classification: Acceptable** **TOXICITY CATEGORY IV**	481657-09
870.2400	Acute Eye Irritation	The maximum average irritation score of 18.3 obtained 1 hour after treatment declined to 17.33 after 24 hours, 2 after 48 hours and 0 after 72 hours following ocular administration of 0.1 mL *B. amyloliquefaciens* strain D747 to New Zealand White rabbits in a 72 hour observation period. **Classification: Acceptable** **TOXICITY CATEGORY III**	481657-10
870.2500	Primary Dermal Irritation	No evidence of irritation was found from dermal administration of 500 mg *B. amyloliquefaciens* strain D747 CX-9030 to rabbits during the 4 hour exposure and 72 observation periods. The dermal irritation score for *B. amyloliquefaciens* strain D747 CX-9030 was 0.00. Classification: **Acceptable** **TOXICITY CATEGORY IV**	481657-11

TABLE 7. Toxicology Data Requirements for the End-Use Product (EP), CX-9032 (40 CFR § 158.2140)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
885.3400	Hypersensitivity Incidents	No hypersensitivity incidents including immediate-type or delayed-type reactions of humans and domestic animals that occurred during research, development, or testing of the EP were observed or reported. All hypersensitivity incidents must be reported per OCSPP Guideline 885.3400.	
870.1100	Acute Oral Toxicity	Waiver request submitted. Requirement satisfied by submitted MP data. Oral exposure to the MP showed no adverse effects including infectivity, pathogenicity and toxicity up to the limit dose. Inerts are exempt from tolerance. No additional oral toxicity is expected from inerts. **Classification: Acceptable**	481655-04
870.1200	Acute Dermal Toxicity	Waiver request submitted. Requirement adequately addressed by CX-9030 EP data as well as, dermal irritation testing on CX-9032-EP. Dermal toxicity and irritation testing for the CX-9030 EP and dermal irritation data on CX-9032 EP showed no adverse effects up to the limit doses. No additional dermal toxicity is expected from inerts. Classification: **Acceptable**	481655-04 481655-06 481655-11 481657-08
870.1300	Acute Inhalation Toxicity	Waiver request submitted. Pulmonary exposure to the MP showed no adverse effects, including infectivity, pathogenicity or toxicity though slight toxicity lasting 2 days from a 4-hour aerosol inhalation administration of 2.18 mg/L, where inert ingredients were also present, was noted in a CX-9030 EP study. No additional toxicity is expected from this EP's inert ingredients. **Classification: Acceptable**	481655-04 481657-06 481657-09
870.2400	Acute Eye Irritation	The maximum average irritation score of 0.667 at 1 hour after treatment declined to 0 after 24 hours following ocular administration of 0.1 mL *B. amyloliquefaciens* strain D747 CX-9032 to New Zealand White rabbits (72-hour observation period). **Classification: Acceptable** **TOXICITY CATEGORY IV**	481655-05

TABLE 7. Toxicology Data Requirements for the End-Use Product (EP), CX-9032 (40 CFR § 158.2140)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
870.2500	Primary Dermal Irritation	No irritation occurred from dermal administration of 0.5 mL undiluted *B. amyloliquefaciens* strain D747 CX-9032 to shaved skin of rabbits during the 4 hour exposure and 72 observation periods. The dermal irritation score for *B. amyloliquefaciens* strain D747 CX-9032 was 0.00. **Classification: Acceptable** **TOXICITY CATEGORY IV**	481655-06

TABLE 8. Nontarget Organism Toxicity and Environmental Fate Data Requirements for the Technical Grade of the Active Ingredient (TGAI), *Bacillus amyloliquefaciens* strain D747 (40 CFR § 158.2150)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
		Tier I	
885.4050	Avian Oral Toxicity	A study showed that *B. amyloliquefaciens* D747 is not toxic to birds at 8.9 x 10^9 spores/bird. **Classification: Supplemental** Scientific rationale is sufficient to conclude that *B. amyloliquefaciens* D747 is not expected to pose a hazard to birds. **Classification: Acceptable**	48165712 48621501
885.4100	Avian Inhalation Toxicity/Pathogenicity	Not required. *B. amyloliquefaciens* D747 is not considered to be pathogenic to birds	
885.4150	Wild Mammal Toxicity/Pathogenicity	Tests required by 40 CFR § 158.2140 are adequate/ appropriate for assessment of hazards to wild mammals. *B. amyloliquefaciens* D747 was not infective, toxic or pathogenic to laboratory rats 1.0 x 10^8 CFU/animal	48165704
885.4200	Freshwater Fish Toxicity/Pathogenicity	A 30-day study shows that the LC_{50} to rainbow trout is 8 x 10^{10} CFU/L. The NOEC for sublethal effects is 1.44 x 10^{10} CFU/L. **Classification: Acceptable**	48165713
885.4240	Freshwater Invertebrate Toxicity/Pathogenicity	A 21-day study shows that the EC_{50} to *Daphnia magna* based on mortality is 3.7 x 10^{10} CFU/L. The NOEC for sublethal effects is 2.84 x 10^8 CFU/L. **Classification: Acceptable**	48165714
885.4280	Estuarine/Marine Fish and Invertebrate Testing	Not required. *B. amyloliquefaciens* D747 is not to be applied directly to water and is not expected to reach estuarine or marine environments in significant quantities.	
885.4300	Nontarget Plant Testing	A study submitted was determined to be unacceptable; however, testing is not required because. *B. amyloliquefaciens* is not related to known plant pathogens	48165715

TABLE 8. Nontarget Organism Toxicity and Environmental Fate Data Requirements for the Technical Grade of the Active Ingredient (TGAI), *Bacillus amyloliquefaciens* strain D747 (40 CFR § 158.2150)

OCSPP Guideline Number	Data Requirement	Results	MRID No.
885.4340	Nontarget Insect Testing	Studies with three species of arthropods were determined to be unacceptable. Additional scientific rationale was submitted to show that *B. amyloliquefaciens* is not expected to be toxic or pathogenic to nontarget insects. **Classification: Acceptable**	48165716 48621502
885.4380	Honey Bee Testing	Two studies showed that *B. amyloliquefaciens* D747 is not toxic to honey bees. **Classification: Supplemental** Additional rationale was sufficient to show that pathogenicity to honey bees is not expected as a result of exposure to *B. amyloliquefaciens* D747. **Classification: Acceptable**	48165717 48621503
Tiers II, III, and IV			
Not required for *Bacillus amyloliquefaciens* strain D747 based on the current uses and application methods.			

APPENDIX B. PESTICIDE PRODUCTS

TABLE 9. Table Title?

EPA Registration Number	Registration Name	Percentage Active Ingredient	Formulation Type	Use Site(s)	Method(s) of Application	Application Rate	Target Pest
70051-107	CX-9032	98.35%	End Use – Aqueous Suspension	Various agricultural and greenhouse crops (e.g., vegetables, tree fruits, berries, grapes and tropical fruit, tree nuts, herbs and spices, coffee, tobacco, hops, forestry seedlings ornamentals, and turf)	Tractor mounted boom, airblast, hose-end, backpack and other pressurized sprayers; foggers or mist blowers; water wheel and other drench applicators; soil injection; aerial; and chemigation with drip or sprinkler irrigation and cutting or root dip	Rate listed on label varies depending on application method from 0.5 pints /acre to 6 quarts/acre	Various fungal and bacterial pests listed on the label including: *Alternaria, Botrytis cinerea Didymella bryaniae Phoma cucurbitacearum Erisphe, Fusarium, Macrophomina phaseoli Monosporascus cannanballus Peronospora , Phytophthora Pseudomonas syringae* pv. *tomato Pseudoperonospora* spp. *Puccinia* spp. *Pythium, Rhizoctonia, Sphaeratheca* spp. *Verticillium*, spp. *Xanthomonas* spp.
70051-108	CX-9030	25.0%	Water Dispersible Granule	Various agricultural and greenhouse crops (e.g., vegetables, ornamentals, and turf)	Tractor mounted boom, airblast, hose-end, backpack and other pressurized sprayers; foggers or mist blowers; water wheel and other drench applicators; shank or other soil injection equipment; aerial; and chemigation with drip or sprinkler irrigation and cutting or root dip	0.25 –3 pounds per acre	Various fungal and bacterial pests listed on the label including: *Alternaria, Botrytis cinerea Didymella bryaniae Phoma cucurbitacearum Erisphe Fusarium, Macrophomina phaseoli Monasporascus cannonballus Peronospora, Phytaphthora Pseudomanas syringae* pv. *tomato Pseudoperonospora* spp. *Puccinia* spp. *Pythium, Rhizoctania, Sphaerotheca* spp. *Verticillium*, spp., *Xanthomonas* spp.

EPA National Organic Program Labeling Request Checklist

Reviewer Name: Chris Pfeifer | **RAL: Susanne Cerrelli**

Product Name: CX 9030 (EPA Reg. No. 70051-RNI (108)) | **Completion Date: 12/6/11**

Determination: Permitted | **Receipt Date: 12/6/11**

#	Check list Item	Yes	No
1	**Active Ingredients** - Are all of the active ingredient(s) "***Allowed***" on the National List?	Y	
2	**Active Ingredients History** - Is the active ingredient on the BPPD list of previous NOP approvals (f:/USER/SHARE/BPPD/Organic/Copy of NOP/**allowableble.pdf** or **ALLOWED.xls**)?	Y	
3	**Inert Ingredients** - Are all of the inert(s) found on the August 2004 EPA list 4A and 4B?	Y	
4	**Inert Ingredients** – Have any inert(s) been recently revoked (Revoked List 4 Inerts)?		N
5	**Use Sites** – Are all the product's use sites within the scope of the designated use patterns cited in the *National List*?	Y	
6	**Language** - Is the requested label language allowable. (Acceptable language includes: "*For Use in Organic Production*"; "*For Organic Production*"; "*For Use in Organic Gardening*"; "*For Organic Gardening*"; "*OMRI Listed*"; the OMRI logo; and the three leaf EPA NOP Logo.	Y*	
7	**OMRI Certification** – Does the application have a current OMRI certificate?	*	
8	**Comments -** #1) The ai is approved for organic use. The source of ai is not GM. There are no intentionally added ingredients in the ai source that are not consumed or accounted for; and none of the impurities are of toxicological significance. #2) The inert ingredients are all List 4 and NOP compliant. Acceptable MSDS were provided for all inert ingredients; and the composition of the mixtures were validated in OPPIN. #3) The use sites for the product are all pre-harvest agricultural, and are acceptable per the Organic Production Standard. #4) The label claims "For Organic Production" and "OMRI Listed" are appropriate for the use pattern on this agricultural label. #5) Because this product is presently unregistered, the product cannot receive an OMRI certificate. It is a reasonable expectation, however, that the registrant will receive a certificate upon application. As such, the registrant can add the "OMRI Listed" claim to the label with the following terms: a) The registrant must add a parenthetical statement to the OMRI claim on the draft label indicating that it is a placeholder. The self-evident expression "(placeholder)" is adequate. b) The Registration Notice must create a term which requires submission of the OMRI certificate to the Agency once it has been received. #6) An alternate CSF dated 11/18/11 was reviewed and found acceptable. **Permit NOP labeling of this product.**		

~~This review contains CONFIDENTIAL BUSINESS INFORMATION (CBI).~~ **Do not release this document to the registrant if it contains confidential information on proprietary mixes.**

Program Links - National Organic Program (AMS - NOP); PR Notice 2003-1 (PR Notice 2003-1)

BPPD Guidance Document – Other Items May be Required

Ingredient Information

Ingredient Name: [redacted]

PC Code: [redacted] CAS: [redacted] Inert Ingredient? Yes No First Registered: [redacted]

Food Use? Yes No Active Ingredient? Yes No Restricted Distribution? Yes No

RRCA #: RRCA List: RRCA Name:

Comments | MSDS Information | Team Owner

Reregistration Case Status | FR Notices | Repository | Inert Mixture | Other IDs | Other CAS #

Assessment/Mode of Action | Cancer Class | Classification | Parent Ingredients | Child Ingredients

Ingredient Names | Pesticide Type | Pesticide Category | Pesticide Attributes | Ingredient Status

Ingredient Name	Name Type	Display Name
[redacted]	Other Common	
	Other Systematic	
	Other Systematic	
	Other Systematic	
	Trade	
	Trade	
	Trade	
	Trade	
	Trade	

Inert ingredient information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

Ingredient Information

Ingredient Name: [redacted]

PC Code: [redacted] CAS: [redacted] Inert Ingredient? Yes No First Registered: [redacted]

Food Use? Yes No Active Ingredient? Yes No Restricted Distribution? Yes No

RRCA #: RRCA List: RRCA Name:

Comments | MSDS Information | Team Owner

Reregistration Case Status | FR Notices | Repository | Inert Mixture | Other IDs | Other CAS #

Assessment/Mode of Action | Cancer Class | Classification | Parent Ingredients | Child Ingredients

Ingredient Names | Pesticide Type | Pesticide Category | Pesticide Attributes | Ingredient Status

Ingredient Name	Name Type	Display Name
[redacted]	Trade	
	Trade	
	Trade	
	Trade	
	Trade	
	Trade	
	Trade	
	Trade	
	Trade	

CX-9030

OMRI Seal placeholder

Water Dispersible Granular Biofungicide
(Alternate brand names: Double Nickel 55; Amylo-X WG)

For Organic Production

Active Ingredient:
Bacillus amyloliquefaciens strain D747* 25.0%
Other Ingredients 75.0%
Total.....100.0%

Contains a minimum of 5×10^{10} colony-forming units (cfu) per gram
EPA Reg. No. 70051-
EPA Est. No. 70051-CA-001

ACCEPTED
DEC 16 2011
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 70051-108

Manufactured by: Certis USA, L.L.C.
9145 Guilford Rd., Suite. 175
Columbia, MD 21046

NET WEIGHT: 5 LBS Lot No:

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID - Agricultural Use

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product label with you when calling a poison control center or doctor.
Hot Line No.:1-800-255-3924 for additional information

PRECAUTIONARY STATEMENTS - Agricultural Use

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants

- Waterproof gloves
- Shoes plus socks

Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause Follow manufacturer's instructions for cleaning and maintaining PPE. In no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. AS soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS- Agricultural Use

Do not apply directly to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply when weather conditions favor drift or runoff from treated areas.

GENERAL INFORMATION

CX-9030 is a broad-spectrum preventative biofungicide for control or suppression of fungal and bacterial plant diseases. The active ingredient of CX-9030 is a naturally occurring strain (D747) of the beneficial rhizobacterium *Bacillus amyloliquefaciens*, which colonizes roots, leaves, and other plant surfaces. D747 rapidly colonizes plant root hairs, leaves, and other surfaces, preventing establishment of disease-causing fungi and bacteria.

CX-9030 can be applied alone or in combination and/or rotation with chemical fungicides as a tool for integrated disease management in agricultural crops, ornamental and nursery plants, and turfgrass, in accordance with the most restrictive of those label limitations and precautions. CX-9030 offers a valuable tool for management of resistance to chemical fungicides through its multiple and unique modes of action.

CX-9030 can be applied up to and including the day of harvest.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the State or Tribal Agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: cover-alls, waterproof gloves, shoes plus socks.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses. Keep unprotected persons out of treated areas until sprays have dried.

MIXING AND HANDLING INSTRUCTIONS

Mix the required amount of CX-9030 in cool water with sufficient agitation to maintain a uniform suspension in the spray or mixing tank. Tank should be cleaned prior to use. Do not use highly alkaline or highly acidic water to mix sprays. Use a buffering agent if necessary to maintain neutrality (pH 6 to 8) of water in the tank. Maintain agitation during application. Apply immediately after mixing; do not allow spray mix to stand overnight.

APPLICATION METHODS

Ground: CX-9030 can be applied in most commonly-used ground application equipment, such as tractor-mounted boom, airblast, high clearance, hose-end, backpack, and other pressurized sprayers; hose-end or hand-held sprayers; foggers or mist blowers; water wheel and other drench applicators; and shank or other soil injection method.

Aerial: CX-9030 can be applied by fixed or rotary winged aircraft in a minimum of 3 gallons of water per acre. Standard precautions should be taken to minimize spray drift.

Chemigation: CX-9030 can be applied through drip (trickle) and sprinkler type irrigation equipment. Refer to the section entitled "Chemigation Instructions" for detailed instructions.

Agricultural crops

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons	
Brassica vegetables such as broccoli, cabbage, cauliflower, Brussels sprouts, kohlrabi, and other cole crops.	Pin rot complex (*Alternaria/Xanthomonas*)* Leaf spots (*Alternaria* spp., *Xanthomonas* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe polygoni*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Bulb vegetables such as unions, garlic, shallots, and others.	*Botrytis* spp. (neck rot, leaf blight) Purple blotch (*Alternaria* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Rust (*Puccinia pari*)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusorium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Cucurbits such as cucumbers, squash (all types), cantaloupes, muskmelons, watermelons, and other melons.	Powdery mildew (*Erisyphe* and *Sphaerotheca* spp.) Downy mildew (*Pseudoperanospora* spp.) Gummy stem blight (*Didymella bryoniae* and *Phoma cucurbitacearum*) See instructions below for "Soil application" against the following diseases: Vine decline (*Monosparascus cannonballus*) Charcoal rot (*Macrophomina phaseoli*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp.
Fruiting vegetables such as tomatoes, peppers, eggplant, tomatillo, okra, and others.	Bacterial spot (*Xanthomonas* spp.)*[1] Bacterial speck (*Pseudomonas syringae* pv. *tomato*)*[1] Gray mold (*Botrytis cinerea*) Powdery mildew* (*Leveillula*, *Oidiopsis*, *Erisyphe*, and *Sphaerotheca* spp.) Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. Southern blight (*Sclerotium rolfsii*)*
Leafy vegetables such as head and leaf lettuce, celery, spinach, radicchio, arugula, watercress, and others (including leafy *Brassica* vegetables such as mustard and collard greens, kale, bok choi, and related crops).	Downy mildew (*Bremia lactucae*, *Peronospora* spp.)* Powdery mildew (*Golovinomyces (Erisyphe) cichoracearum*)* Bacterial blights Head and leaf drop (*Sclerotinia* spp.)[2] Pink rot (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* spp.) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. Bottom rot (*Rhizoctonia solani*)
Legume vegetables succulent and dried beans and peas such as green, snap, shell, and Lima beans, garbanzo beans, chickpeas, soybeans, dry beans, peas, split peas, lentils, and other legumes.	White mold (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Microsphaera diffusa*) Rusts*, including *Uromyces appendiculatus*, *Puccinia* spp., and Asian soybean rust (*Phayospora pachyrhizi*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Root, tuber, and corm vegetables such as potato, sweet potato, carrot,	Black root/crown rot (*Alternaria* spp.) Bacterial leaf blight (*Xanthomonas campestris*)

cassava, beets, ginger, radish, horseradish[22], ginseng, turnip, and other root, tuber and corm crops.	Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Gray mold (*Botrytis* spp.) White mold (*Sclerotinia sclerotiarum*)[2] Black leg /bacterial soft rot (*Erwinia carotovora*) Early blight (*Alternario solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: Black scurf (*Rhizoctonia solani*) Cavity spot (*Pythium* spp.) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp.
Other vegetables such as sweet corn, popcorn, asparagus, peanut, and watercress	*Botrytis* spp. Rusts (*Puccinia* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* and *Cercosporidium* spp.)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Tree fruits and nuts	
Citrus such as orange, lemon, lime, grapefruit, tangerine (mandarin), tangelo, pummelo, and other citrus	*Alternaria* leaf spot (*Alternaria alternata*) Postbloom fruit drop (*Colletotrichum acutatum*)* Greasy spot (*Mycosphaerella citri*)*[3] Citrus canker (*Xanthomonas campestris* pv. *citri*)[1] Scab (*Elsinoe fawcetti*)*[4] Melanose (*Diaporthe citri*)*
Pome fruits such as apple, pear, crabapple, quince, and others	Powdery mildew (*Podosphaera leucotricha*)[4] Scab (*Venturia* spp.)* Flyspeck (*Zygophiala jamaicensis*)[6] Sooty blotch disease complex[6] Brooks spot (*Mycosphaerella pomi*)[6] Bat rot/white rot (*Botryosphaeria dothidea*)[6] Bitter rot (*Colletotrichum* spp.)[6] Cedar apple rust (*Gymnosporangium juniperi-virginianae*)[6] Fire blight (*Erwinia amylovora*)*[7]
Stone fruits such as apricot, cherry, nectarine, peach, plum, prune, plum, and others	Powdery mildew (*Sphaerotheca* and *Podosphaera* spp.)*[8] Bacterial canker (*Pseudomonas* spp.) Brown rot blossom blight (*Monilinia laxa*)[9] Brown rot (*Monilinia fructicola*)*[10] Gray mold (*Botrytis cinerea*)[10] Peach leaf curl (*Taphrina deformans*) Bacterial leaf spot (*Xanthomonas arbicola* pv. *pruni*)[1] Rusty spot (*Podosphaera leucotricha*)[1]
Tree nuts such as almond, pistachio, pecan, walnut, filbert, hazelnut, chestnut, macadamia, and other tree nuts.	Walnut blight (*Xanthomonas campestris*)[11] Anthracnose (*Colletotrichum acutatum*)* Bacterial canker (*Pseudomonas syringae*) Shot hole (*Wilsonomyces carpophilus*)* Brown rot (*Monilinia* spp.)* Pecan scab (*Cladosprium caryigenum*)*[1]
Pomegranates	Leaf and fruit spots (*Cercospora*, *Gloeosporium* and *Pestalotia* spp.)[1] Fruit rots (*Alternaria*, *Botrytis*, and other spp.)[10] Powdery mildew (*Sphaerotheca pannosa*)
Other fruits	
Strawberry	Powdery mildew (*Sphaerotheca macularis*, *Erisyphe* spp.)*[12] Gray mold (*Botrytis cinerea*)*[11] Anthracnose (*Colletotrichum acutatum*) Angular leaf spot (*Xanthomonas fragariae*)[1] For the following diseases, see instructions below for "Soil application" (and also rant

	dip instructions[22]): "Damping off" and root or crown diseases caused by *Rhizoctonia*, *Fusarium*, *Pythium*, *Phytophthora*, and/or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*)
Berries, including blueberry, blackberry, raspberry, loganberry, huckleberry, gooseberry, elderberry, cranberry (non-flooded fields), currant, and other berries	Mummy berry (*Monilinia vaccinii-corymbosi*)* Botrytis blight (*Botrytis cinerea*) Bacterial canker (*Pseudomonas* spp.)[11] Anthracnose fruit rot (*Colletotrichum acutatum*)[10]
Grapes including wine grapes, table grapes, and raisins	Powdery mildew (*Erisyphe* (formerly *Uncinula*) *necator*)[14] Gray mold (*Botrytis cinerea*)[15] Sour rot complex[15] Downy mildew (*Plasmopara viticola*)* Phomopsis (*Phomopsis viticola*)[16] Eutypa (*Eutypa lata*)[17]
Tropical fruits such as avocado[18], mango[18], papaya[19], pineapple[19], banana, plantain, and others.	Anthracnose (*Colletotrichum* spp.) Scab (*Sphaceloma perseae*) Bacterial canker (*Xanthomonas campestris*) Sigatoka (*Mycosphaerella fijiensis*)[20]
Other Crops	
Herbs and spices such as basil, thyme, coriander, dill, cilantro, parsley, mint, and others.	Powdery mildews (*Oidium* spp. and others) Downy mildews (*Peronospora* spp. and others)* Damping off diseases (*Rhizoctonia*, *Pythium*, *Alternaria*, and *Fusarium* spp.) Leaf spots (*Alternaria*, *Septoria*, *Colletotrichum*, and *Cercospora* spp.)* Bacterial diseases (*Erwinia*, *Xanthomonas*, and *Pseudomonas* spp.) Rusts (*Puccinia* spp. and others) "Damping off" and root or crown diseases caused by *Rhizoctonia*, *Fusarium*, *Pythium*, *Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Coffee	Coffee berry disease (*Colletotrichum coffeanum*)[1] Coffee rust (*Hemileia vastatrix*)[1] Anthracnose (*Colletotrichum* spp.) *Botrytis* flower blight *Cercospora* leaf spot and berry blotch "Damping off" and root or crown diseases caused by *Rhizoctonia*, *Fusarium*, *Pythium*, *Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Tobacco	Angular leaf spot (*Pseudomonas* spp.) Anthracnose (*Colletotrichum* and *Glomerella* spp.) Blue mold or downy mildew (*Peronospora* spp.)* Brown spot (*Alternaria*) Barn spot/ frogeye leaf spot (*Cercospora nicotianae*)[10] Collar rot (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Erysiphe cichoracearum*) Target spot (*Rhizoctonia solani*) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Olpidium*, *Phytophthora*, or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*) Black root rot (*Thielaviopsis basicola*) Black shank (*Phytophthora* spp.)* Southern blight/southern stem rot (*Sclerotium rolfsii*)*
Mint	Rust (*Puccinia* spp.)
Hops	Powdery mildew (*Sphaerotheca macularis*)[21]
Footnotes: *Suppression only; for improved control mix or rotate with chemical fungicide approved for such use.	

[1] Tank mix or rotate with copper-based fungicides at label rates for improved control.

[2] Apply at or immediately following planting (but before plant emergence) as a banded seedline treatment 4 to 6 inches wide. Make second application at thinning or cultivation in sufficient water and multiple nozzles to ensure thorough coverage of lower leaves and surrounding soil surface. Incorporation with light irrigation after application may improve disease control. Repeat at 10-14 day intervals if conditions promoting disease persist.

[3] For greasy spot suppression, apply at first new foliar flush and repeat with each new flush. Tank mix with spray oil or copper based fungicide at labeled rates.

[4] For suppression of citrus scab, start applications at first new foliage flush and repeat at petal fall and when fruit are ½ inch in diameter.

[5] Make first application at or before tight cluster if conditions favor disease development. Repeat at 7-10 day intervals through the second cover spray or longer on susceptible varieties or if environmental conditions favor rapid disease development.

[6] Begin applications before bloom when environmental conditions favor disease development, repeating at 7 to 14 day intervals or as needed. Control may be enhanced by addition of a surfactant to improve spray coverage. Use only surfactants known to be safe for use on the crop and for which such use is allowed.

[7] Rotate with antibiotics registered for fire blight control for improved performance. Begin applications at 1-5% open blossoms and repeat every 3-7 days as necessary until petal fall, when intervals can be increased to 7 days. CX-9032 can also be used in summer "cover spray" applications to control the shoot blight phase of fire blight and summer diseases. Can be mixed with copper fungicides to improve control.

[8] Make first application at popcorn stage and repeat every 7 days.

[9] Start applying at early bloom stage and repeat every 7 days through petal fall.

[10] Pre-harvest applications in sufficient water to cover fruit or other harvested plant parts may improve control of postharvest infections.

[11] Begin applications at or before pistillate bloom, repeating every 7-10 days. Apply before rainfall if possible, and tank mix or rotate with a copper-based bactericide registered for such use for improved control.

[12] Start applications at or just before flowering and repeat every 7-10 days as needed through harvest.

[13] Apply before fall rains and again during dormancy before spring growth.

[14] Start applications when new shoots are ½ to 1½ inches long. Repeat at 3-5 inches, 8-10 inches, and then at 7-10 day intervals until disease conditions no longer exist.

[15] Apply at bloom, before bunch closure, at veraison, and before harvest.

[16] Apply when shoots are ½ to 1 inch long and again when 6-8 inches long.

[17] Mix 2 fluid ounces CX-9032 per gallon of water and apply to pruning wounds.

[18] Apply at budbreak and repeat on 14-21 day interval as needed through harvest.

[19] Apply at flowering and repeat on 14-21 day interval as needed through harvest

[20] Apply at first appearance of leaves and repeat at 7-21 day intervals as needed, in sufficient water to obtain thorough coverage of foliage. Tank mix with spray oil or other registered fungicides for improved control.

[21] Mix 6 to 10 fluid ounces CX-9032 per 100 gallons of water and apply in minimum of 20 gallons per acre from emergence to training, 50 gallons per acre from training to wire, and 100 gallons per acre from wire touch through harvest.

[22] For treatment of horseradish or strawberry roots immediately before transplanting: immerse bare roots (individually or in bunches) for 10 seconds in a suspension of 1 to 2 pints CX-9032 per gallon of water.

Foliar application: For control of diseases on foliage, flowers, fruit, or other above-ground parts of plants: Mix CX-9030 in water and apply as a spray at a rate of **0.25 to 3 pounds per acre** in sufficient water to achieve thorough coverage of the crop canopy with minimal runoff. Begin applications at crop emergence, transplanting, or when conditions are conducive to development of disease. Repeat application every 7 to 10 days, or as needed, for as long as conditions favor disease development. Lower rates (0.25 to 1 pound per acre) may be applied under light disease pressure, to smaller (e.g. newly-emerged) plants, or when CX-9030 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (1 to 3 pounds per acre), apply more frequently (every 3 to 7 days), and mix or rotate CX-9030 with other fungicides for improved performance.

Soil application: For control of soilborne diseases infecting seeds, seedlings, roots, crown, stems, or other plant parts below ground or in contact with soil: Apply CX-9030 at **0.125 to 1 pound per acre**. Mix the required amount in sufficient water to apply by one of the following methods:

- Soil drench applied to transplants in flats or pots in the greenhouse or nursery any time prior to transplanting (see additional drench instructions under "Nurseries, greenhouses, shade houses, and ornamental plants" below).

- Soil drench at transplanting, using a "water wheel" injector, spray nozzles/hoses, or other method to drench each root ball and/or planting hole.
- Soil or seedline drench, or banded spray (in-furrow) at planting. See the section on "Banded (in-furrow) application" below for additional instructions.

Follow-up (post-planting) preventative applications can be made every 2-4 weeks by one or more of the following methods, if needed:

- Drip (trickle) or any type of sprinkler irrigation, any time after planting or transplanting. See Chemigation Instructions for additional information.
- Spray directly onto the soil surface and/or lower plant parts. If targeting root disease, follow immediately with sufficient overhead sprinkler irrigation to move CX-9030 to the root zone.
- Injection directly into the rooting zone using shanks or similar equipment.

Lower rates (0.125 to 0.5 pounds per acre) may be applied under light disease pressure, to smaller plants, or when CX-9030 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (0.5 to 1 pound per acre), apply more frequently (every 2 weeks), and mix or rotate CX-9030 with other fungicides for improved performance.

Banded (in-furrow) application: Use the table below to determine the correct application rate of CX-9030 per 1,000 row feet, based on row spacing and desired rate per acre. Mix the required amount of CX-9030 in water and apply as banded spray (4" to 6" wide) or seedline drench centered over the planting furrow. Apply directly over seeds in the furrow just before they are covered with soil. The volume of water required per acre or per 1,000 row feet will depend on the application equipment used. Consult your local cooperative extension service if you need assistance calibrating band spraying equipment.

Rates for banded (in-furrow) application: Find desired application rate in the left column. Read across that line to the correct row spacing indicated at the top to find the number of ounces (dry) per 1,000 row feet that will provide the desired application rate per acre. To convert to **level teaspoons**, multiply the number of ounces by 8.2. For **level tablespoons**, multiply the number of ounces by 2.75.

Rate/acre	Space between rows (inches)														
(pounds)	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
0.25	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3
0.5	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6
0.75	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9
1.0	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.2	1.2
1.25	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.4	1.5	1.5
1.5	0.6	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.7	1.8
1.75	0.6	0.7	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1
2.0	0.7	0.9	1.0	1.1	1.2	1.3	1.5	1.6	1.7	1.8	2.0	2.1	2.2	2.3	2.4
2.25	0.8	1.0	1.1	1.2	1.4	1.5	1.7	1.8	1.9	2.1	2.2	2.3	2.5	2.6	2.8
2.5	0.9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1
2.75	1.0	1.2	1.3	1.5	1.7	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.0	3.2	3.4
3.0	1.1	1.3	1.5	1.7	1.8	2.0	2.2	2.4	2.6	2.8	2.9	3.1	3.3	3.5	3.7

Nurseries, greenhouses, shadehouses, and ornamental plants

Spray application: Mix **0.25 to 3 pounds of CX-9030 per 100 gallons of water** and apply as a foliar spray of sufficient volume to wet the entire plant with minimal runoff. Begin preventative applications at plant emergence and repeat every 3-28 days as needed (every 3-7 days if disease

pressure is high or environmental conditions are highly favorable to disease outbreak, 10-28 days under low pressure or less conducive conditions).

Drench application: Mix **0.125 to 2 pounds of CX-9030 per 100 gallons of water** and apply as a drench or coarse spray to soil or other growing media in pots, flats, plugs, trays, or planting beds, for control or suppression of soilborne diseases of seedlings, cuttings, bedding plants, and transplants (including vegetables and other transplanted food crops). Make first application at or immediately before seeding, sticking, germination, or transplanting. Repeat applications every 14-28 days as needed. Transplants can be treated immediately before transplanting into field soils to protect against damping-off and other diseases that reduce plant establishment.

Cutting or root dip: Dip basal end of cuttings or bare roots (individually or in bunches) in a suspension **of 1 to 2 pounds of CX-9030 per gallon of water.** Immerse for 5-10 seconds immediately before planting.

Chemigation: Mix **0.125 to 2 pounds of CX-9030 per 100 gallons of water** and apply via drip, handheld, or sprinkler irrigation systems. Refer to "Chemigation Instructions" for more details.

CROPS/USE SITES	DISEASES/PATHOGENS
Indoor, outdoor, and shade- or other cover-grown ornamental trees and shrubs, flowering plants, foliage plants, tropical plants, potted plants, potted or cut flowers, bedding plants, forestry seedlings, conifer production for reforestation, fruit trees, vegetables and other crops grown in greenhouses or nurseries.	Powdery mildews caused by *Erisyphe, Podosphaera, Sphaerotheca, Oidium,* and *Golovinomyces* spp.) Anthracnose (*Colletotrichum* spp.) Bacterial leaf spots caused by *Erwinia, Pseudomonas,* and *Xanthomonas* spp. Damping-off disease (*Rhizoctonia, Pythium, Fusarium* spp.) Late blight, blackeye, and root rots caused by *Phytophthora* spp. Gray mold and blight caused by *Botrytis cinerea* Black root rot (*Aspergillus* spp.) Black spot of roses (*Diplocarpon rosae*) Downy mildew (*Peronospora* spp.) Leaf spots caused by *Alternaria, Septoria, Cercospora, Entomosporium, Helminthosporium,* and *Myrothecium* spp.) Rust (*Puccinia* spp.) Scab (*Venturia* spp.) Root rot, bottom rot, or stem rot caused by *Rhizoctonia solani* *Sclerotinia* blight *Fusarium* wilts

Turfgrass application: For control of foliar diseases, apply CX-9030 at **0.5 to 1 ounce per 1,000 square feet** as a ground-directed spray in sufficient water to provide thorough coverage. To control root and crown diseases in or on the soil, immediately follow the spray with sufficient overhead sprinkler irrigation to move the product into the root zone.

USE SITES/CROPS	DISEASES/PATHOGENS
Turf, sod, lawns, golf course (fairways, roughs, greens, tees), grass seed production Including but not limited to: Bluegrass, Bentgrass, Bermudagrass (common & hybrid), Dichondra, Fescue, Orchardgrass, *Poa annua*, St. Augustine grass, Ryegrass, *Zoysia*, mixtures, and other grasses or ornamental turf	Anthracnose (*Colletotrichum graminicola*) Brown patch (*Rhizoctonia solani*) Dollar spot (*Lanzia* and *Moellerodiscus* spp., formerly *Sclerotinia homeocarpa*) Powdery mildew (*Erisyphe graminis*) Rust (*Puccinia* spp.) Gray leaf spot (*Pyricularia grisea*) "Damping off" or seedling blights caused by *Pythium*

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a dry area inaccessible to children. Store in original containers only. Keep container closed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CHEMIGATION INSTRUCTIONS

General information:

Apply this product only through drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (including impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

Drip (trickle) and micro-irrigation chemigation

1. The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.

Sprinkler chemigation:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
8. Do not apply when wind speed favors drift beyond the area intended for treatment.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purpose referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the disease problem, condition of the crop, incompatibility with other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

CX 9030

Label Review

File Symbol: 70051-RNI Date: 9/28/11 Reviewer: Cervelli

[Site/Use]	[Res /Ag /Both] [Food /Non-Food /Both]				
[Tox Categories:]	[AcOral: 4 /AcDerm: 4 /AcInhl: 4 /EyeIrr: 3 /SkinIrr: 4 DermSens:]				
Label Requirement	**Acceptable**	**Not Acceptable**	**N/A**	**Comments Recommendations**	**LRM3**
Restricted Use Pesticide	----------	----------	X		**Ch 6**
Product Name	✓				Pg 12-3
Compny Name and Info	✓				Pg 15-1
Identification Numbers		X		Add -108	**Ch 14**
Net Contents weight ✓	✓				**Ch 17**
Ingredients Statement		X		CFU/4 does not make	**Ch 5**
Label Claims				NOP → Preamber make it OMRI → condition	Pgs 4-5, 5-7 11-10 & **Ch 12**
Alternate Formula					5-12

Precautionary Statements

Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
KOROC	✓				3-1 & 9 7-3 & 4
Signal Word	✓				**Ch 3 Ch 7 Ch 10**
General Heading >PRECAUTIONARY STATEMENTS=				Cut + pasted text Allergy?	Ch 7
First Aid (PRN 20001-1)				2. NR	**Ch 3 & 7**

Hazards to Humans and Domestic Animals				?	Ch 3, 7-3
PPE (WPS) Engineering Controls	✓				Ch 7, Pg 7-12 Pgs 10-4, 15
User Safety Requirements		✓		→ adjust	Ch 10
User Safety Recommendations		✓		adjust	Ch 10
Environmental Hazards					Ch 8
Physical and Chemical Hazards					Pg 3-4 **Ch 9**

Directi for USE (FIFRA Text, WPS plus Storage an posal					
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
Header >Directions for Use=					10-16
Violation of Federal Law text		✓		text changes needed	10-26, 11-7
WPS Text (PPE)				Put in box move after 'DFU' header	Ch 10, 7-1 7-11
Non-WPS Text					7-12, Ch 10
Storage and Disposal				~~missing~~	11-16, Ch 13

5 lb paper bag — add box + move

Directions for Use (General Instructions and Information)					
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
General Instructions and Sub-Header					need to connect to mixing instruct
Chemigation / Prohibition	?			now [illegible]	PRN
REI					Pg 10-20

Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
General Info. (non-site specific info. on uses, pests, mixing, and loading, tank mixing, etc.)					
General Precautions and Restrictions					
Directions for Use					
Directions for Application					
Warranty Information					
Consistency with label instructions					12-6
Not false or misleading					

"The warranty section contains an overly broad statement concerning limitations of liability. As such, this statement may be misleading and may constitute misbranding under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It is suggested that the existing statement be preceded by the phrase, **Ato the extent allowable by state lawe**, or otherwise qualified to make it clear that this warranty is not intended to be a statement of law which implies that the buyer has no legal rights to recover damages from the manufacturer if he/she suffered a loss or injury from the product and concludes that it would be futile to pursue what might in reality be a valid claim."

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Consideration of Section 3(c)(5) Unconditional Registrations for *Bacillus amyloliquefaciens* strain D747

----------DECISION MEMORANDUM----------

FROM: Keith A. Matthews, Director
Biopesticides and Pollution Prevention Division

TO: Steven Bradbury, Director
Office of Pesticide Programs

I. ISSUE

Should the Agency, under Section 3(c)(5) of the Federal Insecticide, Fungicide, and RodenticideAct (FIFRA), grant an unconditional registration for the microbial pesticide *Bacillus amyloliquefaciens* strain D747 (EPA File Symbols 70051-RNI, and-RNT) (PC Codes 016482), which are proposed for use to control fungi and bacteria in outdoor agricultural crops, greenhouses, nurseries, shadehouses, ornamentals, and turfgrass. Depending on the use, the end-use product may be applied with tractor mounted boom, airblast, hose-end, backpack and other pressurized sprayers; foggers or mist blowers; water wheel and other drench applicators; soil injection; aerial; and chemigation with drip or sprinkler irrigation and cutting or root dip.

II. APPLICANT INFORMATION

On July 26, 2010, Certis USA, LLC (address: 9145 Guilford Road, Suite 175, Columbia, MD, 21046), submitted applications to register two end-use pesticide products, CX-9032 and CX-9030, under FIFRA section 3(c)(5). EPA announced receipt of these applications to register pesticide products containing a new active ingredient on February 2, 2011 (76 Federal Register (FR) 5805), and opened a 30-day public comment period, pursuant to the provisions of FIFRA section 3(c)(4). No comments were received following this publication.

Concurrent with its registration applications, and under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(d), Certis USA, LLC, submitted a petition to establish an exemption from the requirement of a tolerance for *Bacillus subtilis* variant *amyloliquefaciens* strain D747 (Pesticide Petition (PP) 0F7760). In the Federal Register of February 4, 2011 (76 FR 6465), EPA

announced that Certis USA, LLC proposed to establish an exemption from the requirement of a tolerance for residues of the insecticide, *Bacillus subtilis* variant *amyloliquefaciens* strain D747, in or on all food commodities, and opened a 30-day comment period. No comments were received following this publication. The correct taxonomic designation of the microorganism is *Bacillus amyloliquefaciens* strain D747; therefore, the tolerance exemption, when established, will reflect the correct name of the active ingredient.

The public has had an opportunity to comment on these proposed registrations announced on November 14, 2011 on the EPA websites at http://www.epa.gov/pesticides/chemical/pesticide-registrations/bacillus-amyloliquefaciens-strain.html and http://www.epa.gov/pesticides/regulating/registration-status.html#b. No comments were received to date during this 30 day comment period.

III. BACKGROUND AND CONCLUSIONS

Health Effects and Exemption from the Requirement of a Tolerance

Bacillus amyloliquefaciens strain D747 was previously identified as *Bacillus subtilis* variant *amyloliquefaciens* strain D747 in the submitted application and the petition submitted to exempt the bacterium from the requirement of a tolerance when used as a microbial pesticide in or on all food commodities. *Bacillus subtilis* and *Bacillus amyloliquefaciens* were considered subtypes or variants of the same species. Now, however, *Bacillus amyloliquefaciens* is taxonomically designated as a separate species.

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed the submitted data and other information regarding the numerous proposed uses of *B. amyloliquefaciens* strain D747. Adequate product analysis, mammalian and other information were submitted to support the registrations of pesticide products containing the microbial active ingredient, *B. amyloliquefaciens* strain D747. All toxicology data requirements for *B. amyloliquefaciens* strain D747 have been satisfied. BPPD has concluded that the database is adequate to support the registration of the two end-use pesticide products, CX-9030 (EPA File Symbol 70051- RNT) and CX-9032 (EPA File Symbol 70051- RNI). Tier II and Tier III studies were not required for *B. amyloliquefaciens* strain D747, based upon the lack of acute toxicity/pathogenicity in the Tier I studies.

The acute oral, injection and pulmonary toxicity/pathogenicity studies show that *Bacillus amyloliquefaciens* strain D747 is not toxic, infective, or pathogenic to mammals at the doses tested. No acute, subchronic, chronic, immune, endocrine, or nondietary exposure issues were identified to indicate that the fungicidal use of these active ingredients would be expected to harm infants, children, and the general U.S. population.

Bacillus species, including *Bacillus amyloliquefaciens,* are commonly found in agricultural settings and occur naturally on fresh produce with no known adverse effects. The Manual of

Clinical Microbiology (9th edition) mentions that dried food, such as spices, milk powder, and grains, often contains large amounts of *Bacillus* spores. *Bacillus amyloliquefaciens* is not known to produce mammalian toxins, and no foodborne illnesses associated with *Bacillus amyloliquefaciens* have been reported.

Bacillus amyloliquefaciens is naturally present in soils (Logan and de Vos 2009); therefore, *Bacillus amyloliquefaciens* may occur in surface water and possibly groundwater. According to the World Health Organization, *Bacillus* species are often detected in drinking water even after going through acceptable water treatment processes, largely because the spores are resistant to these disinfection processes (World Health Organization, 2011). Should this microbial pesticide be present, no adverse effects are expected from exposure to *Bacillus amyloliquefaciens* through drinking water, based on the results of submitted toxicity studies.

The use sites for these *Bacillus amyloliquefaciens* strain D747 products include residential gardens, as well as agricultural sites

Based upon the low oral toxicity demonstrated in the submitted studies, the intended uses of this microbial fungicide do not pose a dietary risk to the U.S. population in general, including infants and children. Therefore, a final rule establishing exemptions from the requirement of a tolerance for *Bacillus amyloliquefaciens* strain D747 in 40 CFR 180, in accordance with Section 408 of the Federal Food, Drug, and Cosmetics Act (FFDCA), have been prepared for your signature. These final rules have been reviewed by the Agency's Office of General Counsel, and their concurrence (e-mail from Benjamin Wakefield dated 12/08/11 to Susanne Cerrelli) is attached.

Health Effects Assessment of Bacillus amyloliquefaciens strain D747

As detailed in the accompanying Biopesticides Registration Action Document (BRAD), Acute oral, pulmonary and intravenous injection toxicity studies performed on rats demonstrate *Bacillus amyloliquefaciens* strain D747 is not toxic, infective, or pathogenic to rats when orally dosed with 1.0×10^8 CFU / animal; or when dosed intratracheally or intravenously with 1.0×10^7 CFU/ animal.

Environmental Assessment

The Agency has performed an ecological risk assessment based on the data, literature citations, and data waiver rationale provided by the registrant for *Bacillus amyloliquefaciens* strain D747. *B. amyloliquefaciens* strain D747 is proposed for control of fungal and bacterial pests in a variety of agricultural, greenhouse, and homeowner food and nonfood uses. *B. amyloliquefaciens* is a soil bacterium that is widely distributed. It has been isolated from internal tissues of healthy plants, and is recognized as a plant growth promoting symbiont (Logan and de Vos 2009).

As discussed in detail in the accompanying BRAD, no toxic endpoints have been identified for

non-target mammals, birds, insects, aquatic organisms, or plants. Therefore, no adverse effects to non-target species exposed to *B. amyloliquefaciens* strain D747 from their intended use as a microbial fungicide, when used in accordance with the label directions. The proposed uses of *B. amyloliquefaciens* strain D747 are not expected to pose risk of unreasonable adverse effects to nontarget organisms. A "No Effect" determination is made for direct effects to federally listed threatened and endangered species.

The data, literature citations and other information, including data waivers, submitted by the applicant and reviewed by BPPD support the application to register two end-use pesticide products, CX-9030 (EPA File Symbol 70051-RNT) and CX-9032 (EPA File Symbol 70051-RNI), when applied and/or used as directed on the label and in accordance with good agricultural practices.

IV. OFFICE DIRECTOR CONCURRENCE

Based on the discussion above and the data summarized in the attached BRADs, the Biopesticides and Pollution Prevention Division recommends unconditional registration for the microbial pesticide, *Bacillus amyloliquefaciens* strain D747 as a new active ingredient for use on outdoor and greenhouse agricultural food, ornamental crops, residential gardens, and turf and as a fungicide.

Concurrence: _____

Non-Concurrence: _____

Date: 12/15/11

Certis USA, L.L.C.
9145 Guilford Road
Suite 175
Columbia, MD 21046
(301) 604-7340
FAX (301) 604-7015
www.certisusa.com

November 21, 2011

Ms. Susanne Cerrelli
Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
US Environmental Protection Agency

Re: Certis USA/EPA File Symbol: 70051-RNI/CX-9030
Alternate Confidential Statement of Formula

Dear Ms. Cerrelli:

As discussed in our teleconference, attached is an alternate Confidential Statement of Formula (CSF) that Certis would like to include in the pesticide application referenced. This alternate CSF is substantially similar to the primary formulation, with the exception of the direct substitution of one inert ingredient. This inert ingredient is on EPA List 4, and has been reviewed and accepted by the Agency in other products that are manufactured by Certis (*Bt* formulations, specifically Agree WG). The percent active ingredient in the formulation has not been changed, nor has any other inert ingredient identity.

Please do not hesitate to contact me if you have any questions about this request. I can be reached by telephone at 301-483-3806 or by email at cdively@certisusa.com.

Sincerely,

Christine A. Dively

Christine A. Dively
Director of Regulatory Affairs
Certis USA

enclosure

Posting an FDMS Docket without a Federal Register Notice

MEMORANDUM

SUBJECT: Posting EPA-HQ-OPP-2011-0853 to Regulations.gov for Public Access

FROM: Keith A. Matthews
Director, Biopesticides and Pollution Prevention Division
Office of Pesticide Programs

TO: Office of Pesticide Programs Docket

This memorandum authorizes the posting of EPA-HQ-OPP-2011-0853 to Regulations.gov for public access. The new active ingredient, *Bacillus amyloliquefaciens* strain D747, is being proposed by Certis U.S.A., L.L.C. for registration as a first food-use and first outdoor-use pesticide. In this docket, the Agency is proposing a regulatory decision that will allow for the use of *Bacillus amyloliquefaciens* strain D747 in and on all food commodities.

The following documents will be available for a 30-day public comment from November 14, 2011 to December 14, 2011.

A. The proposed Biopesticides Registration Action Document for the registered active ingredient, *Bacillus amyloliquefaciens* strain D747.
B. The Environmental risk assessment for *Bacillus amyloliquefaciens* strain D747
C. A copy of the proposed label for the end-use product, CX- 9030.
D. A copy of the proposed label for the end-use product, CX- 9032.

Submit your comments, identified by Docket ID No. EPA-HQ-OPP-2011-0853, by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.
- Mail: EPA-HQ-OPP-2010-0097, Environmental Protection Agency, Mailcode 28221T, 1200 Pennsylvania Ave, NW, Washington, DC 20460.
- Hand Delivery: Office of Pesticide Programs, One Potomac Yard, 2777 S. Crystal Drive, Arlington, VA 22202 (Mail Code: 7502P). Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

EPA's policy is that all comments received will be included in the public docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http://www.regulations.gov or e-mail. The http://www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment

directly to EPA without going through http://www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, avoid any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at http://www.epa.gov/epahome/dockets.htm.

Should you have any questions regarding this memorandum, please contact Susanne Cerrelli at (703) 308-8077, or via email at cerrelli.susanne@epa.gov.

BIOPESTICIDES REGISTRATION ACTION DOCUMENT

DRAFT

Bacillus amyloliquefaciens strain D747

Pesticide Chemical (PC) Code: 016482

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

November 10, 2011 version

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I. EXECUTIVE SUMMARY

Certis USA, LLC, ("Certis" or "applicant) has proposed to register *Bacillus amyloliquefaciens* strain D747 as the active ingredient in two end-use pesticide products, CX-9030 (EPA File Symbol 70051-RNI) and CX-9032 (EPA File Symbol 70051-RNT). The products are intended for use to control fungi and bacteria in outdoor agricultural crops, greenhouses, nurseries, shadehouses, ornamentals, and turfgrass. *B. amyloliquefaciens* strain D747 was initially identified by Certis as "*Bacillus subtilis* variant *amyloliquefaciens strain D747*," since *B. subtilis* and *B. amyloliquefaciens* were originally classified as subtypes or variants of the same species. *B. amyloliquefaciens* is now considered a separate species, and the correct taxonomic designation is used in this Biopesticides Registration Action Document ("BRAD") (Priest et. al., 1987; Logan and de Vos, 2009; and Murray et. al, 2007).

EPA scientists reviewed product analysis, mammalian and nontarget organism toxicity data, and other information submitted by Certis to support the proposed product registrations. The product analysis data requirements for *B. amyloliquefaciens* strain D747, including product chemistry and composition, analysis of samples, and physical and chemical characteristics, were fulfilled by acceptable studies conducted in accordance with Agency guidelines. Mammalian toxicity data (acute oral, injection, and pulmonary toxicity/pathogenicity) and information from peer-reviewed scientific literature demonstrated that *B. amyloliquefaciens* strain D747 is not toxic, infective or pathogenic in laboratory rats. Acceptable nontarget organism data also demonstrated that *B. amyloliquefaciens* strain D747 is not toxic to estuarine and marine fish and invertebrates, nontarget insects (including honey bees), and nontarget plants.

We have assessed human health and environmental risks from the proposed uses of *B. amyloliquefaciens* strain D747, and determined that the pesticide would not cause unreasonable adverse effects to nontarget organisms when used in accordance with the directions on the proposed labels, and in accordance with good agricultural practices. Additional mammalian and nontarget organism toxicity data are not required for the proposed uses and application methods.

Bacillus species, including *B. amyloliquefaciens*, are commonly found in soils, including agricultural settings, and are naturally present on fresh produce. The Manual of Clinical Microbiology (9th Edition) states that dried foods, such as spices, milk powder and grains, often contain large amounts of *Bacillus* spores. *B. amyloliquefaciens* is not known to produce any mammalian toxins, and no food-borne disease outbreaks associated with *B. amyloliquefaciens* have been reported. Given that the microorganism occurs naturally in soils, exposure to *B. amyloliquefaciens* from surface and groundwater may occur. No adverse effects have been reported, and none are expected from exposure to *B. amyloliquefaciens* through drinking water.

Despite the low toxicological profile of *B. amyloliquefaciens* strain D747, personal protective equipment (PPE) is required for pesticide handlers that are frequently exposed to the active ingredient for prolonged periods. Handlers will be directed to wear a long-sleeved shirt, long pants, socks, shoes, waterproof gloves, and a dust/mist filtering respirator meeting National Institute for Occupational Safety and Health (NIOSH) standards of at least N-95, R-95, or P-95. EPA may require additional PPE, other than the standard described above, if additional pesticide uses resulting in increased exposures are proposed in the future.

EPA has concluded that, based upon the results of the toxicity tests and lack of adverse incidents, there is a reasonable certainty that no harm will result to the United States population, including

infants and children, from dietary (including drinking water) and aggregate exposure to residues of *B. amyloliquefaciens* strain D747 from the proposed pesticide uses. The proposed products meet the standards for registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

On October 1, 2009, EPA announced a new policy to provide a more meaningful opportunity for the public to participate in major registration decisions before they occur. According to this policy, EPA intends to provide a public comment period prior to making a registration decision for, at minimum, the following types of applications: new active ingredients; first food uses; first outdoor uses; first residential uses; or any other registration actions for which EPA believes there may be significant public interest.

Consistent with the policy of making registration actions more transparent, the proposed pesticide products containing *B. amyloliquefaciens* strain D747, a new active ingredient, are subject to a 30-day comment period. In addition to containing a new active ingredient, the registration of these products would result in the first outdoor use, first residential use and first food use for *B. amyloliquefaciens* strain D747. The docket identification number, associated with these registration actions and accessed through either http://www.regulations.gov/ or http://www.epa.gov/pesticides/regulating/registration-status.html, is EPA-HQ-OPP-2011-0853. The following documents are available for comment in EPA-HQ-OPP-2011-0853: (1) draft *B. amyloliquefaciens* strain D747 Biopesticides Registration Action Document (BRAD); (2) environmental risk assessment for *B. amyloliquefaciens* strain D747; (3) draft product label for the end-use product, CX-9030 (EPA File Symbol 70051-RNI) ; and (4) draft product label for the end-use product, CX-9032 (EPA File Symbol 70051-RNT). While a final decision on registration is contingent upon review and consideration of public comments, EPA presently believes that, based upon the risk assessment and information submitted in support of the CX-9030 and CX-9032 EPs, it is in the best interest of the public and the environment to issue these registrations. The basis for this preliminary decision can be found in the risk assessment for *B. amyloliquefaciens* strain D747, which is presented in this document.

II. ACTIVE INGREDIENT OVERVIEW

Biological Name:	*Bacillus amyloliquefaciens* strain D747
Culture Deposit:	Agricultural Research Service Culture Collection (also known as the Northern Regional Research Laboratory (NRRL) Collection) in Peoria, Illinois, under Accession Number NRRL B-50405.
OPP Chemical Code:	016482
Type of Pesticide:	Microbial Pesticide – Insecticide See Appendix B for specific information (e.g., use sites, application rates, methods of application, formulation types, and target pests) regarding the registered pesticide products containing this active ingredient.

III. REGULATORY BACKGROUND

A. Applications for Pesticide Product Registration

Certis USA, LLC (address: 9145 Guilford Road, Suite 175, Columbia, MD, 21046), submitted applications to register two end-use pesticide product, CX-9032 and CX-9030, under FIFRA section 3(c)(5) on July 26, 2010. EPA announced receipt of these applications to register pesticide products containing a new active ingredient on February 2, 2011 (76 Federal Register (FR) 5805), and opened a 30-day public comment period, pursuant to the provisions of FIFRA section 3(c)(4). No comments were received following this publication.

B. Food Tolerance Exemption

Concurrent with its registration applications, and under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(d), Certis USA, LLC, submitted a petition to establish an exemption from the requirement of a tolerance for *Bacillus subtilis* variant *amyloliquefaciens* strain D747 (Pesticide Petition (PP) 0F7760). In the Federal Register of February 4, 2011 (76 FR 6465), EPA announced that Certis USA, LLC, proposed to establish an exemption from the requirement of a tolerance for residues of the insecticide, *Bacillus subtilis* variant *amyloliquefaciens* strain D747, in or on all food commodities, and opened a 30-day comment period. No comments were received following this publication. The correct taxonomic designation of the microorganism is *Bacillus amyloliquefaciens* strain D747; therefore, the tolerance exemption, when established, will reflect the correct name of the active ingredient.

IV. RISK ASSESSMENT

In the Federal Register of October 26, 2007, EPA issued a Final Rule establishing changes to the data requirements that support the registration of microbial pesticides. The rule also updated the definition for microbial pesticides (72 FR 61002), and became effective on December 26, 2007. The data and information evaluated for this BRAD were considered in accordance with these requirements.

The classifications or ratings that are given for each data requirement in this BRAD were assigned by the EPA scientists who reviewed the data, and convey the usefulness of the information for the human health and nontarget risk assessment purposes. "Acceptable" indicates that a study is scientifically sound and is useful for risk assessment. A "supplemental" classification indicates the studies provided some information that can be useful for risk assessment. "Supplemental" ratings are given to studies that are not required for registration, as well as those that are required. In the latter case, the study lacks information that should have been obtained if it was conducted according to the guideline associated with the data requirement. Sometimes the missing information would not add anything necessary to inform a risk assessment, and the study classification remains "supplemental." A classification of "supplemental:upgradable" indicates the study lacks necessary information, but if it is made available by the applicant, the study may be upgraded to "acceptable." An "unacceptable" rating indicates that new data must be submitted.

Toxicity categories are assigned to acute toxicity studies, based upon any signs of toxicity (hazards) observed in the test animals during the course of the study, whether the study was conducted in accordance with test guidelines or comes from other sources, such as peer-reviewed, scientific literature. The active ingredient or particular product is classified into Toxicity Category I, II, III, or IV, where Toxicity Category I indicates the highest toxicity, and Toxicity Category IV indicates the lowest toxicity (see 40 CFR § 156.62).

A. Product Analysis Assessment (40 CFR § 158.2120)

All product analysis data requirements for *B. amyloliquefaciens* strain D747 have been fulfilled for the proposed product registrations. Refer to Tables 1, 2, 3, and 4 in Appendix A for a brief summary of the data requirements, including both generic and product-specific information.

B. Human Health Assessment (40 CFR § 158.2140)

1. Toxicity

All Tier I mammalian toxicity data requirements for *B. amyloliquefaciens* strain D747 have been fulfilled for the proposed product registrations. Refer to Tables 5, 6 and 7. Based on the lack of acute toxicity/pathogenicity, Tier II and Tier III studies were not required.

For a comprehensive summary of the generic and product-specific toxicity data requirements described below, refer to Tables 5, 6 and 7 in Appendix A.

a. Acute Toxicity/Pathogenicity – Tier I

Acute Oral Toxicity/Pathogenicity (Office of Chemical Safety and Pollution Prevention (OCSPP) Guideline 885.3050; Master Record Identification Number (MRID No. 481657-04):
B. amyloliquefaciens strain D747 was administered once orally to 14 rats of both sexes (5-weeks old) at a single dosage of 10^8 colony-forming units (CFU) per animals. No deaths occurred, and no abnormalities (clinical signs, body weight) were observed, during the study or at necropsy. The test microbe was detected at $10^3 - 10^5$ CFU/g in feces 1 day after administration of the test material, but was not detected on day14. The examination for internal persistence did not detect the test microbe in any organs or tissues, such as the kidney, brain, liver, lung, spleen, stomach, small intestine (duodenum), large intestine (cecum), mesenteric lymph nodes, or blood, throughout the experimental period. Fecal clearance occurred by day 14, and no viable organisms were recovered from blood or other organs or tissues. The results of this acceptable study demonstrated that *B. amyloliquefaciens* strain D747 was not infective, pathogenic, or toxic to rats when orally dosed with 1.0×10^8 CFU / animal.

Acute Pulmonary Toxicity/Pathogenicity (OCSPP Guideline 885.3150; MRID No.481657-06):
B. amyloliquefaciens strain D747 was administered once intratracheally to 20 male and female Sprague-Dawley rats (5-week old) at a dosage of 10^7 CFU per animal. No deaths occurred, and no abnormalities (clinical signs, body weight) were observed during the study or at necropsy. The examination for internal persistence showed that the test microbe was detected shortly after administration in the lung, trachea, and nasal cavity. The test microbes were not detected in the nasal cavity on day 7, and almost completely cleared from the trachea by day 60, when the study ended. The presence of the test microbes decreased in the lungs by approximately 10^2-10^3 CFU/g from day 0 to day 60. The test microbes were detected in the bronchial lymph nodes on day 3.

Since many test microbes remained in the trachea on day 3, their presence in the bronchial lymph nodes on day 3 was attributed to transfer by macrophages from the respiratory tract to the lymph nodes. This conclusion was supported by the observation that a particle larger than 1 μm in diameter administered into the trachea and bronchi was phagocytized by a macrophage and carried to a lymph node. The presence of the microbes in the lungs, though decreasing throughout the observation period, was attributed to the continuous transfer of viable test organisms to the bronchial lymph nodes. This result is not unusual for spore-forming bacteria, since bacterial spores are extremely tolerant of adverse conditions, and take a longer time for the immune system to clear than bacteria that do not form spores. Since a pattern of clearance was demonstrated, the remaining viable cells were considered to be spores, which take longer for a healthy immune system to clear. This acceptable study demonstrated that *B. amyloliquefaciens* strain D747 was not toxic or pathogenic to rats when dosed intratracheally at 1.0×10^7 CFU/ animal.

Acute Injection Toxicity/Pathogenicity (Intravenous) – Rat (OCSPP Guideline 885.3200; MRID No. 481657-05): In an acute intravenous injection toxicity and pathogenicity study, groups of 17 male and female Sprague-Dawley rats (5-weeks old) were injected with *B. amyloliquefaciens* strain D747 at a dosage of 10^7 CFU per animal, and the influence on the animals was investigated. No deaths occurred, and there were no observed abnormalities (clinical signs, body weight) during the study or at necropsy. The examination for internal persistence of the test microbe showed that the test microbes were mainly detected in the kidney, liver, spleen, and blood shortly after administration. The test microbe decreased after that and was not detected in the blood from day14; clearance from the kidney occurred by day 60. McClintock et al. previously reported that when *B. thuringiensis* and *B. subtilis*, which are both spore-forming bacteria, were administered intravenously to rats, clearance from the liver and spleen is difficult. In this study, the test microbe did not completely disappear from these organs by day 60. No test microbes were detected in the brain, and only a few viable microbes at the limit level were sporadically detected in the small and large intestines, and lymph nodes, but were cleared by day 60. This acceptable study demonstrated that *B. amyloliquefaciens* strain D747 was not toxic, infective, or pathogenic to rats when injected intravenously with 1.0×10^7 CFU/ animal.

Hypersensitivity Incidents (OCSPP Guideline 885.3400; MRID No. 481655-05): No hypersensitivity incidents in humans have been reported, and none occurred during research, development, or testing of *B. amyloliquefaciens* strain D747. Should hypersensitivity or other adverse incidents in humans occur in the future, Certis must report them to EPA, in accordance with FIFRA section 6(a)(2).

Cell Culture (OCSPP Guideline 885.3500): This study was not required because *B. amyloliquefaciens* strain D747 is not a virus (refer to test note #4 of 40 CFR § 158.2140(d)).

b. Acute Toxicity and Subchronic Toxicity/Pathogenicity – Tier II; Reproductive Fertility Effects, Carcinogenicity, Immunotoxicity, and Infectivity/Pathogenicity Analysis – Tier III

Tier II and Tier III studies were not required for *B. amyloliquefaciens* strain D747 based on the lack of acute toxicity/pathogenicity in the Tier I studies.

c. Endocrine Disruptors

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

B. amyloliquefaciens strain D747 is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA section 408(p), EPA must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP orders/data call-ins for all pesticide active ingredients.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: *http://www.epa.gov/endo/*.

2. Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." Additionally, section 408(b)(2)(D) of FFDCA requires that EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information, and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. All of the data requirements have been fulfilled, as described previously, and are presented in Table 5 in Appendix A. The following summarizes the results of EPA's dietary risk assessment for *B. amyloliquefaciens* strain D747.

a. Aggregate Exposure

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground or surface water, and through pesticide use in residential and other indoor uses.

Food Exposure and Risk Characterization: *Bacillus* species, including *B. amyloliquefaciens*, are commonly found in the soil in agricultural settings, and are present on fresh produce of all kinds with no known adverse effects. The Manual of Clinical Microbiology (9th edition) mentions that dried food such as spices, milk powder and grains often contain large amounts of *B.* spores. *B. amyloliquefaciens* is not known to produce any mammalian toxins, and no foodborne disease outbreaks associated with *B. amyloliquefaciens* have been reported.

Based on the data and other information submitted to satisfy the data requirements for registration of the manufacturing-use and end-use pesticide products containing the active ingredient, *B. amyloliquefaciens* strain D747, no toxicity, infectivity, pathogenicity or other adverse effects from dietary exposure to are expected (see section IV(B)(1)(a), above, and Table 5 in Appendix A).

Drinking Water Exposure and Risk Characterization: *B. amyloliquefaciens* is naturally present in soils (Logan and de Vos, 2009); therefore, *B. amyloliquefaciens* may occur in surface and possibly groundwater. According to the World Health Organization, *Bacillus* species are often detected in drinking water even after going through acceptable water treatment processes, largely because the spores are resistant to these disinfection processes (World Health Organization, 2011). Should this microbial pesticide be present, no adverse effects are expected from exposure to *B. amyloliquefaciens* through drinking water, based on the data and other information submitted to satisfy the data requirements for registration of the manufacturing-use and end-use pesticide products containing the active ingredient, *B. amyloliquefaciens* strain D747 (see section IV(B)(1)(a), above, and Table 5 in Appendix A).

Non-occupational, Residential Risk Characterization: The use sites for these products include residential garden sites and agricultural sites. As stated previously, *B. amyloliquefaciens* is naturally present in soil, and based on the data and other information submitted to satisfy the data requirements for registration of the manufacturing-use and end-use pesticide products containing the active ingredient, *B. amyloliquefaciens* strain D747, no toxicity, infectivity, pathogenicity or

other adverse effects from non-occupational exposure are expected (see section IV(B)(1)(a), above, and Table 5 in Appendix A).

b. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance exemption, EPA consider "... available information concerning the cumulative effects of [a particular pesticide's] ... residues and other substances that have a common mechanism of toxicity."

EPA has found that *B. amyloliquefaciens* strain D747 does not share a common mechanism of toxicity with any other microorganism, pesticidal or toxic substance. EPA concludes that there are no cumulative effects associated with *B. amyloliquefaciens* strain D747 that need to be considered. For information regarding how EPA determines common mechanisms of toxicity and evaluates cumulative effects, see EPA's website at: *http://www.epa.gov/pesticides/cumulative*.

c. Determination of Safety for the United States (U.S.) Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

EPA concludes that, based upon the results of the toxicity data and other information considered and described in this document, there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of *B. amyloliquefaciens* strain D747. Such exposure includes all anticipated dietary and other exposures for which there is reliable information. With no threshold effects of concern, an additional margin of safety is not required for infants and children.

3. Occupational Exposure and Risk Characterization

Occupational exposure to *B. amyloliquefaciens* strain D747 is not expected to undue risks to pesticide handlers (mixer/loader/applicators), but EPA requires appropriate personal protective equipment and precautionary statements to mitigate any potential risks (e.g., respiratory allergenicity) to pesticide handlers from prolonged or repeated exposures. Handlers applying *B. amyloliquefaciens* strain D747 end-use products in agricultural settings must wear a long-sleeved shirt, long pants, socks, shoes, waterproof gloves, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95.

4. Human Health Risk Characterization

EPA considered human exposure to *B. amyloliquefaciens* strain D747 in light of the registration standards of FIFRA and the relevant FFDCA safety factors for allowable pesticide residues in food and animal feed commodities. EPA has determined that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result when the proposed pesticide products containing *B. amyloliquefaciens* strain D747 as the active ingredient are used in accordance with the proposed labeling.

C. Environmental Assessment (40 CFR § 158.2150)

The primary habitat of *Bacillus* species is soil, although they have also been isolated from a wide variety of other habitats. *B. amyloliquefaciens* has a wide-spread distribution, owed in part to its ability to form endospores that are resistant to greater variation in environmental conditions than the vegetative cells, should transfer to other climates occur. *B. amyloliquefaciens* has been isolated from internal tissues of healthy plants, and is known to promote plant growth. It is not recognized as a pathogen among *Bacillus* species (Logan and de Vos, 2009).

The data, literature citations, and data waiver rationale submitted by the applicant to support the pesticide products containing *B. amyloliquefaciens* strain D747 fulfilled the Tier I nontarget organism data requirements, and were sufficient for risk assessment purposes. Further testing of nontarget organisms at higher tier levels (i.e., Tiers II, III, and IV) is not required for the proposed uses. EPA performed an environmental risk assessment, and has determined that the proposed use of *B. amyloliquefaciens* strain D747 are not expected to cause unreasonable adverse effects to nontarget organisms.

For a comprehensive summary of the generic data requirements described in sections IV(C)(1) of this BRAD, refer to Table 8 in Appendix A.

1. Ecological Exposure and Risk Characterization

a. Terrestrial Animals and Plants

The end-use products include a water-dispersible granular formulation and an aqueous suspension, proposed for application to agricultural crops, nurseries, ornamental plants, turfgrass, greenhouses, and shadehouses. Applications can be made to both foliar surfaces and soil, so exposure to nontarget organisms is possible. The proposed maximum application rates were used in the assessment of nontarget risk.

Data on the naturally occurring levels of *B. amyloliquefaciens* are not available. Many factors influence the environmental fate of microbial pesticides, and resulting population levels in the environment cannot be predicted. EPA expects that *B. amyloliquefaciens* strain D747 may survive after application if conditions are favorable, but the strain would not significantly add to the overall levels of *B. amyloliquefaciens* already present in the environment.

Birds (OCSPP Guideline 885.4050) and Mammals (OCSPP Guideline 885.4150):
A supplemental study showed that the acute oral LD_{50} for *B. amyloliquefaciens* strain D747 is > 4.5×10^{11} spores/kg BW or > 8×10^{9} spores/bird in Northern bobwhite (*Colinus virginianus*; MRID 48165712). Additionally, *B. amyloliquefaciens* is intentionally included in some

domestic avian food diets as a nutritional additive (e.g., European Food Safety Authority, 2010; Wizna et al., 2009), and it is not known to be pathogenic to animals (Logan and de Vos, 2009). An extensive literature search in several databases returned no reports of toxicity or pathogenicity of *B. amyloliquefaciens* in birds. Based on these lines of evidence, *B. amyloliquefaciens* strain D747 is not expected to pose risk of adverse effects in birds.

A study with laboratory rats (MRID 48165704) also showed that *B. amyloliquefaciens* strain D747 is not toxic, infective, or pathogenic at the maximum hazard dose of 1.0×10^8 CFU/animal. Therefore, adverse effects to wild mammals are also not expected as a result of the proposed applications of *B. amyloliquefaciens* strain D747.

Nontarget Insects (OCSPP Guideline 885.4340) and Honey Bees (OCSPP Guideline 885.4380): Studies with *Orius stricollis*, *Crysoperla carnea*, and *Phytoseiulus persimilis* were submitted for the nontarget insect data requirement (MRID 48165716). While no effects of *B. amyloliquefaciens* strain D747 were observed in these studies, they were not acceptable for use in the ecological risk assessment. Two honey bee studies were also submitted that showed no adverse effects of *B. amyloliquefaciens* D747 after 48 hours (MRID 48165717) and 17 days (no MRID currently assigned). These studies were rated Supplemental because they were not of sufficient duration (30 days); however, except in rare cases, bacteria that are pathogenic to insects typically produce toxins that kill the insect within a few days (Tanada and Kaya, 1993). Adverse effects resulting from exposure to *B. amyloliquefaciens* strain D747, therefore, would likely have been evident in the bee studies, especially after 17 days. Scientific rationale was submitted to show that adverse effects are not expected to nontarget insects (MRIDs 48621502 and 48621503). Entomopathogenic *B.* species (e.g., *B. thuringiensis*, *B. sphaericus*) have been extensively studied, and their pathobiology is well-known. *B. amyloliquefaciens* is not among the *B.* species recognized as frank pathogens to insects or other animals (Logan and de Vos, 2009). There are some accounts in the literature of effects of *B. subtilis* on insects; however, none of these were associated with *B. amyloliquefaciens* or *B. subtilis* var. *amyloliquefaciens*. Therefore, based on the studies and other information provided, *B. amyloliquefaciens* strain D747 is not expected to pose risk to honey bees and other nontarget insects as a result of its proposed applications.

Nontarget Plants (OCSPP Guideline 885.4300):
Studies with plants exposed to *B. amyloliquefaciens* strain D747 were unacceptable, based on several deficiencies (MRID 48165715). *B. amyloliquefaciens* is not taxonomically related to any known plant pathogens. As discussed previously, however, the microorganism has been isolated from tissues of healthy plants and is known as a plant growth-promoting rhizobacterium. It is, therefore, not expected to pose risk to nontarget plants as a result of the proposed applications.

b. Aquatic Animals and Plants

B. amyloliquefaciens strain D747 is not intended to be applied directly to water, but some of the applied product may reach aquatic habitats through runoff or spray drift. Spray drift at application is the primary mechanism by which the pesticide is expected to reach water. A spray drift analysis was included in the aquatic risk assessment to determine exposure, and further detail is provided in the environmental risk assessment for *B. amyloliquefaciens* strain D747.

Freshwater Fish (OCSPP 885.4200) Guideline and Invertebrates (OCSPP Guideline 885.4240): In a 30-day study with rainbow trout (*Oncorhynchus mykiss*), the LC_{50} for *B. amyloliquefaciens*

strain D747 was 8.1 x 10^{10} CFU/L, and the NOEC based on sub-lethal effects was 1.44 x 10^{10} CFU/L. If the proposed maximum broadcast application rate (4 fluid ounces/1000 ft^2 or 2.55 x 10^6 CFU/cm^2) is applied directly to a 1-ha body of water 15 cm deep (the EPA Standard Wetland), the resulting concentration would be 1.7 x 10^8 CFU/L. This would be the maximum possible aquatic concentration at this application rate, but is not a proposed use. The NOEC and LC_{50} are approximately 85X and 476X higher than this concentration, respectively. Exposure in freshwater environments will be well below the concentrations that would produce adverse effects, and the proposed applications of *B. amyloliquefaciens* strain D747 are not expected to pose risks to freshwater fish.

A study with *Daphnia magna* provided an EC_{50} based on mortality/immobility of 3.7 x 10^{10} CFU/L, and a NOEC for sub-lethal effects of 2.84 x 10^8 CFU/L. Based on the spray drift analysis, the NOEC would be approximately 20X the expected environmental concentration (EEC), and the EC_{50} would be 218X the EEC; therefore, the proposed applications of *B. amyloliquefaciens* strain D747 are not expected to result in adverse effects to freshwater invertebrates.

Marine/Estuarine Fish (OCSPP 885. 4280) and Invertebrates (OCSPP 885.4240):
Concentrations reaching marine or estuarine areas are expected to be less than those calculated above for freshwater animals, due to further dilution in deeper water. *B. amyloliquefaciens* strain D747 is not expected to reach marine or estuarine environments in significant concentrations, and risk to animals in these environments is not anticipated.

Aquatic Plants (OCSPP Guideline 885.4300):
B. amyloliquefaciens strain D747 is not related to known plant pathogens; therefore, adverse effects to aquatic plants are not anticipated.

2. Environmental Fate Data

The information provided for the proposed uses and application methods was sufficient to satisfy the Tier I nontarget organism data requirements and for nontarget organism risk assessment for *B. amyloliquefaciens* strain D747; further testing at higher tier levels (i.e., Tiers II, III, and IV) is not required.

3. Threatened and Endangered Species Assessment

Since EPA has determined that no effects are anticipated for any nontarget species exposed to *B. amyloliquefaciens* strain D747 as a result of the proposed applications, effects to federally listed threatened and endangered species and their designated critical habitats are also not expected. Therefore, a "No Effect" determination is made for direct and indirect effects to listed species and their designated critical habitats resulting from the proposed uses of *B. amyloliquefaciens* strain D747.

V. ENVIRONMENTAL JUSTICE

EPA seeks to achieve environmental justice—the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income—with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. Fair treatment means that no group of people, including racial, ethnic, or socioeconomic groups,

should bear a disproportionate share of the negative environmental consequences resulting from industrial, municipal, and commercial operations or the execution of federal, state, local, and tribal environmental programs and policies. Meaningful involvement means that (1) potentially affected community residents have an appropriate opportunity to participate in decisions about a proposed activity that will affect their environment and/or health; (2) the public's contribution can influence the regulatory agency's decision; (3) the concerns of all participants involved will be considered in the decision-making process; and (4) the decision-makers seek out and facilitate the involvement of those potentially affected. EPA has this goal for all communities and persons across the United States.

To help address potential environmental justice issues, EPA seeks information on any groups or segments of the population who, as a result their location, cultural practices, or other factors, may have atypical, unusually high exposure to *B. amyloliquefaciens* strain D747, compared to the general population. Please comment if you are aware of any subpopulations that may have atypical, unusually high exposure compared to the general population.

For additional information regarding environmental justice issues, please visit EPA's web site at *http://www.epa.gov/compliance/environmentaljustice/index.html*.

VI. RISK MANAGEMENT DECISION

Section 3(c)(5) of FIFRA permits for the registration of a pesticide provided that all the following determinations are made:

(1) Its composition is such as to warrant the proposed claims for it;
(2) Its labeling and other material required to be submitted comply with the requirements of FIFRA;
(3) It will perform its intended function without unreasonable adverse effects on the environment; AND
(4) When used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

To satisfy criterion 1, the *B. amyloliquefaciens* strain D747 pesticide products have well-known properties. EPA has no knowledge that would contradict the claims made for these products, the CX-9030 and CX-9032 EP labels, and we have concluded that such products are not expected to cause unreasonable adverse effects on the environment when used according to the label instructions. Criterion 2 is satisfied by the current product labels, as well as the data and information presented in this document. It is believed that the *B. amyloliquefaciens* strain D747 pesticide products will not cause any unreasonable adverse effects on the environment, and CX-9030 and CX-9032 (end-use pesticide product), in particular, are likely to provide protection against fungal and bacterial pests as claimed, satisfying criterion 3. Criterion 4 is satisfied in that the *B. amyloliquefaciens* strain D747 pesticide products are not expected to cause unreasonable adverse effects when used according to label instructions. Therefore the end-use products, CX-9030 and CX-9032, containing *B. amyloliquefaciens* strain D747 as a new active ingredient, are eligible for registration under FIFRA section 3(c)(5) for the labeled uses. Should uses that are more extensive be proposed in the future (e.g., aquatic uses), EPA will likely require that additional data be submitted.

VII. ACTIONS REQUIRED BY THE REGISTRANT

A. Final Printed Labeling

Before releasing pesticide products containing *B. amyloliquefaciens* strain D747 for shipment, the registrant is required to provide appropriate final printed labeling to EPA prior to shipment of product.

B. Terms of Registration

As a term of the registration CX-9032 EP, the registrant must submit the following data within one year of this product's registration:

(1) Storage Stability (OCSPP Guideline 830.6317) and Corrosion Characteristics (OCSPP Guideline 830.6320): The results of a one-year storage stability and corrosion characteristics study.

C. Reporting of Adverse Effects and Hypersensitivity Incidents

Notwithstanding the information stated previously, it should be clearly understood that certain specific data are required to be reported to EPA as a requirement for maintaining the federal registration for a pesticide product. A brief summary of these types of data are described below.

Reports of all incidents of adverse effects to the environment must be submitted to EPA under the provisions stated in FIFRA section 6(a)(2). Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to EPA under the provisions of 40 CFR § 158.2140(d).

VIII. GLOSSARY OF ACRONYMS AND ABBREVIATIONS

ASAE	American Society of Agricultural Engineers
BPPD	Biopesticides and Pollution Prevention Division
BRAD	Biopesticides Registration Action Document
CFR	Code of Federal Regulations
CFU	colony-forming unit(s)
cfu/kg	colony-forming units per kilogram
cfu/mL	colony-forming units per milliliter
cP	centipoise
EDSP	Endocrine Disruptor Screening Program
EP	end-use product
EPA	Environmental Protection Agency (the "Agency")
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
g/mL	gram per milliliter
LC_{50}	median lethal concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is

	usually expressed as the weight of substance per weight or volume of water, air, or feed (e.g., mg/L, mg/kg, or ppm).
LD_{50}	median lethal dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, or inhalation). It is expressed as a weight of substance per unit weight of animal (e.g., mg/kg).
mg/kg	milligrams per kilogram
mg/L	milligrams per liter
MP	manufacturing-use product
mPa·s	milliPascal-second, term used as the unit of dynamic viscosity.
MRID No.	Master Record Identification Number
NIOSH	National Institute for Occupational Safety and Health
NRRL	Northern Regional Research Laboratory
OCSPP	Office of Chemical Safety and Pollution Prevention
OPP	Office of Pesticide Programs
PC Code	Pesticide Chemical Code
PP	Pesticide Petition
PPE	personal protective equipment
ppm	parts per million
TGAI	technical grade of the active ingredient
U.S.	United States

IX. BIBLIOGRAPHY

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APPENDIX A. MICROBIAL PESTICIDES DATA REQUIREMENTS (40 CFR PART 158 – SUBPART V)

TABLE 1. Product Analysis Data Requirements for the End-Use Product (EP), CX-9030 (40 CFR § 158.2120)

OCSPP Guideline Number	Data Requirement	Results	MRID No.
885.1100	Product Identity	Submitted data fulfill the requirement for product identity. CX-9030 contains 25.0% by weight *Bacillus amyloliquefaciens strain* strain D747 (minimum of 5x 10^{10} CFU/g)	481655-01 CSF dated 10/18/2011
885.1200	Manufacturing Process	Submitted data fulfill the requirement for manufacturing process.	481655-01
Not applicable	Deposition of a Sample in a Nationally Recognized Culture Collection	Submitted data fulfill the requirement for deposition. Culture on deposit under Accession Number NRRL B-50405.	481655-01
885.1300	Discussion of Formation of Unintentional Ingredients	Submitted data fulfill the requirement for discussion of formation of unintentional ingredients.	481655-01
885.1400	Analysis of Samples	Submitted date fulfill the requirement for analysis of samples.	481655-01
885.1500	Certification of Limits	Limits listed on the confidential statement of formula are adequate/acceptable	CSF dated 10/18/2011
Additional Studies			
830.1800	Enforcement Analytical Method	Submitted data fulfill the requirement for an enforcement analytical method	481655-01

TABLE 2. Product Analysis Data Requirements for the End-Use Product (EP), CX-9032 (40 CFR § 158.2120)

OCSPP Guideline Number	Data Requirement	Results	MRID No.
885.1100	Product Identity	Submitted data fulfill the requirement for product identity. CX-9030 contains 98.95% by weight *Bacillus amyloliquefaciens strain* strain D747 (minimum of 1x 10^{10} CFU/g)	481655-01 CSF dated 10/18/2011
885.1200	Manufacturing Process	Submitted data fulfill the requirement for manufacturing process.	481657-01 481655-01
Not applicable	Deposition of a Sample in a Nationally Recognized Culture Collection	Submitted data fulfill the requirement for deposition. Culture on deposit under Accession Number NRRL B-50405.	481657-01 481655-01
885.1300	Discussion of Formation of Unintentional Ingredients	Submitted data fulfill the requirement for discussion of formation of unintentional ingredients.	481657-01 481655-01
885.1400	Analysis of Samples	Submitted date fulfill the requirement for analysis of samples.	481655-01 481657-01
885.1500	Certification of Limits	Limits listed on the confidential statement of formula are adequate/acceptable	CSF dated 10/18/2011
Additional Studies			
830.1800	Enforcement Analytical Method	Submitted data fulfill the requirement for an enforcement analytical method	481655-01

TABLE 3. Physical and Chemical Characteristics for the Technical Grade of the Active Ingredient (TGAI) *Bacillus. amyloliquefaciens strain* strain D747 / CX-9030 (EP). (40 CFR § 158.2120)

OCSPP Guideline Number	Data Requirement	Results		MRID No.
		TGAI	CX-9030 (EP)	
830.6302	Color	Beige	Not Applicable	481657-02
830.6303	Physical State	Fine powder	Not applicable	481657-02
830.6304	Odor	Yeast odor	Not applicable	481657-02
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Spores inactivated at 54°C	Not applicable	481657-02
830.6314	Oxidation/Reduction: Chemical Incompatibility	Not applicable, the product does not contain oxidizing or reducing agents		481657-02
830.6315	Flammability	Not applicable, the product does not contain flammable ingredients		481657-02
830.6316	Explodability	Not applicable, the product does not contain explosive ingredients		481657-02
830.6317	Storage Stability	Stable up to one year at 25°C without loss of viability		481657-02 481657-03
830.6319	Miscibility	Not applicable, the product is not an emulsifiable liquid. (refer to test note #2 of 40 CFR § 158.2120(d)).		481657-02
830.6320	Corrosion Characteristics	Not applicable, the product is a powder.		481657-02
830.6321e	Dielectric Breakdown Voltage	Not applicable, the product is not for use around electrical equipment		481657-02
830.7000	pH	6.5 – 7.0 (1% w/w)	7.5- 8.0	481657-02
830.7100	Viscosity	Not applicable, the product is a powder.	Not Applicable.CX-9030 is not a liquid.	481657-02
830.7300	Density/Relative Density/Bulk Density (Specific Gravity)	0.307- 0.375 g/ml	0.60-.0.78 g/ cm^3	481657-02

TABLE 4. Physical and Chemical Characteristics for CX-9032 (EP). (40 CFR § 158.2120)

OCSPP Guideline Number	Data Requirement	Results		MRID No.
		TGAI	CX-9030 (EP)	
830.6302	Color	Beige	Light brown	481655-02
830.6303	Physical State	Fine powder	Liquid	481655-02
830.6304	Odor	Yeast odor	Yeast odor	481655-02
830.6313	Stability to Normal & Elevated Temperatures, Metals, & Metal Ions	Spores inactivated at 54°C..		481655-02
830.6317	Storage Stability	Stable up to one year at 25°C without loss of viability	Stable up to 78 days at 25°C without loss of viability. **As a term of the registration, EPA will require the results of a one-year storage stability and corrosion characteristics study be submitted within one year.**	481655-02
830.6319	Miscibility	Not applicable; product is not an emulsifiable liquid. (refer to test note #2 of 40 CFR § 158.2120(d)).		481655-02
830.6320	Corrosion Characteristics	Not applicable; product is a powder.	None evident to polyethylene packaging after 78 days. **As a term of the CX-9032 (EP) registration, EPA will require submission of the results of a one-year storage stability & corrosion characteristics within one year.**	481655-02
830.7000	pH	6.5 – 7.0 (1% w/w)	4.2 - 4.3 (1% w/w).	481655-02
830.7100	Viscosity	Not applicable, the product is a powder.	4.6 - 16.0 milliPascal-second (mPa s) at 25°C	481655-02
830.7300	Density/Relative Density/Bulk Density (Specific Gravity)	0.307- 0.375 g/ml	1.02 – 1.03 g/mL	481655-02

TABLE 5. Toxicology Data Requirements for the Technical Grade of the Active Ingredient (TGAI) (40 CFR § 158.2140)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
		TGAI	
Tier I			
885.3050	Acute Oral Toxicity/Pathogenicity	No evidence of infectivity, pathogenicity or toxicity was found from oral administration of 1.0×10^8 CFU *Bacillus amyloliquefaciens* strain D747 to rats. Clearance from fecal material occurred by day 14 and no viable organisms were recovered from blood or any other organ or tissue. **Classification: Acceptable**	481657-04
885.3150	Acute Pulmonary Toxicity/Pathogenicity	No evidence of infectivity, pathogenicity or toxicity was found from intratracheal administration of 1.0×10^7 spores *B. amyloliquefaciens* strain D747 to rats. **Classification: Acceptable**	481657-06
885.3200	Acute Injection Toxicity/Pathogenicity (Intravenous)	Not toxic, infective, and/or pathogenic to rats when dosed intravenously at 1.0×10^7 spores per animal. **Classification: Acceptable**	481657-05
885.3400	Hypersensitivity Incidents	No hypersensitivity incidents, including immediate-type or delayed-type reactions of humans and domestic animals that occurred during research, development, or testing of the TGAI/MP, were reported. Future hypersensitivity incidents must be reported (For reporting format: OCSPP Guideline 885.3400).	479450-23
885.3500	Cell Culture	Not required. *B. amylaliquefaciens* strain D747 is not a virus (Test note #4 of 40 CFR § 158.2140(d)).	
Tiers II and III			
Not required for *Bacillus amyloliquefaciens* strain D747 based on the lack of acute toxicity/pathogenicity in the Tier 1 studies.			

TABLE 6. Toxicology Data Requirements for the End-Use Product (EP), CX-9030 (40 CFR § 158.2140)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
885.3400	Hypersensitivity Incidents	No hypersensitivity incidents, including immediate-type or delayed-type reactions of humans and domestic animals that occurred during research, development, or testing of the EP, were reported by the applicant. Any future hypersensitivity incidents must be reported per OCSPP Guideline 885.3400.	
870.1100	Acute Oral Toxicity	Oral LD_{50} > 5000 mg/Kg **Classification: Acceptable** Toxicity Category IV	481657-07
870.1200	Acute Dermal Toxicity	Dermal LD_{50} > 5050 mg/Kg **Classification: Acceptable** **TOXICITY CATEGORY** IV	481657-08
870.1300	Acute Inhalation Toxicity	Inhalation LC_{50} > 2.18 mg/L **Classification: Acceptable** **TOXICITY CATEGORY IV**	481657-09
870.2400	Acute Eye Irritation	The maximum average irritation score of 18.3 obtained 1 hour after treatment declined to 17.33 after 24 hours, 2 after 48 hours and 0 after 72 hours following ocular administration of 0.1 mL *B. amyloliquefaciens* strain D747 to New Zealand White rabbits in a 72 hour observation period. **Classification: Acceptable** **TOXICITY CATEGORY III**	481657-10
870.2500	Primary Dermal Irritation	No evidence of irritation was found from dermal administration of 500 mg *B. amyloliquefaciens* strain D747 CX-9030 to rabbits during the 4 hour exposure and 72 observation periods. The dermal irritation score for *B. amyloliquefociens* strain D747 CX-9030 was 0.00. **Classification: Acceptable** **TOXICITY CATEGORY IV**	481657-11

TABLE 7. Toxicology Data Requirements for the End-Use Product (EP), CX-9032 (40 CFR § 158.2140)

OCSPP Guideline Number	Data Requirement	Results	MRID No.
885.3400	Hypersensitivity Incidents	No hypersensitivity incidents including immediate-type or delayed-type reactions of humans and domestic animals that occurred during research, development, or testing of the EP were observed or reported. All hypersensitivity incidents must be reported per OCSPP Guideline 885.3400.	
870.1100	Acute Oral Toxicity	Waiver request submitted. Requirement satisfied by submitted MP data. Oral exposure to the MP showed no adverse effects including infectivity, pathogenicity and toxicity up to the limit dose. Inerts are exempt from tolerance. No additional oral toxicity is expected from inerts. **Classifieation: Acceptable**	481655-04
870.1200	Acute Dermal Toxicity	Waiver request submitted. Requirement adequately addressed by CX-9030 EP data as well as, dermal irritation testing on CX-9032-EP. Dermal toxicity and irritation testing for the CX-9030 EP and dermal irritation data on CX-9032 EP showed no adverse effects up to the limit doses. No additional dermal toxicity is expected from inerts. **Classification: Acceptable**	481655-04 481655-06 481655-11 481657-08
870.1300	Acute Inhalation Toxicity	Waiver request submitted. Pulmonary exposure to the MP showed no adverse effects, including infectivity, pathogenicity or toxicity though slight toxicity lasting 2 days from a 4-hour aerosol inhalation administration of 2.18 mg/L, where inert ingredients were also present, was noted in a CX-9030 EP study. No additional toxicity is expected from this EP's inert ingredients. **Classification: Acceptable**	481655-04 481657-06 481657-09
870.2400	Acute Eye Irritation	The maximum average irritation score of 0.667 at 1 hour after treatment declined to 0 after 24 hours following ocular administration of 0.1 mL *B. amyloliquefaciens* strain D747 CX-9032 to New Zealand White rabbits (72-hour observation period). **Classification: Acceptable** **TOXICITY CATEGORY IV**	481655-05

TABLE 7. Toxicology Data Requirements for the End-Use Product (EP), CX-9032 (40 CFR § 158.2140)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
870.2500	Primary Dermal Irritation	No irritation occurred from dermal administration of 0.5 mL undiluted *B. amyloliquefaciens* strain D747 CX-9032 to shaved skin of rabbits during the 4 hour exposure and 72 observation periods. The dermal irritation score for *B. amyloliquefaciens* strain D747 CX-9032 was 0.00. **Classification: Acceptable** **TOXICITY CATEGORY IV**	481655-06

TABLE 8. Nontarget Organism Toxicity and Environmental Fate Data Requirements for the Technical Grade of the Active Ingredient (TGAI), *Bacillus amyloliquefaciens* strain D747 (40 CFR § 158.2150)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
		Tier I	
885.4050	Avian Oral Toxicity	A study showed that *B. amyloliquefaciens* D747 is not toxic to birds at 8.9 x 10^9 spores/bird. **Classification: Supplemental** Scientific rationale is sufficient to conclude that *B. amyloliquefaciens* D747 is not expected to pose a hazard to birds. **Classification: Acceptable**	48165712 48621501
885.4100	Avian Inhalation Toxicity/Pathogenicity	Not required. *B. amyloliquefaciens* D747 is not considered to be pathogenic to birds	
885.4150	Wild Mammal Toxicity/Pathogenicity	Tests required by 40 CFR § 158.2140 are adequate/ appropriate for assessment of hazards to wild mammals. *B. amyloliquefaciens* D747 was not infective, toxic or pathogenic to laboratory rats 1.0 x 10^8 CFU/animal	48165704
885.4200	Freshwater Fish Toxicity/Pathogenicity	A 30-day study shows that the LC_{50} to rainbow trout is 8 x 10^{10} CFU/L. The NOEC for sublethal effects is 1.44 x 10^{10} CFU/L. **Classification: Acceptable**	48165713
885.4240	Freshwater Invertebrate Toxicity/Pathogenicity	A 21-day study shows that the EC_{50} to *Daphnia magna* based on mortality is 3.7 x 10^{10} CFU/L. The NOEC for sublethal effects is 2.84 x 10^8 CFU/L. **Classification: Acceptable**	48165714
885.4280	Estuarine/Marine Fish and Invertebrate Testing	Not required. *B. amyloliquefaciens* D747 is not to be applied directly to water and is not expected to reach estuarine or marine environments in significant quantities.	
885.4300	Nontarget Plant Testing	A study submitted was determined to be unacceptable; however, testing is not required because. *B. amyloliquefaciens* is not related to known plant pathogens	48165715

TABLE 8. Nontarget Organism Toxicity and Environmental Fate Data Requirements for the Technical Grade of the Active Ingredient (TGAI), *Bacillus amyloliquefaciens* strain D747 (40 CFR § 158.2150)

OCSPP Guideline Number	Data Requirement	Results	MRID No.
885.4340	Nontarget Insect Testing	Studies with three species of arthropods were determined to be unacceptable. Additional scientific rationale was submitted to show that *B. amyloliquefaciens* is not expected to be toxic or pathogenic to nontarget insects. **Classification: Acceptable**	48165716 48621502
885.4380	Honey Bee Testing	Two studies showed that *B. amyloliquefaciens* D747 is not toxic to honey bees. **Classification: Supplemental** Additional rationale was sufficient to show that pathogenicity to honey bees is not expected as a result of exposure to *B. amyloliquefaciens* D747. **Classification: Acceptable**	48165717 48621503
Tiers II, III, and IV			
Not required for *Bacillus amylaliquefaciens* strain D747 based on the current uses and application methods.			

APPENDIX B. PESTICIDE PRODUCTS

TABLE 9. Table Title?

EPA Registration Number	Registration Name	Percentage Active Ingredient	Formulation Type	Use Site(s)	Method(s) of Application	Application Rate	Target Pest
70051-107	CX-9032	98.35%	End Use – Aqueous Suspension	Various agricultural and greenhouse crops (e.g., vegetables, tree fruits, berries, grapes and tropical fruit, tree nuts, herbs and spices, coffee, tobacco, hops, forestry seedlings ornamentals, and turf)	Tractor mounted boom, airblast, hose-end, backpack and other pressurized sprayers; foggers or mist blowers; water wheel and other drench applicators; soil injection; aerial; and chemigation with drip or sprinkler irrigation and cutting or root dip	Rate listed on label varies depending on application method from 0.5 pints /acre to 6 quarts/acre	Various fungal and bacterial pests listed on the label including: *Alternaria, Botrytis cinerea Didymella bryoniae Phoma cucurbitacearum Erisphe, Fusarium, Macrophomina phaseoli Monosporascus cannonballus Peronospora , Phytophthara Pseudomonas syringae* pv. *tomato Pseudoperonospora* spp. *Puccinia* spp. *Pythium, Rhizoctonia, Sphaerotheca* spp. *Verticillium*, spp. *Xanthamonas* spp.
70051-108	CX-9030	25.0%	Water Dispersible Granule	Various agricultural and greenhouse crops (e.g., vegetables, ornamentals, and turf)	Tractor mounted boom, airblast, hose-end, backpack and other pressurized sprayers; foggers or mist blowers; water wheel and other drench applicators; shank or other soil injection equipment; aerial; and chemigation with drip or sprinkler irrigation and cutting or root dip	0.25 –3 pounds per acre	Various fungal and bacterial pests listed on the label including: *Alternaria, Botrytis cinerea Didymella bryoniae Phoma cucurbitacearum Erisphe Fusarium, Macrophamina phaseoli Monosporascus cannonballus Peronospora, Phytophthora Pseudomonas syringae* pv. *tomato Pseudoperonospora* spp. *Puccinia* spp. *Pythium, Rhizoctonia, Sphaeratheca* spp. *Verticillium*, spp., *Xanthomonas* spp.

Certis USA, L.L.C.
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(301) 604-7340
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www.certisusa.com

November 21, 2011

Ms. Susanne Cerrelli
Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
US Environmental Protection Agency

Re: Certis USA/EPA File Symbol: 70051-RNI/CX-9030
Alternate Confidential Statement of Formula

Dear Ms. Cerrelli:

As discussed in our teleconference, attached is an alternate Confidential Statement of Formula (CSF) that Certis would like to include in the pesticide application referenced. This alternate CSF is substantially similar to the primary formulation, with the exception of the direct substitution of one inert ingredient. This inert ingredient is on EPA List 4, and has been reviewed and accepted by the Agency in other products that are manufactured by Certis (*Bt* formulations, specifically Agree WG). The percent active ingredient in the formulation has not been changed, nor has any other inert ingredient identity.

Please do not hesitate to contact me if you have any questions about this request. I can be reached by telephone at 301-483-3806 or by email at cdively@certisusa.com.

Sincerely,

Christine A. Dively

Christine A. Dively
Director of Regulatory Affairs
Certis USA

enclosure

Pages 242-247*Product ingredient source information may be entitled to confidential treatment*

EPA National Organic Program Labeling Request Checklist

Reviewer Name: Chris Pfeifer | **RAL: Susanne Cerrelli**

Product Name: CX 9030 (EPA Reg. No. 70051-RNI (108)) | **Completion Date: 11/16/11**

Determination: Permitted | **Receipt Date: 9/30/11**

#	Check list Item	Yes	No
1	**Active Ingredients** - Are all of the active ingredient(s) "***Allowed***" on the National List?	Y	
2	**Active Ingredients History** - Is the active ingredient on the BPPD list of previous NOP approvals (f:/USER/SHARE/BPPD/Organic/Copy of NOP/**allowableble.pdf** or **ALLOWED.xls**)?	Y	
3	**Inert Ingredients** - Are all of the inert(s) found on the August 2004 EPA list 4A and 4B?	Y	
4	**Inert Ingredients** – Have any inert(s) been recently revoked (Revoked List 4 Inerts)?		N
5	**Use Sites** – Are all the product's use sites within the scope of the designated use patterns cited in the *National List*?	Y	
6	**Language** - Is the requested label language allowable. (Acceptable language includes: "*For Use in Organic Production*"; "*For Organic Production*"; "*For Use in Organic Gardening*"; "*For Organic Gardening*"; "*OMRI Listed*"; the OMRI logo; and the three leaf EPA NOP Logo.	Y*	
7	**OMRI Certification** – Does the application have a current OMRI certificate?	*	
8	**Comments -** #1) The ai is approved for organic use. The source of ai is not GM. There are no intentionally added ingredients in the ai source that are not consumed or accounted for; and none of the impurities are of toxicological significance. #2) The inert ingredients are all List 4 and NOP compliant. Acceptable MSDS were provided for all inert ingredients; and the composition of the mixtures were validated in OPPIN. #3) The use sites for the product are all pre-harvest agricultural, and are acceptable per the Organic Production Standard. #4) The label claims "For Organic Production" and "OMRI Listed" are appropriate for the use pattern on this agricultural label. #5) Because this product is presently unregistered, the product cannot receive an OMRI certificate. It is a reasonable expectation, however, that the registrant will receive a certificate upon application. As such, the registrant can add the "OMRI Listed" claim to the label with the following terms: a) The registrant must add a parenthetical statement to the OMRI claim on the draft label indicating that it is a placeholder. The self-evident expression "(placeholder)" is adequate. b) The Registration Notice must create a term which requires submission of the OMRI certificate to the Agency once it has been received. **Permit NOP labeling of this product.**		

~~**This review contains CONFIDENTIAL BUSINESS INFORMATION (CBI).**~~ **Do not release this document to the registrant if it contains confidential information on proprietary mixes.**

Program Links - National Organic Program (AMS - NOP); PR Notice 2003-1 (PR Notice 2003-1)

BPPD Guidance Document – Other Items May be Required

FW: CBI Statement
Dively, Chris
to:
Susanne Cerrelli
10/25/2011 03:23 PM
Cc:
"Dively, Chris"
Hide Details
From: "Dively, Chris" <cdively@certisusa.com>

To: Susanne Cerrelli/DC/USEPA/US@EPA

Cc: "Dively, Chris" <cdively@certisusa.com>

History: This message has been forwarded.

Dear Susanne,
On behalf of Certis USA, I would like to amend the CBI Statement in the previous email.
Information submitted to support the registration applications and tolerance exemption petition for CX-9030 and CX-9032, that does not have a Confidentiality Statement in the data volume (Per PR Notice 86-5) is not considered as Confidential Business Information per FIFRA and Part 158 Guuidfelines. Data volumes that include CBI are manufacturing process data, formation of unintentional ingredients, Certification of Ingredients –CSFs, and
Analyses of Samples.

Sincerely,

Chris Dively
Director of Regulatory Affairs

From: Dively, Chris
Sent: Tuesday, October 25, 2011 2:59 PM
To: Dively, Chris
Subject: FW: CBI Statement

From: Dively, Chris

Sent: Friday, October 21, 2011 5:02 PM
To: 'Cerrelli.Susanne@epamail.epa.gov'
Cc: Dively, Chris
Subject: CBI Statement

Dear Susanne,

On behalf of Certis USA, information that was submitted to EPA in support of D-747 petition and registration outside of the Section 158 Guidelines are not claimed as CBI. All product chemistry information, including Confidential Statements of Formula, Product ID and characterization, product properties information, all analytical data, and other manufacturing process data is claimed as Confidential Business Information per PR Notice 86-5.

Sincerely,

Chris Dively
Director of Regulatory Affairs

Susanne: If this statement is not what you are referencing please let me know.

Ms. Christine Dively
Certis USA, L.L.C.
9145 Guilford Road, Suite 175
Columbia, MD 21046

Subject: EPA File Symbol 70051- RNI and RNT, CX-9030 and CX 9032
Modifications Required to Labels submitted and October 17, 2011 and CSF

Dear Ms. Dively,

The following modifications are needed to be made to your product labels for the above listed products. Once these changes are made, please email a PDF of the labels to ensure that the file doesn't reformat on my computer.

The minimum colony forming units (CFU) values on the labels and the CSFs must agree.

On the basic formulation of CX-9030, the CFU per a gram listed does not match that listed on the label.

The following changes are required for the CX-9030 label.

On page 1:

1. Insert a summation line beneath "75%."

On page 2 of the CX-9030 label:

2. Delete "Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet" under "User safety recommendations" heading as this information will be added to the precautionary statement.
3. The last sentence in the General Information section referencing NOP must be removed because it is not in accord with the allowable language laid out in PR Notice 2003-1.

On page 3 of the CX-9030 label:

4. The Agricultural use Requirement box needs to be reformatted to fit on the page.

On pages 5 and 6 of the CX-9030 label:

5. Remove the phrase "including but not limited to" that appear after the general crop groupings.

For the CX 9032 label the following label changes are needed.

On page 2 of the CX-9032 label:

6. Move the following text to the Agricultural Use Requirements Box.

   "Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

7. The last sentence in the General Information section referencing NOP must be removed because it is not in accord with the allowable language laid out in PR Notice 2003-1. Delete the phrase: "CX-9032 complies with the USDA National Organic Program (NOP)."

On page 5 of the CX-9032 label:

8. Remove the phrase "including but not limited to" that appear after the general crop groupings.

On page 10 of the CX-9032 label:

9. **In the table**, it needs to be clear what substance is being measured. Is it the CX-9032 or a diluted mixture? **Insert "CX-9032" so the rate heading reads:** "*Rate CX-9032/acre.*"

On page 16 of the CX-9032 label:

10. The specific use sites were not provided. In your phone message you expressed that you did not wish to add a lengthy list to this residential label. The general groups with some examples would be adequate to clarify for the home owner where your product should be used.

Please contact Susanne Cerrelli, if you have any questions about the content of this letter.

Re: *Confidential: B. amyloliquiefaciens D747 BRAD - please indicate if you concur with comments - preferably by 10/21 and Endocrine disruption question

Joel Gagliardi to: Susanne Cerrelli 10/18/2011 01:37 PM

This message is encrypted and digitally signed.

From: Joel Gagliardi/DC/USEPA/US
To: Susanne Cerrelli/DC/USEPA/US@EPA

Susanne,
I am fairly sure that this is not confidential since it is a public documents.
As far as endocrine effects, I do not know of any cases where a microbe, which primarily affect animals by an infection process, could also affect the endocrine system through the infection process. I think if an infection were to occur there would be general effects not endocrine specific - in this case B. amyloliquefaciens D747 was shown to not be infective.
The other issue is unintentional ingredients, or metabolites. Sometimes foodborne illness for instance is due to toxin production, or the bad outcome of an infection is due to toxin production and not just the infection. There is a very remote possibility that a microbial metabolite could have endocrine effects, though since most hormones are cholesterol derivatives and microbes do not use cholesterol for their cell walls like eukaryotes, I know of no instances where this occurs. I wrote up in the DER a bit about metabolites including enzymes and antibiotic production though we have no evidence of either for D747.
"Bergey's Manual mentions that *Bacillus amyloliquefaciens* are sources of industrial α-amylase and protease enzymes. The Manual of Clinical Microbiology (9th edition) mentions that dried food such as spices, milk powder and grains often contain large amounts of *Bacillus* spores."
Size has little to do with the issue.
Good work on the updated CSFs and label.
Joel

****

Joel V. Gagliardi, Ph.D.
U.S. Environmental Protection Agency, Mailcode 7511-P
OCSPP, OPP, BPPD, Microbial Pesticides Branch
1200 Pennsylvania Avenue, NW
Washington, DC 20460

703-308-0116 - phone / 703-305-0118 or 703-308-7026 - fax
http://www.epa.gov/pesticides/biopesticides
****

Susanne Cerrelli From: Susanne Cerrelli/DC/USEPA/US To: Joel... 10/18/2011 11:25:32 AM

From: Susanne Cerrelli/DC/USEPA/US
To: Joel Gagliardi/DC/USEPA/US@EPA
Date: 10/18/2011 11:25 AM
Subject: *Confidential: B. amyloliquiefaciens D747 BRAD - please inicate if you concur with comments - preferably by 10/21 and Endocrine disruption question

---

Joel-

Before I send this to DRT or Keith I wanted to check if you can concur with comments on the science content .

I also need to check with you about a paragraph for the endocrine disrupter section.

Certis needs to make changes to CSF to be in compliance for product chemistry, On this round there is typo and math error on CSF, but I wrote BRAD as if CSF corrected since time is limited .
So I realize if you concur you need to concur with that condition that the CSF and label are corrected.

Please let me know if any other corrections needed to Executive summary, Product chemistry/characterization FQPA, human health assessment , and tables in Appendices.

I will need update Bibliography later, as some data were submitted that did not have MRIDs.

If you need anything , please let me know.

[attachment "D747 BRAD started6.docx" deleted by Joel Gagliardi/DC/USEPA/US]

Thanks!!

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

Ms. Christine Dively
Certis USA, L.L.C.
9145 Guilford Road, Suite 175
Columbia, MD 21046

Subject: EPA File Symbol 70051- RNI and RNT, CX-9030 and CX 9032
Modifications Required to Labels submitted and September 23, 2011 and CSF

Dear Ms. Dively,

The following modifications are needed to be made to your confidential statement of formulas (CSFs) and product labels for the above listed products. We are currently evaluating your "Organic" claims and may require additional changes to the label at a future date.

The minimum colony forming units (CFU) values on the labels and the CSFs must agree in order to upgrade the submitted Product Identity and a characterization data to acceptable.

On the basic and alternative formulation of CX-9030, the CFU per a gram listed does not match that listed on the label.

On the basic and alternative formulation of CX-9032, the CFU per a gram listed was not listed. The CFU/g listed on the CSF must indicate the microbial activity and the number listed must match that listed on the label.

The following changes are required for the CX-9030 label.

On page 1:

1. Insert a summation line beneath "75%."
2. Correct the colony forming units (CFU) per gram."
3. Ensure that the appropriate font is used when preparing the final printed labels. (Consult page 3-12 of the label review manual).
4. For both the first aid and precautionary statement sections, the text may be modified because the acute dermal acute inhalation and skin irritation were toxicity category 4. Certis must list the "IF IN EYES" first aid statement first. The "IF ON SKIN" or "IF INHALED" first aid statements may be removed.

5. I suggest the following precautionary statement under "Caution:"

   Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

On page 1 and 2 of the CX-9030 label:

6. Edit the " PERSONAL PROTECTIVE EQUIPMENT (PPE)" section to read as follows

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- *Long-sleeved shirt and long pants*
- *Waterproof gloves*
- *Shaes plus sacks*

"Mixer/loaders and applicatars must wear a dust/mist filtering respiratar meeting NIOSH standards af at least N-95, R-95, or P-95. Repeated exposure to high concentratians af microbial prateins can cause allergic sensitization."

Follow manufacturer's instructions for cleaning and maintaining PPE. In no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

On page 2 of the CX-9030 label:

7. Delete "Wash hands before eating, drinking, ehewing gum, using tobaeeo, or using the toilet" under "User safety recommendations" heading as this information will be added to the precautionary statement.
8. Put the "Agrieultural use Requirements" in a bordered text box after the "Direction for use" heading.
9. Put the Storage and disposal information in a bordered text box and move it to the "Direction For Use Seetion."

On page 3 of the CX-9030 label:

10. All the text belongs in the "Direction For Use Seetion."

On page 4 -5 of the CX-9030 label:

11. Insert "State or Tribal" text in the seeond sentence so that it reads:

"For any requirements specific to your State or Tribe, consult the State ar Tribal agency respansible for pesticide regulatian".

12. Remove the phrase "including but not limited to" that appear after the general crop groupings.

On pages 7-9 of the CX-9030 label, the applieation rates require elarification:

13. There is a large range in dosage applied with soil, spray, dreneh and ehemigation (8 -12 fold). Can you give more guidance as to when a low rate or medium rate is adequate? If it is based on erop it may be better to add the information to the use site table. The elearer the instruetions the more likely the produet will work as intended.

14. The label needs to indicate the quantity of water to be applied per acre to achieve efficacy, but not cause runoff or excessive leaching. A range of quantities may be appropriate.
15. **The spray drench and chemigation instructions need to give an indication of area of coverage.**

On page 10 of the chemigation portion of the label:

16. Modify the first paragraph as listed below:

Apply this product only through ~~pressurized irrigation systems such as~~ drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (including impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.

17. The earlier mixing directions need to be refered to if appropriate. For chemigation, the following subjects must by addressed using the registrants own wording:

    a. Indicate whether agitation is or is not recommended in the pesticide supply tank. If it is not always recommended, identify the situations when it is recommended (e.g. when tank mixing with other pesticides or fluid fertilizers).
    b. Indicate if the pesticide is to be applied continuously for the duration of the water application. If not, indicate when during the water application the pesticide is to be applied.
    c. Provide mixing instructions for dilution of the pesticide in the supply tank.
18. How much water per an acre (or other measured area) is needed for application? The label needs to indicate the quantity of water to be applied per acre to achieve efficacy, but not cause runoff or excessive leaching. A range of quantities may be appropriate.

On page 12 of the CX-9030 label:

19. Insert the phrase "To the extent consistent with applicable law," in the warranty paragraph preceding the sentence that states "*buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein.*"

For the CX 9032 label the following label changes are needed.

On page 1 and 15 of the CX-9032 label:

20. The nominal concentration of the active ingredient needs to be listed (which is 98.9%) and the other ingredients corrected accordingly (1.1%).
21. Insert a summation line above the 100.00% listed.
22. Correct the minimum colony forming units (CFU) per gram, so that it is correct and matches what is listed on the most current CSF.
23. For both the first aid and precautionary statement sections, the text may be modified because the referenced acute dermal acute inhalation , eye irritation and skin irritation were toxicity category IV. In this case the First Aid text is not required.
24. Suggested Precautionary statements are as follows:

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

On page 2 of the CX-9032 label:

25. Insert *"For Terrestrial Uses:" at* the start of the Environmental Hazard Section.
26. Edit the " PERSONAL PROTECTIVE EQUIPMENT (PPE)" section to read as follows

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

"Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization."

Follow manufacturer's instructions for cleaning and maintaining PPE. In no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

27. Delete "Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet" under "User safety recommendations" heading as this information will be added to the precautionary statement.

28. Move the "Agricultural use Requirements" box to the "Direction For Use Section."

On page 3 of the CX-9032 label:

29. **All the text belongs in the** "Direction For Use Section."

On pages 5-7 of the CX-9032 label:

30. Insert "State or Tribal" text in the second sentence so that it reads:

"For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation".

31. Remove the phrase "including but not limited to" that appear after the general crop groupings.

On pages 8 of the CX-9032 label:

In the last paragraph, insert "of CX-9032" so that the second sentence reads:

Mix CX-9032 in water and apply as a spray at a rate of **0.5 to 6** quarts of CX-9032 **per acre** in sufficient water to achieve thorough coverage of the crop canopy with minimal runoff.

On page 10 of the CX-9032 label:

32. **In the table**, it needs to be clear what substance is being measured. Is it the CX-9032 or a diluted mixture? **Insert "CX-9032" so the rate heading reads:** *"Rate CX-9032/acre."*

On page 12 of the chemigation portion of the label:

33. Modify the first paragraph as listed below:

Apply this product ***only*** *through ~~pressurized irrigation systems such as~~ drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (including impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.*

On pages 14 and 17 of the CX-9032 label:

34. Insert the phrase "To the extent consistent with applicable law," in the warranty paragraph preceding the sentence that states "b*uyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein."*

This box may be placed anywhere in the Directions for Use section of the label after the Agricultural Use Requirements box and must contain the following statements (*PR Notice 93-7, Supplement 3*):
"Non-Agricultural Use Requirements
The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses".
In addition, place into the Non-Agricultural Use Requirements box all the entry restrictions, notification requirements, or other statements and instructions (except personal protective equipment requirements) that apply to the non-WPS uses on the label. Examples: "Keep children and pets out of the treated area until sprays have dried"; or, "Keep unprotected persons out of treated areas until sprays have dried".

On page 15 of the CX-9032 label:

35. *"Residential Use"* is preferred over the term "Homeowner Use."

On page 16 of the CX-9032 label:

36. How much water per an acre (or other measured area) is needed for application? The label needs to indicate the quantity of water to be applied per acre to achieve efficacy, but not cause runoff or excessive

leaching. A range of quantities may be appropriate. How much water is "sufficient water to move the product into the roots? For residential treatment very specific directions that specify the amount of CX-9032 spray solution per a 1000 square feet are recommended and appropriate.

37. The specific use sites were not provided. What plants in the home garden are to be treated with CX-9032? A list of specific use sites needs to be provided in the directions for use section

Please contact Susanne Cerrelli, if you have any questions about the content of this letter.

CBI Statement
Dively, Chris
to:
Susanne Cerrelli
10/21/2011 05:02 PM
Cc:
"Dively, Chris"
Hide Details
From: "Dively, Chris" <cdively@certisusa.com>

To: Susanne Cerrelli/DC/USEPA/US@EPA

Cc: "Dively, Chris" <cdively@certisusa.com>

History: This message has been forwarded.

Dear Susanne,

On behalf of Certis USA, information that was submitted to EPA in support of D-747 petition and registration outside of the Section 158 Guidelines are not claimed as CBI. All product chemistry information, including Confidential Statements of Formula, Product ID and characterization, product properties information, all analytical data, and other manufacturing process data is claimed as Confidential Business Information per PR Notice 86-5.

Sincerely,

Chris Dively
Director of Regulatory Affairs

Susanne: If this statement is not what you are referencing please let me know.

CBI Statement
Dively, Chris
to:
Susanne Cerrelli
10/21/2011 05:02 PM
Cc:
"Dively, Chris"
Hide Details
From: "Dively, Chris" <cdively@certisusa.com>

To: Susanne Cerrelli/DC/USEPA/US@EPA

Cc: "Dively, Chris" <cdively@certisusa.com>

History: This message has been forwarded.

Dear Susanne,

On behalf of Certis USA, information that was submitted to EPA in support of D-747 petition and registration outside of the Section 1S8 Guidelines are not claimed as CBI. All product chemistry information, including Confidential Statements of Formula, Product ID and characterization, product properties information, all analytical data, and other manufacturing process data is claimed as Confidential Business Information per PR Notice 86-5.

Sincerely,

Chris Dively
Director of Regulatory Affairs

Susanne: If this statement is not what you are referencing please let me know.

Bacillus amyloliquiefaciens strain D747 Team meeting
Calendar Entry
Tue 11/01/2011 11:00 AM - 11:30 AM
Rooms: BPPD Conference Room - S-8771/Potomac Yard One@EPA

Required:	Joel Gagliardi/DC/USEPA/US@EPA, John Kough/DC/USEPA/US@EPA, Shannon Borges/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA
Optional:	Alan Reynolds/DC/USEPA/US@EPA

Description

Goal- To clarify any remaining issues and update team on status. Please if anyone has specific questions for D747 or Agenda items, please let me know.

Sheryl Reilly has the current BRAD.

The only outstanding data identified in the BRAD that will be required is:

As a term of the registration CX-9032 EP , the registrant must submit the following data within one year of this product's registration:

(1) Storage Stability (OCSPP Guideline 830.6317) and Corrosion Characteristics (OCSPP Guideline 830.6320): The results of a one-year storage stability and corrosion characteristics study.

Right now I am waiting for Dively to fix labels, again. She fixed the CSFS and ingredient statement on the labels. She just didn't address other items I need. If they don't remove one organic claim they will not get NOP claim approved for one of their labels, and I may be forced to issue registration with label requirement comments on the labels. Chris Pfeifer is waiting for label amendment before he processes further.

The tolerance exemption FR Notice is with Keith Matthews. It has not gone to OGC yet.

Shannon- can you email me the phone number I should use to contact you offsite?

-THANKS!!

CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC) REQUEST FORM

CR# 11-421

REQUESTOR NAME:	SUSANNE CERRELL		Request date:
Tel: 308-8077	ORG.: BPPD	CUBE:	MAIL CODE: 7511P

CSF ATTACHED:
[X] YES — If CSF is attached complete Item A and the chemical name in item C.
[ ] NO — If CSF is not attached complete Item A through C.

A. INFORMATION REQUIRED:

Check Applicable Category

[ ] Provide PCC and Tolerance Exemption Status For Food-Use Inert ingredient (s).
[ ] Provide PCC for Non-Food Use inert Ingredient (s).
[X] Provide PCC for Active Ingredient (s). → NOTE confirm that new nomenclature for AI still PC code 016482
[ ] Provide PCC for Dye.
[ ] Determine if Fragrance is Acceptable for Use In Formulation.
[ ] *Other (Describe):*_____

B. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No/File Symbol: 70051-RNI and 70051-RNT	Product Name: CX 9030 + CX 9032
Registrant: Certis LLC	Food-Use Pesticide: [X] Yes [ ] No
Percent in Formulation (for fragrance or dye): 25 and 98, 85	

C. INGREDIENT INFORMATION:

Ingredient No.1

	INFORMATION REPORTED:
Chem. Name: Bacillus amyloliquefaciens strain D-747	PCC:
Trade Name:	TOL. STATUS: exemption in progress
CAS Reg. No.: N/A	OTHER INF.: New AI

Ingredient No.2:

Chem. Name:	PCC:
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

Ingredient No.3:

Chem. Name:	PCC:
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

Completed By: D. Rose
Date Completed: 10/28/11

USDA

United States Department of Agriculture

Research, Education and Economics
Agricultural Research Service

July 20, 2010

Dr. Yoshihiro Maeda
Kumiai Chemical Industry Company
4-26 Ikenohata 1-chome
Taitoh-ku, Tokyo 110-8782
JAPAN

Dear Dr. Maeda:

Your check for $500.00 arrived on July 19, 2010 for the deposit under the Budapest Treaty of the below listed strain into the Agricultural Research Service (ARS) Patent Culture Collection. Therefore, I am now able to send you the International Receipt Form (BP/4) and the Viability Statement for:

Name	Strain Designation	NRRL Number
Bacillus sp.	D747	NRRL B-50405

I will send, under separate cover, our lyophilized preparation for this strain. As soon as you confirm the equivalency of this preparation to your original deposit, complete, sign, and return the original Viability Statement to me.

Sincerely,

J. L. Swezey, Collections Manager
ARS Culture and Patent Culture Collections
Bacterial Foodborne Pathogens and Mycology Research Unit
Tel: (309) 681-6398
Fax: (309) 681-6672
Email: James.Swezey@ars.usda.gov

2 Enclosures

ars

Midwest Area • National Center for Agricultural Utilization Research
Bacterial Foodborne Pathogens & Mycology Research Unit
1815 N University Street • Peoria, Illinois 61604
Phone: (309) 681-6560 • Fax: (309) 681-6672 • E-mail: Dianna.Halcumb@ars.usda.gov
ARS Culture Collection (NRRL) Website: http://nrrl.ncaur.usda.gov
An Equal Opportunity Employer

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSE OF PATENT PROCEDURES

INTERNATIONAL FORM

TO

Patent Dept.
KUMIAI Chemical Industry Co.,LTD
4-26
Ikenohata 1-Chome
Taitoh-ku
Tokyo 110-8782
Japan

VIABILITY STATEMENT

issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this page

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY STATEMENT IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: Dr. Maeda Kumiai Chemical Industry Co. 4-26 Address: Ikenohata 1-Chome Taitoh-ku Tokyo 110-8782 Japan	Depositor's taxonomic designation and accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY *Bacillus sp.* NRRL B-50405 Date of: June 29, 2010 ☒ Original Deposit ☐ New Deposit ☐ Repropagation of Original Deposit

III. (a) VIABILITY STATEMENT

Deposit was found:
☒ [2]Viable ☐ [2]Nonviable on June 30, 2010 (Date)
International Depositary Authority's preparation was found viable on July 3, 2010 (Date)[3]

III. (b) DEPOSITOR'S EQUIVALENCY DECLARATION

Depositor determined the International Depositary Authority's preparation was
☐ [2]Equivalent
☐ [2]Not equivalent to deposit on _____ (Date)

Signature of Depositor

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST WAS PERFORMED (Depositors/Depositary)[4]

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Agricultural Research Culture Collection (NRRL) International Depositary Authority Address: 1815 N. University Street Peoria, Illinois 61604 U.S.A.	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date: 7-20-10

[1] Indicate the date of the original deposit or when a new deposit has been made.
[2] Mark with a cross the applicable box.
[3] In the cases referred to in Rule 10.2(i)(ii) and (iii), refer to the most recent viability test.
[4] Fill in if the information has been requested.

USDA

United States Department of Agriculture

Research, Education and Economics
Agricultural Research Service

July 20, 2010

Dr. Yoshihiro Maeda
Kumiai Chemical Industry Company
4-26 Ikenohata 1-chome
Taitoh-ku, Tokyo 110-8782
JAPAN

Dear Dr. Maeda:

Your check for $500.00 arrived on July 19, 2010 for the deposit under the Budapest Treaty of the below listed strain into the Agricultural Research Service (ARS) Patent Culture Collection. Therefore, I am now able to send you the International Receipt Form (BP/4) and the Viability Statement for:

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Bacillus sp.	D747	NRRL B-50405

I will send, under separate cover, our lyophilized preparation for this strain. As soon as you confirm the equivalency of this preparation to your original deposit, complete, sign, and return the original Viability Statement to me.

Sincerely,

J. L. Swezey, Collections Manager
ARS Culture and Patent Culture Collections
Bacterial Foodborne Pathogens and Mycology Research Unit
Tel: (309) 681-6398
Fax: (309) 681-6672
Email: James.Swezey@ars.usda.gov

2 Enclosures

ars

Midwest Area • National Center for Agricultural Utilization Research
Bacterial Foodborne Pathogens & Mycology Research Unit
1815 N University Street • Peoria, Illinois 61604
Phone: (309) 681-6560 • Fax: (309) 681-6672 • E-mail: Dianna.Halcumb@ars.usda.gov
ARS Culture Collection (NRRL) Website: http://nrrl.ncaur.usda.gov
An Equal Opportunity Employer

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSE OF PATENT PROCEDURES

INTERNATIONAL FORM

TO

Patent Dept.
KUMIAI Chemical Industry Co. LTD
4-26
Ikenohata 1-Chome
Taitoh-ku
Tokyo 110-8782
Japan

VIABILITY STATEMENT

issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this page

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY STATEMENT IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: Dr. Maeda Kumiai Chemical Industry Co. 4-26 Address: Ikenohata 1-Chome Taitoh-ku Tokyo 110-8782 Japan	Depositor's taxonomic designation and accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY *Bacillus sp.* NRRL B-50405 Date of: June 29, 2010 ☒ Original Deposit ☐ New Deposit ☐ Repropagation of Original Deposit

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Deposit was found:
☒ [2]Viable ☐ [2]Nonviable on June 30, 2010 (Date)
International Depositary Authority's preparation was found viable on July 3, 2010 (Date)[3]

III. (b) DEPOSITOR'S EQUIVALENCY DECLARATION

Depositor determined the International Depositary Authority's preparation was
☐ [2]Equivalent
☐ [2]Not equivalent to deposit on _____ (Date)

Signature of Depositor

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST WAS PERFORMED (Depositors/Depositary)[4]

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Agricultural Research Culture Collection (NRRL) International Depositary Authority Address: 1815 N. University Street Peoria, Illinois 61604 U.S.A.	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date: 7-20-10

[1] Indicate the date of the original deposit or when a new deposit has been made.
[2] Mark with a cross the applicable box.
[3] In the cases referred to in Rule 10.2(i)(ii) and (iii), refer to the most recent viability test.
[4] Fill in if the information has been requested.

Manufacturing process information may be entitled to confidential treatment

Certis
USA, LLC
Company Number: 70051

Bacillus amyloliquefaciens strain D-747

Response to BPPD Health Effects and Product Chemistry Data Review for 70051-RNT and 70051-RNI; Pesticide Petition OF7760

OCSPP Guidelines: 885.1100, 885.1200, 885.1300, 885.1400, 830.1800, 830.6302, 830.7950

Potential Allergenicity

The protein source used in the fermentation process of B.amyloliquefaciens a. i. (animal, plant, marine) is [redacted]

Clarification of the test material used in the acute toxicity studies

The test material used in the Acute Eye Irritation study and Acute Dermal Irritation study was the end use formulation, which is the formulation listed on the CSF for CX-9032. The test material description of [redacted] Please refer to the Certificate of Analysis for further clarification.

label Changes needed CX- 9030 and CX-9032 Please see attached file- I will call you today

Susanne Cerrelli to: Dively, Chris 10/18/2011 10:08 AM

label notes3 no CBI.docx

I also need some minor math corrections and typo corrections for latest CSFs.

I will call you at 11 today if that is ok with you. Will Certis allow us to discuss some CBI items on the phone?

Regards,

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

"Dively, Chris" Hi Susanne, I am sending the WORD docs. of b... 10/17/2011 02:57:38 PM

From: "Dively, Chris" <cdively@certisusa.com>
To: Susanne Cerrelli/DC/USEPA/US@EPA
Cc: "Dively, Chris" <cdively@certisusa.com>
Date: 10/17/2011 02:57 PM
Subject:

Hi Susanne,
I am sending the WORD docs. of both the labels, removing all references to OMRI listing or OMRI approval.

Thanks for your comments.

st,
s[attachment "CX-9032EPArevise1014 Draft Label 14Jul2010 (3).docx" deleted by Susanne lli/DC/USEPA/US] (attachment "CX-9030Revised Draft LabelperEPA.101411.docx" deleted by ne Cerrelli/DC/USEPA/US]

Ms. Christine Dively
Certis USA, L.L.C.
9145 Guilford Road, Suite 175
Columbia, MD 21046

Subject: EPA File Symbol 70051- RNI and RNT, CX-9030 and CX 9032
Modifications Required to Labels submitted and October 17, 2011 and CSF

Dear Ms. Dively,

The following modifications are needed to be made to your product labels for the above listed products. Once these changes are made, please email a PDF of the labels to ensure that the file doesn't reformat on my computer.

The minimum colony forming units (CFU) values on the labels and the CSFs must agree.

On the basic formulation of CX-9030, the CFU per a gram listed does not match that listed on the label.

The following changes are required for the CX-9030 label.

On page 1:

1. Insert a summation line beneath "75%."

On page 2 of the CX-9030 label:

2. Delete "Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet" under "User safety recommendations" heading as this information will be added to the precautionary statement.
3. The last sentence in the General Information section referencing NOP must be removed because it is not in accord with the allowable language laid out in PR Notice 2003-1.

On page 3 of the CX-9030 label:

4. The Agricultural use Requirement box needs to be reformatted to fit on the page.

On pages 5 and 6 of the CX-9030 label:

5. Remove the phrase "including but not limited to" that appear after the general crop groupings.

For the CX 9032 label the following label changes are needed.

On page 2 of the CX-9032 label:

6. Move the following text to the Agricultural Use Requirements Box.

   "Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

7. The last sentence in the General Information section referencing NOP must be removed because it is not in accord with the allowable language laid out in PR Notice 2003-1. Delete the phrase: "CX-9032 complies with the USDA National Organic Program (NOP)."

On page 5 of the CX-9032 label:

8. Remove the phrase "including but not limited to" that appear after the general crop groupings.

On page 10 of the CX-9032 label:

9. **In the table**, it needs to be clear what substance is being measured. Is it the CX-9032 or a diluted mixture? **Insert "CX-9032"** so **the rate heading reads:** *"Rate CX-9032/acre."*

On page 16 of the CX-9032 label:

10. The specific use sites were not provided. In your phone message you expressed that you did not wish to add a lengthy list to this residential label. The general groups with some examples would be adequate to clarify for the home owner where your product should be used.

Please contact Susanne Cerrelli, if you have any questions about the content of this letter.

EPA National Organic Program Labeling Request Checklist

Reviewer Name: Chris Pfeifer | **RAL: Susanne Cerrelli**

Product Name: CX 9030 (EPA Reg. No. 70051-RNI (108)) | **Completion Date: 10/13/11**

Determination: Not Permitted | **Receipt Date: 9/30/11**

#	Check list Item	Yes	No
1	**Active Ingredients** - Are all of the active ingredient(s) "***Allowed***" on the National List?	Y	
2	**Active Ingredients History** - Is the active ingredient on the BPPD list of previous NOP approvals (f:/USER/SHARE/BPPD/Organic/Copy of NOP/**allowableble.pdf** or **ALLOWED.xls**)?	Y	
3	**Inert Ingredients** - Are all of the inert(s) found on the August 2004 EPA list 4A and 4B?	Y	
4	**Inert Ingredients** – Have any inert(s) been recently revoked (Revoked List 4 Inerts)?		N
5	**Use Sites** – Are all the product's use sites within the scope of the designated use patterns cited in the *National List*?	Y	
6	**Language** - Is the requested label language allowable. (Acceptable language includes: "*For Use in Organic Production*"; "*For Organic Production*"; "*For Use in Organic Gardening*"; "*For Organic Gardening*"; "*OMRI Listed*"; the OMRI logo; and the three leaf EPA NOP Logo.	Y*	
7	**OMRI Certification** – Does the application have a current OMRI certificate?	*	
8	**Comments** - #1) The ai is approved for organic use. The source of ai is not GM. There are no intentionally added ingredients in the ai source that are not consumed or accounted for; and none of the impurities are of toxicological significance. #2) The inert ingredients are all List 4 and NOP compliant. Acceptable MSDS were provided for all inert ingredients; and the composition of the mixtures were validated in OPPIN. #3) The use sites for the product are all pre-harvest agricultural, and are acceptable per the Organic Production Standard. #4) The label claims "For Organic Production" and "OMRI Listed" are appropriate for the use pattern on this agricultural label. #5) Because this product is presently unregistered, the product cannot receive an OMRI certificate. It is a reasonable expectation, however, that the registrant will receive a certificate upon application. As such, the registrant can add the "OMRI Listed" claim to the label with the following terms: a) The registrant must add a parenthetical statement to the OMRI claim on the draft label indicating that it is a placeholder. The self-evident expression "(placeholder)" is adequate. b) The Registration Notice must create a term which requires submission of the OMRI certificate to the Agency once it has been received. #6) The last sentence in the 'General Information' section referencing the NOP (p.3 of 12) must be removed because it is not in accord with the allowable language laid out in PR Notice 2003-1. #7) The OMRI claims laid out on p.12 of 12 must be qualified as 'placeholders.' **Do Not Permit NOP labeling of this product.**		

~~This review contains CONFIDENTIAL BUSINESS INFORMATION (CBI).~~ **Do not release this document to the registrant if it contains confidential information on proprietary mixes.**

Program Links - National Organic Program (AMS - NOP); PR Notice 2003-1 (PR Notice 2003-1)

BPPD Guidance Document – Other Items May be Required

CX-9030

place-holder for OMRI Seal

Water Dispersible Granular Biofungicide

For Organic Production

Active Ingredient:

Bacillus amyloliquefaciens strain D747* 25.0%

Other Ingredients 75.0%

Total 100.0%

*Contains a minimum of 5×10^{10} colony-forming units (cfu) per gram

EPA Reg. No. 70051-

EPA Est. No. 70051-CA-001 RNT

Manufactured by: Certis USA, L.L.C.
9145 Guilford Rd., Suite. 175
Columbia, MD 21046

NET WEIGHT: 5 LBS

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID - Agricultural Use

IF ON SKIN: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for further treatment advice.

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for further treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product label with you when calling a poison control center or doctor.
Hot Line No.:1-800-255-3924

PRECAUTIONARY STATEMENTS - Agricultural Use

HAZARDS TO HUMANS & DOMESTIC ANIMALS
CAUTION

Harmful if absorbed through skin. Harmful if inhaled. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants

- Waterproof gloves
- Shoes plus socks
- NIOSH approved respirator with any N, P, R or HE filter

Follow manufacturer's instructions for cleaning and maintaining PPE. In no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. AS soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS- Agricultural Use

Do not apply directly to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply when weather conditions favor drift or runoff from treated areas.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: cover-alls, waterproof gloves, shoes plus socks.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area in there will be no contact with anything that has been treated.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a dry area inaccessible to children. Store in original containers only. Keep container closed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

GENERAL INFORMATION

CX-9030 is a broad-spectrum preventative biofungicide for control or suppression of fungal and bacterial plant diseases. The active ingredient of CX-9030 is a naturally occurring strain (D747) of the beneficial rhizobacterium *Bacillus amyloliquefaciens*, which colonizes roots, leaves, and other plant surfaces, killing pathogenic organisms by means of antibiotic compounds (iturins) which disrupt pathogen cell wall production. D747 rapidly colonizes plant root hairs, leaves, and other surfaces, preventing establishment of disease-causing fungi and bacteria.

CX-9030 can be applied alone or in combination and/or rotation with chemical fungicides as a tool for integrated disease management in agricultural crops, ornamental and nursery plants, and turfgrass. CX-9030 offers a valuable tool for management of resistance to chemical fungicides through its multiple and unique modes of action.

CX-9030 is exempt from the requirement for residue tolerance and therefore can be applied up to and including the day of harvest.

CX-9030 complies with the USDA National Organic Program (NOP)

MIXING AND HANDLING INSTRUCTIONS

Mix the required amount of CX-9030 in cool water with sufficient agitation to maintain a uniform suspension in the spray or mixing tank. Tank should be cleaned prior to use. Do not use highly alkaline or highly acidic water to mix sprays. Use a buffering agent if necessary to maintain neutrality (pH 6 to 8) of water in the tank. Maintain agitation during application. Apply immediately after mixing; do not allow spray mix to stand overnight.

APPLICATION METHODS

Ground: CX-9030 can be applied in most commonly-used ground application equipment, such as tractor-mounted boom, airblast, high clearance, hose-end, backpack, and other pressurized sprayers; hose-end or hand-held sprayers; foggers or mist blowers; water wheel and other drench applicators; and shank or other soil injection method.

Aerial: CX-9030 can be applied by fixed or rotary winged aircraft in a minimum of 3 gallons of water per acre. Standard precautions should be taken to minimize spray drift.

Chemigation: CX-9030 can be applied through drip (trickle) and sprinkler type irrigation equipment. Refer to the section entitled "Chemigation Instructions" for detailed instructions.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the Agency responsible for pesticide regulation.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Agricultural crops

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons, including but not limited to:	
Brassica vegetables such as broccoli, cabbage, cauliflower, Brussels sprouts, kohlrabi, and other cole crops.	Pin rot complex (*Alternaria/Xanthomonas*)* Leaf spots (*Alternaria* spp., *Xanthomonas* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe polygoni*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").
Bulb vegetables such as onions, garlic, shallots, and others.	*Botrytis* spp. (neck rot, leaf blight) Purple blotch (*Alternaria* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Rust (*Puccinia pori*)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. (see instructions below for "Soil application").
Cucurbits such as cucumbers, squash (all types), cantaloupes, muskmelons, watermelons, and other melons.	Powdery mildew (*Erisyphe* and *Sphaerotheca* spp.) Downy mildew (*Pseudoperonospora* spp.) Gummy stem blight (*Didymella bryoniae* and *Phoma cucurbitocearum*) See instructions below for "Soil application" against the following diseases: Vine decline (*Monosporascus cannonbollus*) Charcoal rot (*Macrophomina phaseoli*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp.
Fruiting vegetables such as tomatoes, peppers, eggplant, tomatillo, okra, and others.	Bacterial spot (*Xanthomonas* spp.)*[1] Bacterial speck (*Pseudomonas syringoe* pv. *tomato*)*[1] Gray mold (*Botrytis cinerea*) Powdery mildew* (*Leveillula, Oidiopsis, Erisyphe,* and *Sphaerotheca* spp.) Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. Southern blight (*Sclerotium rolfsii*)*
Leafy vegetables such as head and leaf lettuce, celery, spinach, radicchio, arugula, watercress, and others (including leafy *Brassica* vegetables such as mustard and collard greens, kale, bok choi, and related crops).	Downy mildew (*Bremia lactucae, Peronospora* spp.)* Powdery mildew (*Golovinomyces (Erisyphe) cichorocearum*)* Bacterial blights Head and leaf drop (*Sclerotinia* spp.)[2] Pink rot (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* spp.) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Phytophthora,* or *Verticillium** spp. Bottom rot (*Rhizoctonia solani*)

Legume vegetables succulent and dried beans and peas such as green, snap, shell, and Lima beans, garbanzo beans, chickpeas, soybeans, dry beans, peas, split peas, lentils, and other legumes.	White mold (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Microsphaera diffusa*) Rusts*, including *Uromyces appendiculatus*, *Puccinia* spp., and Asian soybean rust (*Phayospora pachyrhizi*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Root, tuber, and corm vegetables such as potato, sweet potato, carrot, cassava, beets, ginger, radish, horseradish[22], ginseng, turnip, and other root, tuber and corm crops.	Black root/crown rot (*Alternaria* spp.) Bacterial leaf blight (*Xanthomonas campestris*) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Gray mold (*Botrytis* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Black leg /bacterial soft rot (*Erwinia carotovora*) Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: Black scurf (*Rhizoctonia solani*) Cavity spot (*Pythium* spp.) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp.
Other vegetables such as sweet corn, popcorn, asparagus, peanut, and watercress	*Botrytis* spp. Rusts (*Puccinia* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* and *Cercosporidium* spp.)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Tree fruits and nuts, including but not limited to:	
Citrus such as orange, lemon, lime, grapefruit, tangerine (mandorin), tangelo, pummelo, and other citrus	*Alternaria* leaf spot (*Alternaria alternata*) Postbloom fruit drop (*Colletotrichum acutatum*)* Greasy spot (*Mycosphaerello citri*)*[3] Citrus canker (*Xanthomonas campestris* pv. *citri*)[1] Scab (*Elsinoe fawcetti*)*[4] Melanose (*Diaporthe citri*)*
Pome fruits such as apple, pear, crabapple, quince, and others	Powdery mildew (*Podosphaera leucotricha*)[5] Scab (*Venturia* spp.)* Flyspeck (*Zygophiala jamaicensis*)[6] Sooty blotch disease complex[6] Brooks spot (*Mycosphaerella pomi*)[6] Bot rot/white rot (*Botryosphaeria dothidea*)[6] Bitter rot (*Colletotrichum* spp.)[6] Cedar apple rust (*Gymnosporangium juniperi-virginianae*)[6] Fire blight (*Erwinia amylovora*)*[7]
Stone fruits such as apricot, cherry, nectarine, peach, plum, prune, pluot, and others	Powdery mildew (*Sphaeratheca* and *Podosphaera* spp.)*[8] Bacterial canker (*Pseudomonas* spp.) Brown rot blossom blight (*Monilinia laxa*)[9] Brown rot (*Monilinia fructicola*)*[10] Gray mold (*Botrytis cinerea*)[10] Peach leaf curl (*Taphrina deformans*) Bacterial leaf spot (*Xanthomonas arbicola* pv. *pruni*)[1] Rusty spot (*Podosphaera leucotricha*)[1]
Tree nuts such as almond, pistachio, pecan, walnut, filbert, hazelnut, chestnut, macadamia, and other tree nuts.	Walnut blight (*Xanthomonas campestris*)[11] Anthracnose (*Colletotrichum acutatum*)* Bacterial canker (*Pseudomonas syringae*) Shot hole (*Wilsonomyces carpaphilus*)* Brown rot (*Monilinia* spp.)* Pecan scab (*Cladasprium caryigenum*)*[1]

Pomegranates	Leaf and fruit spots (*Cercospora, Gloeosporium* and *Pestalotia* spp.)[1] Fruit rots (*Alternaria, Botrytis*, and other spp.)[10] Powdery mildew (*Sphaerotheca pannosa*)
Other fruits, including but not limited to:	
Strawberry	Powdery mildew (*Sphaerotheca macularis, Erisyphe* spp.)*[12] Gray mold (*Botrytis cinerea*)*[11] Anthracnose (*Colletotrichum acutatum*) Angular leaf spot (*Xanthomonas fragariae*)[1] For the following diseases, see instructions below for "Soil application" (and also root dip instructions[22]): "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*)
Berries, including blueberry, blackberry, raspberry, loganberry, huckleberry, gooseberry, elderberry, cranberry (non-flooded fields), current, and other berries	Mummy berry (*Monilinia vaccinii-corymbosi*)* Botrytis blight (*Botrytis cinerea*) Bacterial canker (*Pseudomonas* spp.)[13] Anthracnose fruit rot (*Colletotrichum acutatum*)[10]
Grapes including wine grapes, table grapes, and raisins	Powdery mildew (*Erisyphe* (formerly *Uncinula*) *necator*)[14] Gray mold (*Botrytis cinerea*)[15] Sour rot complex[15] Downy mildew (*Plasmopara viticola*)* Phomopsis (*Phomopsis viticola*)[16] Eutypa (*Eutypa lata*)[17]
Tropical fruits such as avocado[18], mango[18], papaya[19], pineapple[19], banana, plantain, and others.	Anthracnose (*Colletotrichum* spp.) Scab (*Sphaceloma perseae*) Bacterial canker (*Xanthomonas campestris*) Sigatoka (*Mycosphaerella fijiensis*)[20]
Other Crops	
Herbs and spices such as basil, thyme, coriander, dill, cilantro, parsley, mint, and others.	Powdery mildews (*Oidium* spp. and others) Downy mildews (*Peronospora* spp. and others)* Damping off diseases (*Rhizoctonia, Pythium, Alternaria*, and *Fusarium* spp.) Leaf spots (*Alternaria, Septoria, Colletotrichum*, and *Cercospora* spp.)* Bacterial diseases (*Erwinia, Xanthomonas*, and *Pseudomonas* spp.) Rusts (*Puccinia* spp. and others) "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Coffee	Coffee berry disease (*Colletotrichum coffeanum*)[1] Coffee rust (*Hemileia vastatrix*)[1] Anthracnose (*Colletotrichum* spp.) *Botrytis* flower blight *Cercospora* leaf spot and berry blotch "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Tobacco	Angular leaf spot (*Pseudomonas* spp.) Anthracnose (*Colletotrichum* and *Glomerella* spp.) Blue mold or downy mildew (*Peronospora* spp.)* Brown spot (*Alternaria*) Barn spot/ frogeye leaf spot (*Cercospora nicotianae*)[10] Collar rot (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Erysiphe cichoracearum*) Target spot (*Rhizoctonia solani*) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Olpidium, Phytophthora*, or *Verticillium** spp.

	Charcoal rot (*Macrophomina phaseolina*) Black root rot (*Thielaviopsis basicola*) Black shank (*Phytophthora* spp.)* Southern blight/southern stem rot (*Sclerotium rolfsii*)*
Mint	Rust (*Puccinia* spp.)
Hops	Powdery mildew (*Spliaerotheca macularis*)[21]

Footnotes:

*Suppression only; for improved control mix or rotate with chemical fungicide approved for such use.

[1] Tank mix or rotate with copper-based fungicides at label rates for improved control.

[2] Apply at or immediately following planting (but before plant emergence) as a banded seedline treatment 4 to 6 inches wide. Make second application at thinning or cultivation in sufficient water and multiple nozzles to ensure thorough coverage of lower leaves and surrounding soil surface. Incorporation with light irrigation after application may improve disease control. Repeat at 10-14 day intervals if conditions promoting disease persist.

[3] For greasy spot suppression, apply at first new foliar flush and repeat with each new flush. Tank mix with spray oil or copper based fungicide at labeled rates.

[4] For suppression of citrus scab, start applications at first new foliage flush and repeat at petal fall and when fruit are ½ inch in diameter.

[5] Make first application at or before tight cluster if conditions favor disease development. Repeat at 7-10 day intervals through the second cover spray or longer on susceptible varieties or if environmental conditions favor rapid disease development.

[6] Begin applications before bloom when environmental conditions favor disease development, repeating at 7 to 14 day intervals or as needed. Control may be enhanced by addition of a surfactant to improve spray coverage. Use only surfactants known to be safe for use on the crop and for which such use is allowed.

[3] Rotate with antibiotics registered for fire blight control for improved performance. Begin applications at 1-5% open blossoms and repeat every 3-7 days as necessary until petal fall, when intervals can be increased to 7 days. CX-9032 can also be used in summer "cover spray" applications to control the shoot blight phase of fire blight and summer diseases. Can be mixed with copper fungicides to improve control.

[8] Make first application at popcorn stage and repeat every 7 days.

[9] Start applying at early bloom stage and repeat every 7 days through petal fall.

[10] Pre-harvest applications in sufficient water to cover fruit or other harvested plant parts may improve control of postharvest infections.

[11] Begin applications at or before pistillate bloom, repeating every 7-10 days. Apply before rainfall if possible, and tank mix or rotate with a copper-based bactericide registered for such use for improved control.

[11] Start applications at or just before flowering and repeat every 7-10 days as needed through harvest.

[13] Apply before fall rains and again during dormancy before spring growth.

[14] Start applications when new shoots are ½ to 1½ inches long. Repeat at 3-5 inches, 8-10 inches, and then at 7-10 day intervals until disease conditions no longer exist.

[15] Apply at bloom, before bunch closure, at veraison, and before harvest.

[16] Apply when shoots are ½ to 1 inch long and again when 6-8 inches long.

[13] Mix 2 fluid ounces CX-9032 per gallon of water and apply to pruning wounds.

[18] Apply at budbreak and repeat on 14-21 day interval as needed through harvest.

[19] Apply at flowering and repeat on 14-21 day interval as needed through harvest

[20] Apply at first appearance of leaves and repeat at 7-21 day intervals as needed, in sufficient water to obtain thorough coverage of foliage. Tank mix with spray oil or other registered fungicides for improved control.

[31] Mix 6 to10 fluid ounces CX-9032 per 100 gallons of water and apply in minimum of 20 gallons per acre form emergence to training, 50 gallons per acre from training to wire, and 100 gallons per acre from wire touch through harvest.

[12] For treatment of horseradish or strawberry roots immediately before transplanting: immerse bare roots (individually or in bunches) for 10 seconds in a suspension of 1 to 2 pints CX-9032 per gallon of water.

Foliar application: For control of diseases on foliage, flowers, fruit, or other above-ground parts of plants: Mix CX-9030 in water and apply as a spray at a rate of **0.25 to 3 pounds per acre** in sufficient water to achieve thorough coverage of the crop canopy with minimal runoff. Begin applications at crop emergence, transplanting, or when conditions are conducive to development of disease. Repeat application every 7 to 10 days, or as needed, for as long as conditions favor disease development. Lower rates (0.25 to 1 pound per acre) may be applied under light disease pressure, to smaller (e.g. newly-emerged) plants, or when CX-9030 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (1 to 3 pounds per acre), apply more frequently (every 3 to 7 days), and mix or rotate CX-9030 with other fungicides for improved performance.

Soil application: For control of soilborne diseases infecting seeds, seedlings, roots, crown, stems, or other plant parts below ground or in contact with soil: Apply CX-9030 at **0.125 to 1 pound per acre**. Mix the required amount in sufficient water to apply by one of the following methods:

- Soil drench applied to transplants in flats or pots in the greenhouse or nursery any time prior to transplanting (see additional drench instructions under "Nurseries, greenhouses, shade houses, and ornamental plants" below).
- Soil drench at transplanting, using a "water wheel" injector, spray nozzles/hoses, or other method to drench each root ball and/or planting hole.
- Soil or seedline drench, or banded spray (in-furrow) at planting. See the section on "Banded (in-furrow) application" below for additional instructions.

Follow-up (post-planting) preventative applications can be made every 2-4 weeks by one or more of the following methods, if needed:

- Drip (trickle) or any type of sprinkler irrigation, any time after planting or transplanting. See Chemigation Instructions for additional information.
- Spray directly onto the soil surface and/or lower plant parts. If targeting root disease, follow immediately with sufficient overhead sprinkler irrigation to move CX-9030 to the root zone.
- Injection directly into the rooting zone using shanks or similar equipment.

Lower rates (0.125 to 0.5 pounds per acre) may be applied under light disease pressure, to smaller plants, or when CX-9030 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (0.5 to 1 pound per acre), apply more frequently (every 2 weeks), and mix or rotate CX-9030 with other fungicides for improved performance.

Banded (in-furrow) application: Use the table below to determine the correct application rate of CX-9030 per 1,000 row feet, based on row spacing and desired rate per acre. Mix the required amount of CX-9030 in water and apply as banded spray (4" to 6" wide) or seedline drench centered over the planting furrow. Apply directly over seeds in the furrow just before they are covered with soil. The volume of water required per acre or per 1,000 row feet will depend on the application equipment used. Consult your local cooperative extension service if you need assistance calibrating band spraying equipment.

Rates for banded (in-furrow) application: Find desired application rate in the left column. Read across that line to the correct row spacing indicated at the top to find the number of ounces (dry) per 1,000 row feet that will provide the desired application rate per acre. To convert to **level teaspoons**, multiply the number of ounces by 8.2. For **level tablespoons**, multiply the number of ounces by 2.75.

Rate/acre	Space between rows (inches)														
(pounds)	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
0.25	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3
0.5	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6
0.75	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9
1.0	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.2	1.2
1.25	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.4	1.5	1.5
1.5	0.6	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.7	1.8
1.75	0.6	0.7	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1
2.0	0.7	0.9	1.0	1.1	1.2	1.3	1.5	1.6	1.7	1.8	2.0	2.1	2.2	2.3	2.4
2.25	0.8	1.0	1.1	1.2	1.4	1.5	1.7	1.8	1.9	2.1	2.2	2.3	2.5	2.6	2.8
2.5	0.9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1
2.75	1.0	1.2	1.3	1.5	1.7	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.0	3.2	3.4
3.0	1.1	1.3	1.5	1.7	1.8	2.0	2.2	2.4	2.6	2.8	2.9	3.1	3.3	3.5	3.7

Nurseries, greenhouses, shadehouses, and ornamental plants

Spray application: Mix **0.25 to 3 pounds of CX-9030 per 100 gallons of water** and apply as a foliar spray of sufficient volume to wet the entire plant with minimal runoff. Begin preventative applications at plant emergence and repeat every 3-28 days as needed (every 3-7 days if disease pressure is high or environmental conditions are highly favorable to disease outbreak, 10-28 days under low pressure or less conducive conditions).

Drench application: Mix **0.125 to 2 pounds of CX-9030 per 100 gallons of water** and apply as a drench or coarse spray to soil or other growing media in pots, flats, plugs, trays, or planting beds, for control or suppression of soilborne diseases of seedlings, cuttings, bedding plants, and transplants (including vegetables and other transplanted food crops). Make first application at or immediately before seeding, sticking, germination, or transplanting. Repeat applications every 14-28 days as needed. Transplants can be treated immediately before transplanting into field soils to protect against damping-off and other diseases that reduce plant establishment.

Cutting or root dip: Dip basal end of cuttings or bare roots (individually or in bunches) in a suspension of **1 to 2 pounds of CX-9030 per gallon of water**. Immerse for 5-10 seconds immediately before planting.

Chemigation: Mix **0.125 to 2 pounds of CX-9030 per 100 gallons of water** and apply via drip, handheld, or sprinkler irrigation systems. Refer to "Chemigation Instructions" for more details.

CROPS/USE SITES	DISEASES/PATHOGENS
Indoor, outdoor, and shade- or other cover-grown ornamental trees and shrubs, flowering plants, foliage plants, tropical plants, potted plants, potted or cut flowers, bedding plants, forestry seedlings, conifer production for reforestation, fruit trees, vegetables and other crops grown in greenhouses or nurseries.	Powdery mildews caused by *Erisyphe, Podosphaera, Sphaerotheca, Oidium,* and *Golovinamyces* spp.) Anthracnose (*Colletatrichum* spp.) Bacterial leaf spots caused by *Erwinia, Pseudomonas,* and *Xanthomanas* spp. Damping-off disease (*Rhizoctania, Pythium, Fusarium* spp.) Late blight, blackeye, and root rots caused by *Phytaphthara* spp. Gray mold and blight caused by *Botrytis cinerea* Black root rot (*Aspergillus* spp.) Black spot of roses (*Diplocarpon rosae*) Downy mildew (*Peranaspora* spp.) Leaf spots caused by *Alternaria, Septoria, Cercospora, Entomosporium, Helminthosporium,* and *Myrothecium* spp.) Rust (*Puccinia* spp.) Scab (*Venturia* spp.) Root rot, bottom rot, or stem rot caused by *Rhizoctonia solani* *Scleratinia* blight *Fusarium* wilts

Turfgrass application

For control of foliar diseases, apply CX-9030 **at 0.5 to 1 ounce per 1,000 square feet** as a ground-directed spray in sufficient water to provide thorough coverage. To control root and crown diseases in or on the soil, immediately follow the spray with sufficient overhead sprinkler irrigation to move the product into the root zone.

USE SITES/CROPS	DISEASES/PATHOGENS
Turf, sod, lawns, golf course (fairways, roughs, greens, tees), grass seed production Including but not limited to: Bluegrass, Bentgrass,	Anthracnose (*Colletotrichum graminicola*) Brown patch (*Rhizactonia solani*) Dollar spot (*Lanzia* and *Maellerodiscus* spp., formerly *Sclerotinia hameocarpa*) Powdery mildew (*Erisyphe graminis*) Rust (*Puccinia* spp.)

Bermudagrass (common & hybrid), Dichondra, Fescue, Orchardgrass, *Poa annua*, St. Augusline grass, Ryegrass, *Zoysia*, mixtures, and other grasses or ornamental turf	Gray leaf spot (*Pyricularia grisea*) "Damping off" or seedling blights caused by *Pythium*

CHEMIGATION INSTRUCTIONS

General information:

Apply this product through pressurized irrigation systems such as drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (including impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

Drip (trickle) and micro-irrigation chemigation

1. The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.

Sprinkler chemigation:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
8. Do not apply when wind speed favors drift beyond the area intended for treatment.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purpose referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the disease problem, condition of the crop, incompatibility with other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

The following claims may be presented on the product's labeling:

OMRI Listed
OMRI seal

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

SEP 27 2011

***** CONTAINS FIFRA CONFIDENTIAL BUSINESS INFORMATION *****

MEMORANDUM

SUBJECT: *Bacillus subtilis* var. *amyloliquefaciens* strain D747 currently *Bacillus amyloliquefaciens* strain D747.

TO: Susanne Cerrelli, M.S., Regulatory Action Leader
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511P)

FROM: Joel V. Gagliardi, Ph.D., Microbial Ecologist
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511P)

Joel V. Gagliardi

THROUGH: John L. Kough, Ph.D., Senior Scientist
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511P)

John L. Kough

ACTION REQUESTED: Review responses to deficiencies.

CONCLUSIONS: Product Identity and Characterization – **SUPPLEMENTAL but upgradeable**; Acute Eye and dermal Irritation studies for CX-9032 – **ACCEPTABLE** – EPA Toxicity Category IV.

DATA REVIEW RECORD:

Active Ingredient:	*Bacillus amyloliquefaciens* strain D747.
Product Names:	CX-9032; CX-9030.
Company Name:	Certis USA, LLC.
EPA Reg. Nos.:	70051-RNT; 70051-RNI; 0F7760.
Chemical Number:	016482.
Decision Numbers:	437753; 437757; 437758.
DP Barcodes:	382918; 382984; 390005.
MRID Nos.:	None.

Manufacturing process information may be entitled to confidential treatment

Quality control process information may be entitled to confidential treatment

BACKGROUND:
Another *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is registered (PC Code 006480) for non-food greenhouse and indoor uses on ornamentals, shrubs, shade and forest tree seedlings for plant strengthening, enhancing growth, increasing yields, and as a fungicide for suppressing selected soil-borne diseases such as *Rhizoctonia* and *Fusarium*. Most reports are that *Bacillus subtilis* and *B. amyloliquefaciens* were subtypes or variants of the same species however more recent work has established *Bacillus amyloliquefaciens* as a separate species. *Bacillus amyloliquefaciens* is in the *Bacillus subtilis* 'group' but is now considered a separate species, rather than a *B. subtilis* variant. The correct taxonomic designation is therefore *Bacillus amyloliquefaciens* strain D747. After conversations with Chris Dively at Certis, EPA will ask that this organism be renamed. Further steps at EPA will require alteration of the name under PC Code 016482, changing the tolerance exemption to reflect the new name, and asking Certis to provide new labels and CSFs for all affected products containing *Bacillus amyloliquefaciens* strain D747.

SUMMARY OF PREVIOUSLY REVIEWED DATA:
STUDY TYPES: Product Identity; Manufacturing Process; Discussion of Formation of Unintentional Ingredients; Analysis of Samples; Certification of Limits; Enforcement Analytical Method; Physical and Chemical Characteristics.
OCSPP Guidelines: 885.1100; 885.1200; 885.1300; 885.1400; 885.1500; 830.1800; 830.6302-830.7950.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 (CX-9030 contains the ai CX-9025).
MRID NOS.: 481657-01; 481657-02; 481657-03.
DISCUSSION: *Bacillus amyloliquefaciens* D747 is a member of the *Bacillus subtilis* group of bacteria. Several other registrations and food tolerance exemptions exist for pesticidal applications of other similar *Bacillus* strains. This isolate is from an air sample in Japan and is on deposit with ATCC, though accessibility was unclear. Standard fermentation procedures are utilized though variable components for fermentation broth were not sufficiently described. Of concern ingredients [redacted]

CLASSIFICATION: SUPPLEMENTAL but upgradeable – when accessibility of the ATCC deposit is clarified, information is provided for potential allergen residues that may become part of pesticides applied to foods, and amended CSFs and labels are provided.

STUDY TYPES: Product Identity; Manufacturing Process; Discussion of Formation of Unintentional Ingredients; Analysis of Samples; Certification of Limits; Enforcement Analytical Method; Physical and Chemical Characteristics.
OCSPP Guidelines: 885.1100; 885.1200; 885.1300; 885.1400; 885.1500; 830.1800; 830.6302-830.7950.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 (CX-9032) liquid concentrate.
MRID NOS.: 481655-01; 481655-02; 481655-03.
DISCUSSION: *Bacillus amyloliquefaciens* strain D747 (CX-9032) liquid concentrate is produced from the same process as the MUP CX-9030 except [redacted]
Standard fermentation procedures are utilized though variable feed stocks for fermentation broth were not sufficiently described. Of concern ingredients [redacted]

Quality control process information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

[redacted]

CLASSIFICATION: SUPPLEMENTAL but upgradeable – when accessibility of the ATCC deposit is clarified, information is provided for potential allergen residues that may become part of pesticides applied to foods, and amended CSFs and labels are provided.

STUDY TYPE: Acute Eye Irritation – Rabbit.
OCSPP Guideline: 870.2400.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9032.
MRID NO.: 481655-05.
DISCUSSION: The maximum average irritation score of 0.667 obtained 1 hour after treatment declined to 0 after 24 hours following ocular administration of 0.1 mL *Bacillus amyloliquefaciens* strain D747 CX-9032 to New Zealand White rabbits in a 72 hour observation period.
CLASSIFICATION: SUPPLEMENTAL but upgradeable – potentially practically non-irritating – EPA Toxicity Category IV; the test material described here as 7% ai should be clarified how it differs from the CSF provided.

STUDY TYPE: Acute Dermal Irritation.
OCSPP Guideline: 870.2500.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9032.
MRID NO.: 481655-06.
DISCUSSION: No evidence of irritation was found from dermal administration of 0.5 mL undiluted *Bacillus amyloliquefaciens* strain D747 CX-9032 to rabbits during a 72 hour exposure and observation period. The dermal irritation score for *Bacillus amyloliquefaciens* strain D747 CX-9032 was 0.00.
CLASSIFICATION: SUPPLEMENTAL but upgradeable – potentially essentially non-irritating – EPA Toxicity Category IV; the test material described here as 7% ai should be clarified how it differs from the CSF provided.

SUMMARY OF CURRENTLY REVIEWED DATA:
STUDY TYPES: Product Identity; Manufacturing Process; Discussion of Formation of Unintentional Ingredients; Analysis of Samples; Certification of Limits; Enforcement Analytical Method; Physical and Chemical Characteristics.
OCSPP Guidelines: 885.1100; 885.1200; 885.1300; 885.1400; 885.1500; 830.1800; 830.6302-830.7950.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 (CX-9030 contains the ai CX-9025).
MRID NOS.: 481657-01; 481657-02; 481657-03.
DISCUSSION: *Bacillus amyloliquefaciens* D747 is a member of the *Bacillus subtilis* group of bacteria. Several other registrations and food tolerance exemptions exist for pesticidal applications of other similar *Bacillus* strains. This isolate is from an air sample in Japan and is on deposit with ATCC, though accessibility was unclear. Standard fermentation procedures are utilized though variable components for fermentation broth were not sufficiently described. Of concern ingredients [redacted]

CLASSIFICATION: SUPPLEMENTAL but upgradeable – when amended CSFs and labels are provided that contain matching minimum CFU values.

STUDY TYPES: Product Identity; Manufacturing Process; Discussion of Formation of Unintentional Ingredients; Analysis of Samples; Certification of Limits; Enforcement Analytical Method; Physical and Chemical Characteristics.
OCSPP Guidelines: 885.1100; 885.1200; 885.1300; 885.1400; 885.1500; 830.1800; 830.6302-830.7950.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 (CX-9032) liquid concentrate.
MRID NOS.: 481655-01; 481655-02; 481655-03.
DISCUSSION: *Bacillus amyloliquefaciens* strain D747 (CX-9032) liquid concentrate is produced from the same process as the MUP CX-9030 except [redacted] Standard fermentation procedures are utilized though variable feed stocks for fermentation broth were not sufficiently described. Of concern ingredients [redacted]
CLASSIFICATION: SUPPLEMENTAL but upgradeable – when amended CSFs and labels are provided that contain matching minimum CFU values.

STUDY TYPE: Acute Eye Irritation – Rabbit.
OCSPP Guideline: 870.2400.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9032.
MRID NO.: 481655-05.
DISCUSSION: The maximum average irritation score of 0.667 obtained 1 hour after treatment declined to 0 after 24 hours following ocular administration of 0.1 mL *Bacillus amyloliquefaciens* strain D747 CX-9032 to New Zealand White rabbits in a 72 hour observation period.
CLASSIFICATION: ACCEPTABLE – practically non-irritating – EPA Toxicity Category IV.

STUDY TYPE: Acute Dermal Irritation.
OCSPP Guideline: 870.2500.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9032.
MRID NO.: 481655-06.
DISCUSSION: No evidence of irritation was found from dermal administration of 0.5 mL undiluted *Bacillus amyloliquefaciens* strain D747 CX-9032 to rabbits during a 72 hour exposure and observation period. The dermal irritation score for *Bacillus amyloliquefaciens* strain D747 CX-9032 was 0.00.
CLASSIFICATION: ACCEPTABLE – essentially non-irritating – EPA Toxicity Category IV.

***** CONTAINS FIFRA CONFIDENTIAL BUSINESS INFORMATION *****

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Types	Product Identity (OCSPP 885.1100); Manufacturing Process (885.1200); Discussion of Formation of Unintentional Ingredients (885.1300); Analysis of Samples (885.1400); Certification of Limits (885.1500); Enforcement Analytical Method (830.1800); Physical and Chemical Characteristics (830.6302 - 830.7950).
MRID Nos.	481657-01; 481657-02; 481657-03.
Test Material	*Bacillus amyloliquefaciens* strain D747 (CX-9030 contains the ai CX-9025).
Study Nos.	None.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Titles of Reports	*Bacillus subtilis* var. *amyloliquefaciens* strain D-747 (CX-9030) – Microbial Pesticide Data Requirements; *Bacillus subtilis* var. *amyloliquefaciens* strain D-747 End-use product (ID Code CX-9030) – Product Properties / Storage Stability.
Authors	Chang-Yan Chen; William E. DeVane; Alec Simpson.
Studies Completed	July 12, 2010; June 22, 2010; July 7, 2010.
Study Summaries	*Bacillus amyloliquefaciens* D747 is a member of the *Bacillus subtilis* group of bacteria. Several other registrations and food tolerance exemptions exist for pesticidal applications of other similar *Bacillus* strains. This isolate is from an air sample in Japan and is on deposit with ATCC, though accessibility was unclear. Standard fermentation procedures are utilized though variable components for fermentation broth were not sufficiently described. Of concern ingredients [redacted]
Classifications	**SUPPLEMENTAL but upgradeable** – when amended CSFs and labels are provided that contain matching minimum CFU values.
Good Laboratory Practice	The studies do not comply with the requirements of 40 CFR Part 160 but use sound scientific methods and procedures.

Test Material: *Bacillus amyloliquefaciens* strain D747 (formerly *Bacillus subtilis* var. *amyloliquefaciens* strain D747); (CX-9030 contains the ai CX-9025); NRRL B-50405.

I. PRODUCT IDENTITY:

Deficiencies: It is not clear if the ATCC culture is available to anyone but the depositor.

Response: The registrant provided paperwork demonstrating the isolate, *Bacillus* sp. strain D747 is on deposit under the Budapest Treaty as NRRL B-50405. NRRL has ascertained the culture is viable.

II. MANUFACTURING PROCESS:

Deficiencies: The registrant must clarify all sources for the [redacted] component of their fermentation broth, and discuss potential for residual allergens as defined in 40 CFR 180.950(2)(ii).

Response: The registrant responded that [redacted]

V. CERTIFICATION OF LIMITS:

TABLE 2. Nominal concentration and certified limits for *Bacillus amyloliquefaciens strain* strain D747 / CX-9030.

Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Bacillus amyloliquefaciens strain D-747 TGAI (ID Code CX-9025) 2 x 10^{11} CFU/g	016482	Active ingredient	25.0	24.25	25.75
Inert Ingredients					
[redacted]					

[a]Data from 9/29/2011 CSFs.

Deficiencies: The CSFs and labels should be amended from *Bacillus subtilis* var. *amyloliquefaciens* to the current *Bacillus amyloliquefaciens*.

Response: The registrant updated all CSFs to reflect the new taxonomy. The CSFs state [redacted]

***** CONTAINS FIFRA CONFIDENTIAL BUSINESS INFORMATION *****

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Types	Product Identity (OCSPP 885.1100); Manufacturing Process (885.1200); Discussion of Formation of Unintentional Ingredients (885.1300); Analysis of Samples (885.1400); Certification of Limits (885.1500); Enforcement Analytical Method (830.1800); Physical and Chemical Characteristics (830.6302 - 830.7950).
MRID Nos.	481655-01; 481655-02; 481655-03.
Test Material	*Bacillus amyloliquefaciens* strain D747 (CX-9032) liquid concentrate.
Study Nos.	None.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Titles of Reports	*Bacillus subtilis* var. *amyloliquefaciens* strain D747 (CX-9032) – Microbial Pesticide Data Requirements; *Bacillus subtilis* var. *amyloliquefaciens* strain D-747 End-use product (ID Code CX-9032) – product Properties / Storage Stability – Interim Study Report.
Authors	Chang-Yan Chen; William E. DeVane; Alec Simpson.
Studies Completed	July 2, 2010; July 14, 2010; July 7, 2010.
Study Summaries	*Bacillus amyloliquefaciens* strain D747 (CX-9032) liquid concentrate is produced from the same process as the MUP CX-9030 except [redacted] Standard fermentation procedures are utilized though variable feed stocks for fermentation broth were not sufficiently described. Of concern ingredients to [redacted]
Classifications	**SUPPLEMENTAL but upgradeable** – when amended CSFs and labels are provided that contain matching minimum CFU values.
Good Laboratory Practice	The studies do not comply with the requirements of 40 CFR Part 160 but use sound scientific methods and procedures.

Test Material: *Bacillus subtilis* var. *amyloliquefaciens* strain D747 (CX-9032) liquid concentrate.

I. MANUFACTURING PROCESS:

Deficiencies: The registrant must clarify all sources for the [redacted] component of their fermentation broth, and discuss potential for residual allergens as defined in 40 CFR 180.950(2)(ii).

Response: The registrant responded that [redacted]

II. CERTIFICATION OF LIMITS:

TABLE 2. Nominal concentration and certified limits for *Bacillus amyloliquefaciens strain* strain D747 / CX-9032 liquid concentrate.

Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient – formulation 1					
Bacillus amyloliquefaciens strain D-747 fermentation solids, and spores (ID Code CX-9025 Liquid).	016482	Active ingredient	98.90	96.40	99.35
Inert Ingredients – formulation 1					
[redacted]					
Active Ingredient – formulation 2					
Bacillus amyloliquefaciens strain D-747 fermentation solids, and spores (ID Code CX-9025 Liquid).	016482	Active ingredient	98.90	96.40	99.35
Inert Ingredients – formulation 2					
[redacted]					

[a]Data from 9/29/2011 CSFs.

Deficiencies: The upper and lower limits for the active ingredient in formulation 1 are uneven; the [redacted] content should reflect the composition of the product, not just [redacted] in final formulation; CSFs and labels should be amended from *Bacillus subtilis* var. *amyloliquefaciens* to the current *Bacillus amyloliquefaciens*.

Response: The registrant updated all labels CSFs to reflect the new taxonomy. Formulations percentages were corrected and some added inert ingredients were removed from the present CSFs. However, the minimum guarantee of viable cells, previously listed as [redacted]

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Type	Acute Eye Irritation – Rabbit (OCSPP 870.2400).
MRID No.	481655-05.
Test Material	*Bacillus amyloliquefaciens* strain D747 CX-9032.
Study No.	14046-10.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Stillmeadow, Inc.; 12852 Park One Drive; Sugar Land, TX 77478.
Titles of Reports	*Bacillus subtilis* CX-9030 Acute Eye Irritation Study in Rabbits.
Author	Janice O. Kuhn, Ph.D., DABT.
Study Completed	June 22, 2010.
Study Summary	The maximum average irritation score of 0.667 obtained 1 hour after treatment declined to 0 after 24 hours following ocular administration of 0.1 mL *Bacillus amyloliquefaciens* strain D747 CX-9032 to New Zealand White rabbits in a 72 hour observation period.
Classification	**ACCEPTABLE** – practically non-irritating – EPA Toxicity Category IV.
Good Laboratory Practice	Signed and dated GLP statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: *Bacillus amyloliquefaciens* strain D747.
   - Description: *Bacillus amyloliquefaciens* strain D747 CX-9032.
   - Lot/Batch #: 0104-23-8.
   - Purity: As formulated.
   - CAS #: n/a
   - Storage conditions: Shipped and stored at room temperature.
   - Microbiology: Certificate of analysis provided by study sponsor – the laboratory did not perform further characterization.
2. Sample Preparation: 88.3 mg equivalent to 0.1 mL was used for dosing.
3. Controls: A naive control group was not included.
4. Test animals: Rabbit
   - Species: Not stated (*Oryctolagus cuniculus*)
   - Strain: New Zealand White albino rabbits.
   - Age/weight at dosing: Rabbits were approximately 4 months old; 2.550-3.175 Kg (1 male and 2 females).
   - Source: Myrtle's Rabbitry, Inc., Thompson Station, TN.
   - Housing: Stainless steel cages, 1 rabbit/cage.
   - Diet: PMI Feeds, Inc.™ Lab Rabbit Diet #5321, ~8 oz. daily.
   - Water: Municipal water, ad libitum.
   - Environmental conditions: Temperature: 19-23°C; Humidity: 59-95%; Air changes: 10-12 per hour.; Photoperiod: 12 hrs dark / 12 hrs light
   - Acclimation period: 5 days

B. STUDY DESIGN and METHODS:

1. In life dates: Start: 22 March 2010; End: 25 March 2010
2. Preliminary Challenge Assay: Not performed.
3. Animal assignment and treatment: Test substance was applied at 0.1 mL (pH 4.29) undiluted to the conjunctival sac of the right eye to three animals (one male and two female rabbits).

4. Clinical Observations and Body Weights: Observations were made at 1 hour then daily following dosing; fluorescein was used and the eyes scored for lesions and opacity.
5. Feed Consumption: Feed consumption was not measured.
6. Necropsy and Organ Weight Determination: Necropsy was not performed.
7. Microbial Enumeration: This component was not measured.
8. Sensitivity of Detection: n/a.
9. Statistics: There were no treatment-related mortalities, so statistics were not required to calculate the LD_{50}.

II. RESULTS AND DISCUSSION:
A. MORTALITY: There were no mortalities. The ocular LD > 0.1 mL.
B. CLINICAL OBSERVATIONS: Ocular or non-ocular adverse effects were noted.
C. BODY WEIGHT: Not measured.

TABLE 1. Individual Male (M) and Female (F) Eye Scores w/ Time: Cornea (A=Density of Opacity, B=Area of Opacity)

Animal No.		1 hour		24 hours		48 hours		72 hours		4 days		7 days		10 days		14 days		17 days		21 days	
		A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B
Non-washed eyes																					
M	4872	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
F	4873	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
	4877	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
Washed eyes																					
M	4872	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
F	4873	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
	4877	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd

TABLE 2. Summary of Eye Irritation Scores with Time: Conjunctiva and Iris

Score Conditions	1 hour	24 hours	48 hours	72 hours	4 days	7 days	10 days	14 days	17 days	21 days
Non-washed eyes										
Conjunctiva										
Erythema	0	0	0	0	nd	nd	nd	nd	nd	nd
Chemosis	0	0	0	0	nd	nd	nd	nd	nd	nd
Discharge	1	0	0	0	nd	nd	nd	nd	nd	nd
Iris	0	0	0	0	nd	nd	nd	nd	nd	nd
Washed eyes										
Conjunctiva										
Erythema	0	0	0	0	nd	nd	nd	nd	nd	nd
Chemosis	0	0	0	0	nd	nd	nd	nd	nd	nd
Discharge	0	0	0	0	nd	nd	nd	nd	nd	nd
Iris	0	0	0	0	nd	nd	nd	nd	nd	nd

Irritation score is based on the Draize Method (1959); nd = not done.

TABLE 3. Summary of Average and Primary Eye Irritation Scores with Time

Animal #		1 hour	24 hour	48 hour	72 hour	4 day	7 day	10 day	14 day	17 day	21 day
Non-washed eyes											
M	4872	0	0	0	0	nd	nd	nd	nd	nd	nd
F	4873	2	0	0	0	nd	nd	nd	nd	nd	nd
	4877	0	0	0	0	nd	nd	nd	nd	nd	nd
Average		0.667	0	0	0	nd	nd	nd	nd	nd	nd
Washed eyes											
M	4872	0	0	0	0	nd	nd	nd	nd	nd	nd
F	4873	0	0	0	0	nd	nd	nd	nd	nd	nd
	4877	0	0	0	0	nd	nd	nd	nd	nd	nd
Average		0	0	0	0	nd	nd	nd	nd	nd	nd

D. FEED CONSUMPTION: Feed consumption was not measured.
E. NECROPSY: Not performed.
F. ORGAN WEIGHTS: Not measured.

G. MICROBIAL ENUMERATION: Not measured.

H. STUDY AUTHORS' CONCLUSIONS: The maximum average irritation score of 0.7, obtained 1 hour after treatment, was used to rate *Bacillus subtilis* CX-9032 practically non-irritating. Fluorescein staining did not occur in any eyes. Toxicity categories are determined by the presence and duration of corneal involvement, iridic irritation, and positive conjunctival irritation. Any corneal involvement or iridic irritation with a score of 1 or more is considered positive. Any conjunctival irritation (redness or chemosis) with a score of 2 or more is considered positive.

I. REVIEWERS' CONCLUSIONS: The maximum average irritation score of 0.667 obtained 1 hour after treatment declined to 0 after 24 hours following ocular administration of 0.1 mL *Bacillus amyloliquefaciens* strain D747 CX-9032 to New Zealand White rabbits in a 72 hour observation period.

DEFICIENCIES: None.

TABLE 4: Grading Ocular Lesions based on the Draize Method.

CORNEA	Opacity - degree of density	None	0	
		Scattered or diffuse area; details of iris are clearly visible	* 1	+
		Easily discernible translucent areas; details of iris slightly obscured	* 2	
		Opalescent areas; no details of iris visible, size of pupil barely discernible	* 3	
		Opaqae; iris invisible	* 4	
	Area of cornea involved	None	**0**	
		1-25 %	1	
		26-50 %	2	
		51-75 %	3	
		76-100 %	4	
	The opacity reading is taken at the most dense area.			
	Cornea score = (Opacity points) * (Area of cornea involved points) * 5; minimum 0, maximum 80.			
IRIS	No change from normal		0	
	Iris still reacts to light (slaggish response is positive). Any or all of the following or any combination: ~ Folds above normal ~ Congestion ~ Swelling ~ Circumconneal injection		* 1	
	Any or all of the following: ~ No reaction to light ~ Hemorrhage ~ Gross destruction		* 2	
	Iris score = (Iris points) * 5; minimum 0, maximum 10.			
CONJUNCTIVAE	Redness / Erythema	Normal	0	
		Vessels definitely injected above normal	1	
		More diffuse deeper crimson red individual vessels not easily discernible	* 2	
		Diffuse beefy red	* 3	
	Chemosis	Normal	**0**	
		Any swelling above normal including the nictitating membrane	1	
		Obvious swelling with partial eversion of lids	* 2	
		Swelling with lids about half closed	* 3	
		Swelling with lids about half closed to completely closed	* 4	
	Discharge	Normal	0	
		Any amount different from normal (does not include the small amoant observed in inner canthus of normal animals)	1	
		Discharge with moistening of the lids and hairs just adjacent to the lids	2	
		Discharge with moistening of the lids and considerable area around the eyes	3	
	Redness refers to palpebral conjunctivae only (The palpebral conjunctiva covers the posterior sarface of the eyelid).			
	Conjunctivae score = (Redness points) + (Chemosis points) + (Discharge points) * 2; minimum 0, maximum 20.			
Total score = (Corneal score) + (Iris score) + (Conjunctivae score); minimum 0, maximum 110.				

* Significant or notable irritation per OCSPP Guideline 870.2400.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Type	Acute Dermal Irritation – Rabbits (OCSPP 870.2500).
MRID No.	481655-06.
Test Material	*Bacillus amyloliquefaciens* strain D747 CX-9032.
Study No.	14047-10.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Stillmeadow, Inc.; 12852 Park One Drive; Sugar Land, TX 77478.
Titles of Reports	*Bacillus subtilis* CX-9032 Acute Dermal Irritation Study in Rabbits.
Author	Janice O. Kuhn, Ph.D., DABT.
Study Completed	June 15, 2010.
Study Summary	No evidence of irritation was found from dermal administration of 0.5 mL undiluted *Bacillus amyloliquefaciens* strain D747 CX-9032 to rabbits during a 72 hour exposure and observation period. The dermal irritation score for *Bacillus amyloliquefaciens* strain D747 CX-9032 was 0.00.
Classification	**ACCEPTABLE** – essentially non-irritating – EPA Toxicity Category IV.
Good Laboratory Practice	Signed and dated GLP statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: *Bacillus amyloliquefaciens* strain D747.
   - Description: *Bacillus amyloliquefaciens* strain D747 CX-9032.
   - Lot/Batch #: 0104-23-8.
   - Purity: As formulated.
   - CAS #: n/a
   - Storage conditions: Shipped and stored at room temperature.
   - Microbiology: Certificate of analysis provided by study sponsor – the laboratory did not perform further characterization.
2. Sample Preparation: 0.5 mL was used for dosing.
3. Controls: A naive control group was not included.
4. Test animals: Rabbit
   - Species: Not stated (*Oryctolagus cuniculus*)
   - Strain: New Zealand White albino rabbits.
   - Age/weight at dosing: Rabbits were approximately 4 months old; 3.150-3.200 Kg (1 male and 2 females).
   - Source: Myrtle's Rabbitry, Inc., Thompson Station, TN.
   - Housing: Stainless steel cages, 1 rabbit/cage.
   - Diet: PMI Feeds, Inc.™ Lab Rabbit Diet #5321, ~8 oz. daily.
   - Water: Municipal water, ad libitum.
   - Environmental conditions: Temperature: 19-23°C; Humidity: 55-95%; Air changes: 10-12 per hour.; Photoperiod: 12 hrs dark / 12 hrs light
   - Acclimation period: 5 days

B. STUDY DESIGN and METHODS:

1. In life dates: Start: 24 May 2010; End: 28 May 2010
2. Preliminary Challenge Assay: performed on one animal 24 hours prior to treating other animals.

3. Animal assignment and treatment: All animals had fur shaved from the dorsal trunk in an area 8 cm^2 the day of dosing. Live test substance was applied at 0.5 mL undiluted (pH 4.29) to three animals (one male and two female rabbits) and the area was wrapped with 2.5 cm^2 gauze dressing and elastic adhesive bandage for 4 hours, after which the dressing and bandage were removed, the area rinsed with water then wiped to remove residues.
4. Clinical Observations and Body Weights: Observations made before the first hour then daily after dosing.
5. Feed Consumption: Feed consumption was not measured.
6. Necropsy and Organ Weight Determination: not performed.
7. Microbial Enumeration: This component was not measured.
8. Sensitivity of Detection: n/a.
9. Statistics: There were no clinical signs or treatment-related mortalities, so statistics were not required to calculate the LD_{50} though they were used to report differences in organ and body weights.

II. RESULTS AND DISCUSSION:
A. MORTALITY: There were no mortalities; dermal LD > 0.5 mL.
B. CLINICAL OBSERVATIONS: No signs of dermal irritation, edema or eschar were observed.
C. BODY WEIGHT: Not measured.
D. FEED CONSUMPTION: Feed consumption was not measured.
E. NECROPSY: Not performed.
F. ORGAN WEIGHTS: Not measured.
G. MICROBIAL ENUMERATION: Not measured.
H. STUDY AUTHORS' CONCLUSIONS: The primary irritation index of 0.0 out of a possible 8.0 was obtained from the observations at 1, 24, 48 and 72 hours, and was used to give *Bacillus subtilis* CX-9032 a descriptive rating of non-irritating. Based on the 72-hour observations only, *Bacillus subtilis* CX-9032 is assigned to toxicity category IV.
I. REVIEWERS' CONCLUSIONS: No evidence of irritation was found from dermal administration of 0.5 mL undiluted *Bacillus amyloliquefaciens* strain D747 CX-9032 to rabbits during a 72 hour exposure and observation period. The dermal irritation score for *Bacillus amyloliquefaciens* strain D747 CX-9032 was 0.00.

DEFICIENCIES: None.

Appendix I: Description of Skin Reactions

Evaluation of Skin Reactions Score

Erythema and eschar formation
No erythema 0
Very slight erythema (barely perceptible) 1
Well-defined erythema 2
Moderate to severe erythema 3
Severe erythema (beet redness) to slight eschar formation (injuries in depth) 4

Edema Formation
No edema 0
Very slight edema (barely perceptible) 1
Slight edema (edges of area well-defined by definite raising) 2
Moderate edema (raised approximately 1 mm) 3
Severe edema (raised more than 1 mm and extending beyond the area of exposure) 4

Biopesticides and Pollution Prevention Division

FAX

September 15, 2011 Pages: 45 including cover

TO: Chris Dively
FAX Phone:301-604-7015

FROM: Susanne Cerrelli
US Environmental Protection Agency.
Office of Pesticide Programs
Biopesticides & Pollution Prevention Division (7511c)

Phone 703-308-8077 (FAX 703-308-7026)
Email: CERRELLI.SUSANNE@ epa.gov

Subject: Data evaluation records for B. subtilis Var Amyloliquefaciens –D747 EPA Reg. No. 70051-RNI and RNT

Attached is the September 14, 2011 Data Evaluation Record of Product Identity and Characterization and for all the submitted mammalian Toxicity/ pathogenicity studies. I appreciate your assistance in addressing all the guidelines that were determined to be supplemental but upgradable.

If you have any questions, please contact me.

Sincerely,

Susanne Cerrelli

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 1 4 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

***** CONTAINS FIFRA CONFIDENTIAL BUSINESS INFORMATION *****

MEMORANDUM

SUBJECT: *Bacillus subtilis* var. *amyloliquefaciens* strain D747 currently *Bacillus amyloliquefaciens* strain D747.

TO: Susanne Cerrelli, M.S., Regulatory Action Leader
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511P)

FROM: Joel V. Gagliardi, Ph.D., Microbial Ecologist
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511P)

THROUGH: John L. Kough, Ph.D., Senior Scientist
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511P)

ACTION REQUESTED: Review submitted studies for FIFRA section 3 registration of an MUP and 2 new EPs with a food tolerance exemption petition.

CONCLUSIONS: Product Identity and Characterization – **SUPPLEMENTAL but upgradeable**; Acute Oral, Injection and Pulmonary Toxicity / Pathogenicity studies – **ACCEPTABLE** – not infective, pathogenic or toxic; Acute Oral, Inhalation and Dermal Toxicity, Acute Dermal Irritation for CX-9030 – **ACCEPTABLE** – EPA Toxicity Category IV; Acute Eye Irritation for CX-9030 – **ACCEPTABLE** – EPA Toxicity Category III; Acute Eye and dermal Irritation studies for CX-9032 – **SUPPLEMENTAL but upgradeable**; Waiver requests for Acute Oral, Dermal and Inhalation Toxicity studies for CX-9032 – **ACCEPTABLE**; Waiver request for Hypersensitivity – **SUPPLEMENTAL – not a required study**; Exemption from Tolerance – **ACCEPTABLE**.

DATA REVIEW RECORD:

Active Ingredient:	*Bacillus amyloliquefaciens* strain D747.
Product Names:	CX-9032; CX-9030.
Company Name:	Certis USA, LLC.
EPA Reg. Nos.:	70051-RNT; 70051-RNI; 0F7760.
Chemical Number:	016482.
Decision Numbers:	437753; 437757; 437758.
DP Barcodes:	382918; 382984; 390005.
MRID Nos.:	481655-01; 481655-02; 481655-03; 481655-04; 481655-05; 481655-06; 481657-01; 481657-02; 481657-03; 481657-04; 481657-05; 481657-06; 481657-07; 481657-08; 481657-09; 481657-10; 481657-11.

BACKGROUND:

Another *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is registered (PC Code 006480) for non-food greenhouse and indoor uses on ornamentals, shrubs, shade and forest tree seedlings for plant strengthening, enhancing growth, increasing yields, and as a fungicide for suppressing selected soil-borne diseases such as *Rhizoctonia* and *Fusarium*. Most reports are that *Bacillus subtilis* and *B. amyloliquefaciens* were subtypes or variants of the same species however more recent work has established *Bacillus amyloliquefaciens* as a separate species. *Bacillus amyloliquefaciens* is in the *Bacillus subtilis* 'group' but is now considered a separate species, rather than a *B. subtilis* variant. The correct taxonomic designation is therefore *Bacillus amyloliquefaciens* strain D747. After conversations with Chris Dively at Certis, EPA will ask that this organism be renamed. Further steps at EPA will require alteration of the name under PC Code 016482, changing the tolerance exemption to reflect the new name, and asking Certis to provide new labels and CSFs for all affected products containing *Bacillus amyloliquefaciens* strain D747.

SUMMARY OF REVIEWED DATA:

STUDY TYPES: Product Identity; Manufacturing Process; Discussion of Formation of Unintentional Ingredients; Analysis of Samples; Certification of Limits; Enforcement Analytical Method; Physical and Chemical Characteristics.
OCSPP Guidelines: 885.1100; 885.1200; 885.1300; 885.1400; 885.1500; 830.1800; 830.6302-830.7950.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 (CX-9030 contains the ai CX-9025).
MRID NOS.: 481657-01; 481657-02; 481657-03.
DISCUSSION: *Bacillus amyloliquefaciens* D747 is a member of the *Bacillus subtilis* group of bacteria. Several other registrations and food tolerance exemptions exist for pesticidal applications of other similar *Bacillus* strains. This isolate is from an air sample in Japan and is on deposit with ATCC, though accessibility was unclear. Standard fermentation procedures are utilized though variable components for fermentation broth were not sufficiently described. Of concern ingredients [redacted]

CLASSIFICATION: SUPPLEMENTAL but upgradeable – when accessibility of the ATCC deposit is clarified, information is provided for potential allergen residues that may become part of pesticides applied to foods, and amended CSFs and labels are provided.

STUDY TYPES: Product Identity; Manufacturing Process; Discussion of Formation of Unintentional Ingredients; Analysis of Samples; Certification of Limits; Enforcement Analytical Method; Physical and Chemical Characteristics.
OCSPP Guidelines: 885.1100; 885.1200; 885.1300; 885.1400; 885.1500; 830.1800; 830.6302-830.7950.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 (CX-9032) liquid concentrate.
MRID NOS.: 481655-01; 481655-02; 481655-03.
DISCUSSION: *Bacillus amyloliquefaciens* strain D747 (CX-9032) liquid concentrate is produced from the same process as the MUP CX-9030 except [redacted]
Standard fermentation procedures are utilized though variable feed stocks for fermentation broth were not sufficiently described. Of concern ingredients [redacted]

[redacted]

CLASSIFICATION: SUPPLEMENTAL but upgradeable – when accessibility of the ATCC deposit is clarified, information is provided for potential allergen residues that may become part of pesticides applied to foods, and amended CSFs and labels are provided.

STUDY TYPE: Acute Oral Toxicity / Pathogenicity – Rat.
OCSPP Guideline: 885.3050.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747.
MRID NO.: 481657-04.
DISCUSSION: No evidence of infectivity, pathogenicity or toxicity was found from oral administration of $1.0x10^8$ CFU *Bacillus amyloliquefaciens* strain D747 to rats. Clearance from fecal material occurred by day 14 and no viable organisms were recovered from blood or any other organ or tissue.
CLASSIFICATION: ACCEPTABLE – oral LD > $1.0x10^8$ CFU/rat – not infective, pathogenic or toxic.

STUDY TYPE: Acute Injection Toxicity / Pathogenicity – Rat.
OCSPP Guideline: 885.3200.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747.
MRID NO.: 481657-05.
DISCUSSION: No evidence of infectivity, pathogenicity or toxicity was found from intravenous administration of $1.0x10^7$ spores *Bacillus amyloliquefaciens* strain D747 to rats. There were no mortalities, no clinical effects from intravenous administration and steady weight gain of treated rats throughout the study duration. Clearance was steady though residual viable cells remained in the liver and spleen at day 60 on study termination, typical of spore forming bacteria administered to rats. There was no evidence of an increase in viable counts over time that would be indicative of a chronic infection. Since a pattern of clearance was shown it is assumed that the remaining viable cells were spores that take longer to be cleared by healthy immune systems.
CLASSIFICATION: ACCEPTABLE – intravenous LD > $1.0x10^7$ CFU/rat – not infective, pathogenic or toxic.

STUDY TYPE: Acute Pulmonary Toxicity / Pathogenicity – Rat.
OCSPP Guideline: 885.3150.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747.
MRID NO.: 481657-06.
DISCUSSION: No evidence of infectivity, pathogenicity or toxicity was found from intratracheal administration of $1.0x10^7$ spores *Bacillus amyloliquefaciens* strain D747 to rats. There were no mortalities, no clinical effects from intratracheal administration and steady weight gain of treated rats throughout the study duration. Clearance was steady though residual viable cells remained in the lungs and trachea at day 60 on study termination, typical of spore forming bacteria administered to rats. There was no evidence of an increase in viable counts over time that would be indicative of a chronic infection. Since a pattern of clearance was shown it is assumed that the remaining viable cells were spores that take longer to be cleared by healthy immune systems.
CLASSIFICATION: ACCEPTABLE – pulmonary LD > $1.0x10^7$ CFU/rat - not infective, pathogenic or toxic.

STUDY TYPE: Acute Oral Toxicity – Rats.
OCSPP Guideline: 870.1100.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9030.
MRID NO.: 481657-07.
DISCUSSION: No evidence of toxicity was found from oral administration of 5000 mg/Kg *Bacillus amyloliquefaciens* strain D747 CX-9030 to rats in a 14 day acute toxicity study.
CLASSIFICATION: ACCEPTABLE - oral LD > 5000 mg/Kg – EPA Toxicity Category IV.

STUDY TYPE: Acute Dermal Toxicity – Rabbits.
OCSPP Guideline: 870.1200.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9030.
MRID NO.: 481657-08.
DISCUSSION: No evidence of toxicity was found from dermal administration of 5050 mg/Kg *Bacillus amyloliquefaciens* strain D747 CX-9030 to rats in a 14 day acute toxicity study.
CLASSIFICATION: ACCEPTABLE - dermal LD > 5050 mg/Kg – EPA Toxicity Category IV.

STUDY TYPE: Acute Inhalation Toxicity – Rats.
OCSPP Guideline: 870.1300.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9030.
MRID NO.: 481657-09.
DISCUSSION: Slight toxicity lasting two days from 4-hour aerosol inhalation administration of 2.18 mg/L *Bacillus amyloliquefaciens* strain D747 CX-9030 was noted to rats in a 14 day acute toxicity study.
CLASSIFICATION: ACCEPTABLE - inhalation LC > 2.18 mg/L – EPA Toxicity Category IV.

STUDY TYPE: Acute Eye Irritation – Rabbit.
OCSPP Guideline: 870.2400.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9030.
MRID NO.: 481657-10.
DISCUSSION: The maximum average irritation score of 18.3 obtained 1 hour after treatment declined to 17.33 after 24 hours, 2 after 48 hours and 0 after 72 hours following ocular administration of 0.1 mL *Bacillus amyloliquefaciens* strain D747 to New Zealand White rabbits in a 72 hour observation period.
CLASSIFICATION: ACCEPTABLE – mildly-irritating – EPA Toxicity Category III.

STUDY TYPE: Acute Dermal Irritation.
OCSPP Guideline: 870.2500.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9030.
MRID NO.: 481657-11.
DISCUSSION: No evidence of irritation was found from dermal administration of 500 mg *Bacillus amyloliquefaciens* strain D747 CX-9030 to rabbits during a 72 hour exposure and observation period. The dermal irritation score for *Bacillus amyloliquefaciens* strain D747 CX-9030 was 0.00.
CLASSIFICATION: ACCEPTABLE – essentially non-irritating – EPA Toxicity Category IV.

STUDY TYPE: Acute Eye Irritation – Rabbit.
OCSPP Guideline: 870.2400.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9032.
MRID NO.: 481655-05.
DISCUSSION: The maximum average irritation score of 0.667 obtained 1 hour after treatment declined to 0 after 24 hours following ocular administration of 0.1 mL *Bacillus amyloliquefaciens* strain D747 CX-9032 to New Zealand White rabbits in a 72 hour observation period.
CLASSIFICATION: SUPPLEMENTAL but upgradeable – potentially practically non-irritating – EPA Toxicity Category IV; the test material described here as 7% ai should be clarified how it differs from the CSF provided.

STUDY TYPE: Acute Dermal Irritation.
OCSPP Guideline: 870.2500.

TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9032.
MRID NO.: 481655-06.
DISCUSSION: No evidence of irritation was found from dermal administration of 0.5 mL undiluted *Bacillus amyloliquefaciens* strain D747 CX-9032 to rabbits during a 72 hour exposure and observation period. The dermal irritation score for *Bacillus amyloliquefaciens* strain D747 CX-9032 was 0.00.
CLASSIFICATION: SUPPLEMENTAL but upgradeable – potentially essentially non-irritating – EPA Toxicity Category IV; the test material described here as 7% ai should be clarified how it differs from the CSF provided.

WAIVER REQUESTS: for Acute Oral Toxicity; Acute Dermal Toxicity; Acute Inhalation Toxicity; Hypersensitivity.
OCSPP Guidelines: 870.1100; 870.1200; 870.1300; 885.3400.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9032.
MRID NOS.: 481655-04.
DISCUSSION: Oral exposure to the manufacturing use product showed no adverse effects including infectivity, pathogenicity and toxicity up to the limit dose. Dermal toxicity and irritation testing for the end-use products showed no adverse effects up to the limit doses. Pulmonary exposure to the manufacturing use product showed no adverse effects including infectivity, pathogenicity and toxicity though slight toxicity lasting 2 days from 4-hour aerosol inhalation administration of 2.18 mg/L, where inert ingredients were also present, was noted in another study. Inert ingredients all have existing appropriate food tolerance exemptions and most are listed as 40 CFR 180.950 minimal risk; no additional toxicity for oral, dermal or inhalation exposure is expected from the incremental testing of formulations with these inert ingredients added.
CLASSIFICATION: Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity – **ACCEPTABLE**; Hypersensitivity – **SUPPLEMENTAL** – not a required study.

PETITION REQUEST: FFDCA.
Study Title: FOOD TOLERANCE EXEMPTION PETITION.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747.
DISCUSSION: Based on extensive testing of the manufacturing use product and of end-use products containing the active ingredient, no toxicity, infectivity, pathogenicity or other adverse effects from dietary exposure to *Bacillus amyloliquefaciens* strain D747 are expected. *Bacillus* spp. including *Bacillus amyloliquefaciens* are commonly found in agricultural settings (i.e. soils) and are present on fresh produce of all kinds with no known adverse effects. The Manual of Clinical Microbiology (9th edition) mentions that dried food such as spices, milk powder and grains often contain large amounts of *Bacillus* spores. *Bacillus amyloliquefaciens* is not known to produce any mammalian toxins and no foodborne disease outbreaks associated with *Bacillus amyloliquefaciens* or toxin production from *Bacillus amyloliquefaciens* have been reported. Since *Bacillus amyloliquefaciens* is naturally present in soils, exposure to *Bacillus amyloliquefaciens* from surface and possibly groundwater can be expected. Water treatment processes should remove any *Bacillus amyloliquefaciens* present. No adverse effects are expected or have been reported from exposure to *Bacillus amyloliquefaciens* through drinking water.
Oral LD > 1.0×10^8 CFU/rat – not infective, pathogenic or toxic.
Intravenous LD > 1.0×10^7 CFU/rat – not infective, pathogenic or toxic.
Pulmonary LD > 1.0×10^7 CFU/rat - not infective, pathogenic or toxic.
Oral LD > 5000 mg/Kg – EPA Toxicity Category IV.
Dermal LD > 5050 mg/Kg – EPA Toxicity Category IV.
Inhalation LC > 2.18 mg/L – EPA Toxicity Category IV.
Mildly-irritating to the eye – EPA Toxicity Category III.
Essentially non-irritating dermally – EPA Toxicity Category IV.
CLASSIFICATION: ACCEPTABLE.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Types	Product Identity (OCSPP 885.1100); Manufacturing Process (885.1200); Discussion of Formation of Unintentional Ingredients (885.1300); Analysis of Samples (885.1400); Certification of Limits (885.1500); Enforcement Analytical Method (830.1800); Physical and Chemical Characteristics (830.6302 - 830.7950).
MRID Nos.	481657-01; 481657-02; 481657-03.
Test Material	*Bacillus amyloliquefaciens* strain D747 (CX-9030 contains the ai CX-9025).
Study Nos.	None.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Titles of Reports	*Bacillus subtilis* var. *amyloliquefaciens* strain D-747 (CX-9030) – Microbial Pesticide Data Requirements; *Bacillus subtilis* var. *amyloliquefaciens* strain D-747 End-use product (ID Code CX-9030) – Product Properties / Storage Stability.
Authors	Chang-Yan Chen; William E. DeVane; Alec Simpson.
Studies Completed	July 12, 2010; June 22, 2010; July 7, 2010.
Study Summaries	*Bacillus amyloliquefaciens* D747 is a member of the *Bacillus subtilis* group of bacteria. Several other registrations and food tolerance exemptions exist for pesticidal applications of other similar *Bacillus* strains. This isolate is from an air sample in Japan and is on deposit with ATCC, though accessibility was unclear. Standard fermentation procedures are utilized though variable components for fermentation broth were not sufficiently described. Of concern ingredients [redacted]
Classifications	**SUPPLEMENTAL but upgradeable** – when accessibility of the ATCC deposit *is* clarified, information is provided for potential allergen residues that may become part of pesticides applied to foods, and amended CSFs and labels are provided.
Good Laboratory Practice	The studies do not comply with the requirements of 40 CFR Part 160 but use sound scientific methods and procedures.

Test Material: *Bacillus amyloliquefaciens* strain D747 (formerly *Bacillus subtilis* var. *amyloliquefaciens* strain D747); (CX-9030 contains the ai CX-9025); NRRL B-50405.

I. PRODUCT IDENTITY:

Various tests conducted for identification produced results that varied mostly based on the reference consulted, not the identity of the microbe. Phenotypic characterization was Gram +, oxidative spore-former, grows at 30 °C but not 50°C, grows at 6.5% NaCl, VP+, ONPG-, MR-, nitrate reduced, starch hydrolyzed – all indicative of identification as *Bacillus amyloliquefaciens* according to Bergey's Manual, 2nd edition (2009). Further contract work was done by MIDI labs with FAME identification as *Bacillus subtilis*-GC subgroup B with a 0.710 similarity index (caveat – *B. amyloliquefaciens* is not in the FAME clinical database); and a DNA match, with 0.37 % difference, of *Bacillus amyloliquefaciens* based on 16s sequencing; the FAME TSBA database was not assayed. July 28, 2011 communication with Certis resulted in a change to the taxonomy for registration purposes from *Bacillus subtilis* var. *amyloliquefaciens* to *Bacillus amyloliquefaciens* strain D747.

The classification of strain D747 is as follows: Genus: *Bacillus*
Species: *amyloliquefaciens*
Family: Bacillaceae
Order: Bacillales
Class: Bacilli

Phylum: Firmicutes
Kingdom: Bacteria

Known taxonomy of the genus *Bacillus*: http://www.ncbi.nlm.nih.gov/Taxonomy/Browser/wwwtax.cgi

Bacillus subtilis group
- Bacillus amyloliquefaciens
  - Bacillus amyloliquefaciens LL3
  - Bacillus amyloliquefaciens PGK1
  - Bacillus amyloliquefaciens subsp. amyloliquefaciens
  - Bacillus amyloliquefaciens DSM 7
  - Bacillus amyloliquefaciens subsp. plantarum
  - Bacillus amyloliquefaciens FZB42
  - Bacillus amyloliquefaciens TA208
  - Bacillus amyloliquefaciens XH7
- Bacillus atrophaeus
  - Bacillus atrophaeus 1013-1
  - Bacillus atrophaeus 1013-2
  - Bacillus atrophaeus 1942
  - Bacillus atrophaeus ATCC 49822
  - Bacillus atrophaeus ATCC 49822-1
  - Bacillus atrophaeus ATCC 49822-2
  - Bacillus atrophaeus ATCC 9372
  - Bacillus atrophaeus ATCC 9372-1
  - Bacillus atrophaeus ATCC 9372-2
  - Bacillus atrophaeus BACI051-E
  - Bacillus atrophaeus BACI051-N
  - Bacillus atrophaeus Detrick-1
  - Bacillus atrophaeus Detrick-2
  - Bacillus atrophaeus Detrick-3
  - Bacillus atrophaeus str. Dugway
- Bacillus licheniformis
  - Bacillus licheniformis 9945A
  - Bacillus licheniformis ATCC 14580
- Bacillus mojavensis subgroup
  - Bacillus axarquiensis
  - Bacillus malacitensis
  - Bacillus mojavensis
  - Bacillus sonorensis
- Bacillus subtilis
  - Bacillus subtilis Abs3
  - Bacillus subtilis BSn5
  - Bacillus subtilis gtP20b
  - Bacillus subtilis str. 10
  - Bacillus subtilis subsp. amylosacchariticus
  - Bacillus subtilis subsp. chungkookjang
  - Bacillus subtilis subsp. endophyticus
  - Bacillus subtilis subsp. inaquosorum
  - Bacillus subtilis subsp. lactipan
  - Bacillus subtilis subsp. natto
  - Bacillus subtilis subsp. natto BEST195
  - Bacillus subtilis subsp. qingdao
  - Bacillus subtilis subsp. sadata
  - Bacillus subtilis subsp. spizizenii
  - Bacillus subtilis subsp. spizizenii ATCC 6633

Bacillus subtilis subsp. spizizenii RFWG1A3
Bacillus subtilis subsp. spizizenii RFWG1A4
Bacillus subtilis subsp. spizizenii RFWG4C10
Bacillus subtilis subsp. spizizenii RFWG5B15
Bacillus subtilis subsp. spizizenii str. W23
Bacillus subtilis subsp. subtilis
Bacillus subtilis subsp. subtilis str. 168
Bacillus subtilis subsp. subtilis str. AUS198
Bacillus subtilis subsp. subtilis str. JH642
Bacillus subtilis subsp. subtilis str. NCIB 3610
Bacillus subtilis subsp. subtilis str. SMY
Bacillus subtilis YF001
Bacillus vallismortis
Bacillus vallismortis NRRL B-14890
Bacillus sp. M1(2010)
Bacillus sp. M100(2010)
Bacillus sp. M101(2010)
Bacillus sp. M103(2010)
Bacillus sp. M110(2010)
Bacillus sp. M112(2010)
Bacillus sp. M14(2010)
Bacillus sp. M2(2010)
Bacillus sp. M21(2010)
Bacillus sp. M22(2010)
Bacillus sp. M25(2010)
Bacillus sp. M29(2010)
Bacillus sp. M30(2010)
Bacillus sp. M35(2010)
Bacillus sp. M38(2010)
Bacillus sp. M4(2010b)
Bacillus sp. M40(2010)
Bacillus sp. M5(2010)
Bacillus sp. M63(2010)
Bacillus sp. M64(2010)
Bacillus sp. M67(2010)
Bacillus sp. M68(2010)
Bacillus sp. M88(2010)
Bacillus sp. M90(2010)
Bacillus sp. M94(2010)
Bacillus sp. M95(2010)
Bacillus sp. M98(2010)
Bacillus sp. TT106(2010)
Bacillus sp. TT45(2010)
Bacillus sp. TT46(2010)
Bacillus sp. TT53(2010)
Bacillus sp. TT80(2010)

Natural history of *Bacillus amyloliquefaciens* strain D747: Strain D747 was found in an air sample above Kikugawa-Cho, Ogasa-gun, Sinzuoka-Ken, Japan which appears from available maps to be an urban area. Original identification in 2002 based on gyrB sequencing by the Kumai Chemical Industry Co., LTD. was *Bacillus subtilis* var. *amyloliquefaciens*. Bergey's manual states that *Bacillus* spp. are inhabitants of soil or environments that may be contaminated by soil. With the exception of *Bacillus anthracis* in the *B. cereus* group, Bergey's Manual categorizes *Bacillus* spp. as rarely associated with diseases of humans or other animals, other than cases of food

Manufacturing process information may be entitled to confidential treatment

poisoning (from emetic toxin production) and some reports of opportunistic infections; some *Bacillus thuringiensis* spp. also in the *B. cereus* group are pathogens of insects. Bergey's Manual mentions that *Bacillus amyloliquefaciens* are sources of industrial α-amylase and protease enzymes. The Manual of Clinical Microbiology (9th edition) mentions that dried food such as spices, milk powder and grains often contain large amounts of *Bacillus* spores.

Deficiencies: It is not clear if the ATCC culture is available to anyone but the depositor.

II. MANUFACTURING PROCESS:

[redacted]

IV. ANALYSIS OF SAMPLES: See table 1.

[redacted]

[redacted]

V. CERTIFICATION OF LIMITS:

TABLE 2. Nominal concentration and certified limits for *Bacillus amyloliquefaciens strain* strain D747 / CX-9030.

Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Bacillus amyloliquefaciens strain D-747 TGAI (ID Code CX-9025) 2 x 10^{11} CFU/g[b]	016482	Active ingredient	25.0	24.25	25.75
Inert Ingredients					
[redacted]					

[a]Data from 7/9/2010 CSFs; [b] the current CSF lists the ai as *Bacillus subtilis* var. *amyloliquefaciens* and should be amended along with the label.

Deficiencies: The CSFs and labels should be amended from *Bacillus subtilis* var. *amyloliquefaciens* to the current *Bacillus amyloliquefaciens*.

VI. PHYSICAL AND CHEMICAL CHARACTERISTICS: see Table 3.

TABLE 3. Physical and Chemical Properties for *Bacillus amyloliquefaciens strain* strain D747 / CX-9025.

Guideline Reference No./Property	Description of Result
830.6302 Color	Beige.
830.6303 Physical State	Fine powder.
830.6304 Odor	Yeast odor.
830.6313 Stability	Spores inactivated at 54°C.
830.6314 Oxidation/Reduction: Chemical Incompatibility	Not applicable, the product does not contain oxidizing or reducing agents.
830.6315 Flammability	Not applicable, the product does not contain flammable ingredients.
830.6316 Explodability	Not applicable, the product does not contain explosive ingredients.
830.6317 Storage Stability	Stable up to one year at 25°C without loss of viability.
830.6319 Miscibility	Not applicable, the product is not an emulsifiable liquid.
830.6320 Corrosion Characteristics	Not applicable, the product is a powder.
830.6321 Dielectric Breakdown Voltage	Not applicable, the product is not for use around electrical equipment.
830.7000 pH	6.5 – 7.0 (1% w/w)
830.7100 Viscosity	Not applicable, the product is a powder.
830.7200 Melting Range	Not applicable.
830.7220 Boiling Range	Not applicable, the product is not pure active ingredient.
830.7300 Density/Relative Density/Bulk Density	Not reported.
830.7370 Dissociation Constant in Water	Not applicable, the product is not pure active ingredient.
830.7550 Partition Coefficient	Not applicable, the product is not pure active ingredient.
830.7840 Water Solubility	Not applicable, the product is not pure active ingredient.
830.7950 Vapor Pressure	Not applicable, the product is not pure active ingredient.

[a]Data from MRIDs 481657-01; 481657-02; 481657-03.

Deficiencies: None.

***** CONTAINS FIFRA CONFIDENTIAL BUSINESS INFORMATION *****

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Types	Product Identity (OCSPP 885.1100); Manufacturing Process (885.1200); Discussion of Formation of Unintentional Ingredients (885.1300); Analysis of Samples (885.1400); Certification of Limits (885.1500); Enforcement Analytical Method (830.1800); Physical and Chemical Characteristics (830.6302 - 830.7950).
MRID Nos.	481655-01; 481655-02; 481655-03.
Test Material	*Bacillus amyloliquefaciens* strain D747 (CX-9032) liquid concentrate.
Study Nos.	None.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Titles of Reports	*Bacillus subtilis* var. *amyloliquefaciens* strain D747 (CX-9032) – Microbial Pesticide Data Requirements; *Bacillus subtilis* var. *amyloliquefaciens* strain D-747 End-use product (ID Code CX-9032) – product Properties / Storage Stability – Interim Study Report.
Authors	Chang-Yan Chen; William E. DeVane; Alec Simpson.
Studies Completed	July 2, 2010; July 14, 2010; July 7, 2010.
Study Summaries	*Bacillus amyloliquefaciens* strain D747 (CX-9032) liquid concentrate is produced from the same process as the MUP CX-9030 except [redacted] Standard fermentation procedures are utilized though variable feed stocks for fermentation broth were not sufficiently described. Of concern ingredients to [redacted]
Classifications	**SUPPLEMENTAL but upgradeable** – when accessibility of the ATCC deposit is clarified, information is provided for potential allergen residues that may become part of pesticides applied to foods, and amended CSFs and labels are provided.
Good Laboratory Practice	The studies do not comply with the requirements of 40 CFR Part 160 but use sound scientific methods and procedures.

Test Material: *Bacillus subtilis* var. *amyloliquefaciens* strain D747 (CX-9032) liquid concentrate.

I. PRODUCT IDENTITY: The starting material is the concentrated fermentation material as described above except the [redacted]

Deficiencies: None.

II. MANUFACTURING PROCESS: [redacted]

Inert ingredient information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment

[redacted]

IV. ANALYSIS OF SAMPLES: ANALYSIS OF SAMPLES: See table 1.

[redacted]

V. CERTIFICATION OF LIMITS:

TABLE 2. Nominal concentration and certified limits for *Bacillus amyloliquefaciens strain* strain D747 / CX-9032 liquid concentrate.

Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient – formulation 1					
Bacillus amyloliquefaciens strain D-747 fermentation solids, and spores (ID Code CX-9025 Liquid) 2 x 10^{10} CFU/g[b]	016482	Active ingredient	98.35	95.40	100.00
Inert Ingredients – formulation 1					
[redacted]					
Active Ingredient – formulation 2					
Bacillus amyloliquefaciens strain D-747 fermentation solids, and spores (ID Code CX-9025 Liquid) 2 x 10^{10} CFU/g[b]	016482	Active ingredient	98.95	95.98	98.95
Inert Ingredients – formulation 2					
[redacted]					

[a]Data from 10/25/2010 CSFs; [b] the current CSFs and labels list the ai as *Bacillus subtilis* var. *amyloliquefaciens* and should be amended.

Deficiencies: The upper and lower limits for the active ingredient in formulation 1 are uneven; the [redacted] content should reflect the composition of the product, not just [redacted] in final formulation; CSFs and labels should be amended from *Bacillus subtilis* var. *amyloliquefaciens* to the current *Bacillus amyloliquefaciens*.

VI. PHYSICAL AND CHEMICAL CHARACTERISTICS: see Table 3.

TABLE 3. Physical and Chemical Properties for *Bacillus amyloliquefaciens strain* strain D747 / CX-9032 liquid concentrate.

Guideline Reference No./Property	Description of Result
830.6302 Color	Light brown.
830.6303 Physical State	Liquid.
830.6304 Odor	Yeast odor.
830.6313 Stability	Spores inactivated at 54°C.
830.6314 Oxidation/Reduction: Chemical Incompatibility	Not applicable, the product does not come into contact with metals during storage.
830.6315 Flammability	Not applicable, the product does not contain flammable ingredients.
830.6316 Explodability	Not applicable, the product does not contain explosive ingredients.
830.6317 Storage Stability	Stable up to 78 days at 25°C without loss of viability.
830.6319 Miscibility	Not applicable, the product is not an emulsifiable liquid.
830.6320 Corrosion Characteristics	None evident to polyethylene packaging after 78 days.
830.6321 Dielectric Breakdown Voltage	Not applicable, the product is not for use around electrical equipment.
830.7000 pH	4.2 - 4.3 (1% w/w).
830.7100 Viscosity	4.6 – 16.0 mPa s at 25°C.
830.7200 Melting Range	Not applicable, the product is a liquid.
830.7220 Boiling Range	Not applicable, the product is not pure active ingredient.
830.7300 Density/Relative Density/Bulk Density	1.02 – 1.03 g/mL.
830.7370 Dissociation Constant in Water	Not applicable, the product is not pure active ingredient.
830.7550 Partition Coefficient	Not applicable, the product is not pure active ingredient.
830.7840 Water Solubility	Not applicable, the product is not pure active ingredient.
830.7950 Vapor Pressure	Not applicable, the product is not pure active ingredient.

[a]Data from MRIDs 481655-01; 481655-02; 481655-03.

Deficiencies: None.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Type	Acute Oral Toxicity / Pathogenicity – Rat (OCSPP 885.3050).
MRID No.	481657-04.
Test Material	*Bacillus amyloliquefaciens* strain D747.
Study No.	B030504.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Mitsubishi Chemical Safety Institute Ltd.; Kashima Laboratory; 14 Sumayama, Hsaki-machi, Kashima-gun, Ibaraki, Japan.
Titles of Reports	D747 Single Oral Administration Toxicity Study in Rats.
Author	Yasuyuki Onishi.
Study Completed	October 10, 2003.
Study Summary	No evidence of infectivity, pathogenicity or toxicity was found from oral administration of 1.0×10^8 CFU *Bacillus amyloliquefaciens* strain D747 to rats. Clearance from fecal material occurred by day 14 and no viable organisms were recovered from blood or any other organ or tissue.
Classification	**ACCEPTABLE** – oral LD > 1.0×10^8 CFU/rat – not infective, pathogenic or toxic.
Good Laboratory Practice	Signed and dated GLP statements were provided – the study is not compliant with US EPA GLP 40 CFR part 160 standards but is with Japan Ministry of Agriculture standards.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: *Bacillus amyloliquefaciens* strain D747.
   - Description: *Bacillus amyloliquefaciens* strain D747 liquid.
   - Lot/Batch #: K3E001.
   - Purity: 1.0×10^{11} CFU/mL.
   - CAS #: n/a
   - Storage conditions: Shipped and stored at 4-7.5°C.
   - Microbiology: The testing laboratory did not further characterize the test substance.
2. Sample Preparation: The laboratory performed a dilution in sterile saline to 10^8 CFU in 1.0 mL.
3. Controls: A control group was treated with diluent only.
4. Test animals: Rat
   - Species: *Rattus norvegicus*
   - Strain: CD (SD) IGS rats.
   - Age/weight at dosing: Approximately 5 weeks old; 135-149 g (males) and 112-125 g (females) at dosing; none varied more than 20% from the mean weight.
   - Source: Charles River Laboratories, Japan.
   - Housing: Polycarbonate cages with sterile chip bedding, multiple rats/cage.
   - Diet: Experimental animal pellet diet (MF, Oriental Yeast Co., Ltd.), ad libitum.
   - Water: Filtered (5 µm) UV irradiated tap water, ad libitum.
   - Environmental conditions:
     - Temperature: 20.4-22.4°C
     - Humidity: 43.6-63.2%
     - Air changes: 6-10 times per hour.
     - Photoperiod: 12 hrs dark / 12 hrs light
   - Acclimation period: 5 days

B. STUDY DESIGN and METHODS:

1. In life dates: Start: 29 July 2003; End: 23 August 2003
2. Preliminary Challenge Assay: No preliminary challenge was performed.

3. Animal assignment and treatment: All animals were fasted starting the evening prior to the day of dosing. Food, but not water, was withheld, and rats not scheduled to be euthanized the day of dosing were fed within three hours of dosing. A test substance dose group of twenty eight animals (14/sex) were treated once with the test substance ($1.0x10^8$ CFU/mL) administered by oral gavage in a volume equivalent to 1.0 mL. A control group of four rats (2/sex) was administered a single 1.0 mL dose of sterile saline.
4. Clinical Observations and Body Weights: Observations were made periodically (1, 3 and 6 hours) after dosing, then once per day. Body weight was determined on days 0, 7, 14 and 21.
5. Feed Consumption: Feed consumption was not measured.
6. Necropsy and Organ Weight Determination: At necropsy animals were examined grossly though organ weights were not recorded.
7. Microbial Enumeration: Fecal samples were measured for viable organisms prior to dosing then on days 1, 3, 7 and 14. Internal organs and blood were assayed on necropsy. Organ samples were homogenized then subjected to 75°C for 30 minutes and 100 µL plated to three replicate plates. Blood was collected prior to necropsy and EDTA-2K was added as an anti-coagulant prior to plating 100 µL to three replicate plates.
8. Sensitivity of Detection: 10^{-2}-10^{-4}/g.
9. Statistics: There were no clinical signs or treatment-related mortalities, so statistics were not required to calculate the LD_{50} though they were used to report differences in organ and body weights.
II. RESULTS AND DISCUSSION:
A. MORTALITY: There were no treatment-related mortalities. The oral LD > $1.0x10^8$ CFU/rat.
B. CLINICAL OBSERVATIONS: No adverse clinical signs were observed.
C. BODY WEIGHT: All animals not euthanized on day zero regularly gained weight. Mean body weights are presented in Table 1.
Table 1. Mean body weight gain in controls and rats treated with *Bacillus amyloliquefaciens* strain D747.

Group	Dose (CFU/rat)	Sex	Mean body weight (g) (mean ± SD) n = 3[a]			
			Day 0	Day 7	Day 14	Day 21
Live test substance	1.0 mL at $1.0x10^8$	Male	142 ± 4.3	229 ± 7.6	296 ± 9.8	357 ± 9.3
		Female	118 ± 4.6	173 ± 10.3	196 ± 13.4	222 ± 6.6
Shelf control (untreated)	0	Male	139 ± 4.2	231 ± 17.0	302 ± 22.7	364 ± 32.5
		Female	118 ± 2.8	172 ± 19.8	199 ± 17.7	228 ± 25.5

[a] n=3 except for live test substance groups on day 21 where n=5 and untreated controls were n=2.
D. FEED CONSUMPTION: Feed consumption was not measured.
E. NECROPSY: No abnormalities were noted at necropsy.
F. ORGAN WEIGHTS: Organ weights were not determined.
G. MICROBIAL ENUMERATION: Concentrations of the test microorganism in fecal material declined steadily through day 7; on day 14 no viable counts of *Bacillus amyloliquefaciens* strain D747 remained in fecal material shed by rats. No viable *Bacillus amyloliquefaciens* strain D747 was found in any tissues, organs or blood.
H. STUDY AUTHORS' CONCLUSIONS: D747 was administered once orally to 14 SD rats of both sexes (5-week old) at dosage of 10^8 CFU per animals and the influence n the animals was investigated. As a result, no deaths occurred and no abnormalities were observed in the clinical sign, body weight, or necropsy. The test microbe was detected at 10^3 – 10^5 CFU/g in feces 1 day after administration, but gradually decreased and was not detected 14 days after administration. The examination for internal persistence of the test microbe showed no detection in any organs/tissues such as the kidney, brain, liver, lung, spleen, stomach, small intestine (duodenum), large intestine (cecum), mesenteric lymph nodes, or blood through the experiment period. From the above results, D747 was concluded to have no infectivity, pathogenicity, residual potential of viable microbe, or toxicity under the conditions of this study.
I. REVIEWERS' CONCLUSIONS: No evidence of infectivity, pathogenicity or toxicity was found from oral administration of $1.0x10^8$ spores *Bacillus amyloliquefaciens* strain D747 to rats. Clearance from fecal material occurred by day 14 and no viable organisms were recovered from blood or any other organ or tissue.

DEFICIENCIES: None.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Type	Acute Injection Toxicity / Pathogenicity - Rat (OCSPP 885.3200).
MRID No.	481657-05.
Test Material	*Bacillus amyloliquefaciens* strain D747.
Study No.	B030506.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Mitsubishi Chemical Safety Institute Ltd.; Kashima Laboratory; 14 Sumayama, Hsaki-machi, Kashima-gun, Ibaraki, Japan.
Titles of Reports	D747 Single Intravenous Administration Toxicity Study in Rats.
Author	Yasuyuki Onishi.
Study Completed	October 10, 2003.
Study Summary	No evidence of infectivity, pathogenicity or toxicity was found from intravenous administration of 1.0×10^7 spores *Bacillus amyloliquefaciens* strain D747 to rats. There were no mortalities, no clinical effects from intravenous administration and steady weight gain of treated rats throughout the study duration. Clearance was steady though residual viable cells remained in the liver and spleen at day 60 on study termination, typical of spore forming bacteria administered to rats. There was no evidence of an increase in viable counts over time that would be indicative of a chronic infection. Since a pattern of clearance was shown it is assumed that the remaining viable cells were spores that take longer to be cleared by healthy immune systems.
Classification	**ACCEPTABLE** – intravenous LD > 1.0×10^7 CFU/rat – not infective, pathogenic or toxic.
Good Laboratory Practice	Signed and dated GLP statements were provided – the study is not compliant with US EPA GLP 40 CFR part 160 standards but is with Japan Ministry of Agriculture standards.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: *Bacillus amyloliquefaciens* strain D747.
   - Description: *Bacillus amyloliquefaciens* strain D747 liquid.
   - Lot/Batch #: K3E00I.
   - Purity: 1.0×10^{11} CFU/mL.
   - CAS #: n/a
   - Storage conditions: Shipped and stored at 4-7.5°C.
   - Microbiology: The laboratory did not perform further characterization.
2. Sample Preparation: The test substance was diluted to contain 10^8 CFU/mL and 0.1 mL was administered.
3. Controls: A control group was treated with diluent only.
4. Test animals: Rat
   - Species: *Rattus norvegicus*
   - Strain: CD (SD) IGS rats.
   - Age/weight at dosing: Approximately 5 weeks old; 162-182 g (males) and 126-146 g (females) at dosing; none varied more than 20% from the mean weight.
   - Source: Charles River Breeding Laboratories, Japan.
   - Housing: Polycarbonate cages with sterile chip bedding, multiple rats/cage.
   - Diet: Pellet Diet for Experimental Animal (MF, Oriental Yeast Co., Ltd.), ad libitum.
   - Water: Filtered (5 µm) UV irradiated tap water, ad libitum.
   - Environmental conditions:
     - Temperature: 19.7-23.2°C
     - Humidity: 44.3-67.9%
     - Air changes: 6-10 changes per hour.
     - Photoperiod: 12 hrs dark / 12 hrs light

Acclimation period: 5 days

B. STUDY DESIGN and METHODS:

1. In life dates: Start: 24 June 2003; End: 23 August 2003.
2. Preliminary Challenge Assay: No preliminary challenge was performed.
3. Animal assignment and treatment: All animals were fasted starting the evening prior to the day of dosing. Food, but not water, was withheld, and rats not scheduled to be euthanized the day of dosing were fed within three hours of dosing. A test substance dose group of forty animals (20/sex) were treated once with the test substance ($1.0x10^7$ CFU in 0.1 mL) administered by tail vein injection. A control group of four rats (2/sex) was administered a single 0.1 mL dose of sterile saline.
4. Clinical Observations and Body Weights: Observations were made periodically (1, 3 and 6 hours) after dosing, then once per day. Body weight was determined weekly on days 0, 7, 14, 21 - 60.
5. Feed Consumption: Feed consumption was not measured.
6. Necropsy and Organ Weight Determination: At necropsy animals were examined grossly though organ weights were not recorded.
7. Microbial Enumeration: Blood and tissue samples were measured for viable organisms shortly after dosing then on days 1, 3, 7, 14, 21 and 60. Organ and blood samples were homogenized then subjected to 75°C for 30 minutes and 100 µL plated to three replicate plates. Blood was collected prior to necropsy and EDTA-2K was added as an anti-coagulant prior to plating 100 µL to three replicate plates.
8. Sensitivity of Detection: 10^{-2}-10^{-4}/g.
9. Statistics: There were no clinical signs or treatment-related mortalities, so statistics were not required to calculate the LD_{50}.

II. RESULTS AND DISCUSSION:

A. MORTALITY: There were no treatment-related mortalities. The intravenous LD > $1.0x10^7$ CFU/rat.

B. CLINICAL OBSERVATIONS: No adverse clinical signs were observed.

C. BODY WEIGHT: All animals not euthanized on day zero regularly gained weight. Mean body weights are presented in Table 1.

Table 1. Mean body weight gain in controls and rats treated with *Bacillus amyloliquefaciens* strain D747.

Group	Dose (CFU/rat)	Sex	Mean body weight (g) (mean ± SD) n = 3[a]									
			Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 60
Live test substance	0.1 mL at $1.0x10^7$	M	171±5.8	245±8.3	320±15.2	388±27.2	415±30.8	452±31.9	487±28.5	521±32.3	548±34.7	568±33.5
		F	137±6.2	172±9.7	199±14.3	220±18.2	232±20.6	243±19.2	259±14.2	264±20.7	276±18.8	285±18.4
Shelf control (untreated)	0	M	172±3.5	239±3.5	311±4.9	373±17.7	nd	nd	nd	nd	nd	nd
		F	137±3.5	173±8.5	197±0	234±0.7	nd	nd	nd	nd	nd	nd

[a] n=3 except for live test substance groups on day 21 where n=5 and untreated controls were n=2.

D. FEED CONSUMPTION: Feed consumption was not measured.

E. NECROPSY: No abnormalities were noted at necropsy.

F. ORGAN WEIGHTS: Organ weights were not determined.

G. MICROBIAL ENUMERATION: Concentrations of the test microorganism in blood declined from 10^2 on days 0-3 to undetectable levels by day 14; no viable *Bacillus amyloliquefaciens* strain D747 were detected in the brain; in the kidney, liver and spleen counts in the 10^3-10^5 range declined steadily and were undetectable in the kidney by day 60 and decreased in the liver and spleen to the 10^2-10^3 range; low counts in the lymph nodes and intestines were below detection after day 21.

H. STUDY AUTHORS' CONCLUSIONS: D747 was administered once intravenously to 17 SD rats of both sexes (5-week old) at dosage of 10^7 CFU per animal and the influence on the animals was investigated. As a result, no deaths occurred and there was no abnormality in clinical signs, body weight, or necropsy. The examination for internal persistence of the test microbe showed that the test microbes were mainly detected in the kidney, liver, spleen, and blood shortly after administration. The test microbe decreased after that and could not be detected in the blood from day 14. In the kidney, the test microbe was completely disappeared by day 60. The test microbe, *Bacillus subtilis*, is spore-forming bacterium. McClintock et al., reported that when *Bacillus thuringiensis* and

Bacillus subtilis, which are both spore-forming bacteria, were intravenously administered to rats, they are difficult to disappear from the liver and spleen. In this study, the test microbe did not completely disappear even day 60. However, since an increasing tendency was not observed during the experimental period and a decreasing tendency was clearly recognized, it was considered that the test microbe have disappeared even though it takes time. No test microbe was detected in the brain, and only a few viable microbes at the limit level were sporadically detected in the small intestine, large intestine, and inguinal lymph nodes, and they disappeared by 60 days after administration. From the above results, D747 was concluded to have no infectivity, pathogenicity, residual potential of viable microbe, or toxicity under the conditions of this study.

I. REVIEWERS' CONCLUSIONS: No evidence of infectivity, pathogenicity or toxicity was found from intravenous administration of 1.0×10^7 spores *Bacillus amyloliquefaciens* strain D747 to rats. There were no mortalities, no clinical effects from intravenous administration and steady weight gain of treated rats throughout the study duration. Clearance was steady though residual viable cells remained in the liver and spleen at day 60 on study termination, typical of spore forming bacteria administered to rats. There was no evidence of an increase in viable counts over time that would be indicative of a chronic infection. Since a pattern of clearance was shown it is assumed that the remaining viable cells were spores that take longer to be cleared by healthy immune systems.

DEFICIENCIES: None.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Type	Acute Pulmonary Toxicity/Pathogenicity – Rat (OCSPP 885.3150).
MRID No.	481657-06.
Test Material	*Bacillus amyloliquefaciens* strain D747.
Study No.	B030505.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Mitsubishi Chemical Safety Institute Ltd.; Kashima Laboratory; 14 Sumayama, Hsaki-machi, Kashima-gun, Ibaraki, Japan.
Titles of Reports	D747 Single Endotracheal Administration Toxicity Study in Rats.
Author	Yasuyuki Onishi.
Study Completed	October 10, 2003.
Study Summary	No evidence of infectivity, pathogenicity or toxicity was found from intratracheal administration of 1.0×10^7 spores *Bacillus amyloliquefaciens* strain D747 to rats. There were no mortalities, no clinical effects from intratracheal administration and steady weight gain of treated rats throughout the study duration. Clearance was steady though residual viable cells remained in the lungs and trachea at day 60 on study termination, typical of spore forming bacteria administered to rats. There was no evidence of an increase in viable counts over time that would be indicative of a chronic infection. Since a pattern of clearance was shown it is assumed that the remaining viable cells were spores that take longer to be cleared by healthy immune systems.
Classification	**ACCEPTABLE** – pulmonary LD > 1.0×10^7 CFU/rat - not infective, pathogenic or toxic.
Good Laboratory Practice	Signed and dated GLP statements were provided – the study is not compliant with US EPA GLP 40 CFR part 160 standards but is with Japan Ministry of Agriculture standards.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: *Bacillus amyloliquefaciens* strain D747.
   - Description: *Bacillus amyloliquefaciens* strain D747 liquid.
   - Lot/Batch #: K3E001.
   - Purity: 1.0×10^{11} CFU/mL.
   - CAS #: n/a
   - Storage conditions: Shipped and stored at 4-7.5°C.
   - Microbiology: The laboratory did not perform further characterization.
2. Sample Preparation: The test substance was diluted to contain 10^8 CFU/mL and 0.1 mL was administered.
3. Controls: A control group was treated with diluent only.
4. Test animals: Rat
   - Species: *Rattus norvegicus*
   - Strain: CD (SD) IGS rats.
   - Age/weight at dosing: Approximately 5 weeks old; 177-202 g (males) and 137-164 g (females) at dosing; none varied more than 20% from the mean weight.
   - Source: Charles River Breeding Laboratories, Japan.
   - Housing: Polycarbonate cages with sterile chip bedding, multiple rats/cage.
   - Diet: Pellet Diet for Experimental Animal (MF, Oriental Yeast Co., Ltd.), ad libitum.
   - Water: Filtered (5 µm) UV irradiated tap water, ad libitum.
   - Environmental conditions:
     - Temperature: 19.7-23.2°C
     - Humidity: 44.3-67.9%
     - Air changes: 6-10 changes per hour.
     - Photoperiod: 12 hrs dark / 12 hrs light

Acclimation period: 5 days

B. STUDY DESIGN and METHODS:

1. In life dates: Start: 03 July 2003; End: 01 September 2003.
2. Preliminary Challenge Assay: No preliminary challenge was performed.
3. Animal assignment and treatment: All animals were fasted starting the evening prior to the day of dosing. Food, but not water, was withheld, and rats not scheduled to be euthanized the day of dosing were fed within three hours of dosing. A test substance dose group of forty animals (20/sex) were treated once with 0.1 mL of the test substance ($1.0x10^8$ CFU/mL) administered by endotracheal instillation. A control group of four rats (2/sex) was administered a single 0.1 mL dose of sterile saline.
4. Clinical Observations and Body Weights: Observations were made periodically (1, 3 and 6 hours) after dosing, then once per day. Body weight was determined weekly on days 0, 7, 14, 21 - 60.
5. Feed Consumption: Feed consumption was not measured.
6. Necropsy and Organ Weight Determination: At necropsy animals were examined grossly though organ weights were not recorded.
7. Microbial Enumeration: Blood and tissue samples were measured for viable organisms shortly after dosing then on days 1, 3, 7, 14, 21 and 60. Organ and blood samples were homogenized then subjected to 75°C for 30 minutes and 100 µL plated to three replicate plates. Blood was collected prior to necropsy and EDTA-2K was added as an anti-coagulant prior to plating 100 µL to three replicate plates.
8. Sensitivity of Detection: 10^{-2}-10^{-4}/g.
9. Statistics: There were no clinical signs or treatment-related mortalities, so statistics were not required to calculate the LD_{50}.

II. RESULTS AND DISCUSSION:

A. MORTALITY: There were no treatment-related mortalities. The pulmonary LD > $1.0x10^7$ CFU/rat.

B. CLINICAL OBSERVATIONS: No adverse clinical signs were observed.

C. BODY WEIGHT: All animals not euthanized on day zero regularly gained weight. Mean body weights are presented in Table 1.

Table 1. Mean body weight gain in controls and rats treated with *Bacillus amyloliquefaciens* strain D747.

Group	Dose (CFU/rat)	Sex	Mean body weight (g) (mean ± SD) n = 3[a]									
			Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 60
Live test substance	0.1 mL at $1.0x10^7$	M	190±6.2	257±11.0	322±18.1	370±25.2	419±43.0	456±49.5	493±56.0	523±60.5	547±60.1	572±63.6
		F	150±6.5	182±6.6	210±6.9	235±10.5	246±15.1	261±17.3	269±16.6	279±25.8	287±22.5	294±20.5
Shelf control (untreated)	0	M	187±7.0	252±8.5	311±18.4	357±28.3	nd	nd	nd	nd	nd	nd
		F	150±6.4	193±13.4	219±3.5	242±0.7	nd	nd	nd	nd	nd	nd

[a] n=3 except for live test substance groups on day 21 where n=5 and untreated controls were n=2.

D. FEED CONSUMPTION: Feed consumption was not measured.

E. NECROPSY: No abnormalities were noted at necropsy.

F. ORGAN WEIGHTS: Organ weights were not determined.

G. MICROBIAL ENUMERATION: Concentrations of the test microorganism in the lungs, trachea and nasal cavity were in the 10^5-10^7 range shortly after dosing, clearing the nasal cavity by day 7 though viable counts in the 10^4 range remained in the lungs at day 60 with 10^1 detected from tracheal samples; viable *Bacillus amyloliquefaciens* strain D747 was also detected in the bronchial lymph nodes between day 3 and 21 but had cleared by day 60; no viable cells were detected in the blood, brain, kidney, liver or spleen.

H. STUDY AUTHORS' CONCLUSIONS: D747 was administered once intratracheally to 20 SD rats of both sexes (5-week old) at dosage of 10^7 CFU per animal and the influence on the animals was investigated. As a result, no deaths occurred and there was no abnormality in clinical signs, body weight, or necropsy. The examination for internal persistence of the test microbe showed that the test microbe was detected shortly after administration from the administration route such as the lung, trachea, and nasal cavity. These microbes gradually decreased after that, and were not be detected in the nasal cavity on day 7, and almost completely disappeared in the trachea by day 60. Also, the test microbes decreased in the lungs by approximately 10^2-10^3 CFU/g from day 0 to day 60. The test

microbes were detected in the bronchial lymph node on day 3. A particle larger than 1 μm in diameter administered into the trachea and bronchi was phagocytized by macrophages and carried to the lymph node. Since many test microbes remained in the lung (in trachea) on day 3, it was considered that the test microbes in the bronchial lymph node on day 3 was due to transferring excess microbes in the respiratory tract to the lymph nodes until day 3. Thereafter, since the test microbes were continuously transferred to the bronchial lymph node, the viable test microbe was persistently observed in the lymph node. The same tendency can be found in the report by McClintock et al. In other words, when spore-forming bacteria *Bacillus thuringiensis* and *Bacillus subtilis* were intratracheally administered to rats, a transient increase tendency of the microbes was noted in the lymph nodes. McClintock et al. also reported that, spore-forming bacteria did not completely disappeared from the body even 21 days after administration when administered intratracheally. Spore-forming bacteria have an extremely strong tolerance to external adverse conditions, and there were little possibilities that they were self-destructing in the animal body. In this study, the test microbes was not observed during the experimental period and a decreasing tendency was clearly recognized, it was considered that the test microbe have disappeared even though it takes time. From the above results, D747 was concluded to have no infectivity, pathogenicity, residual potential of viable microbe, or toxicity under conditions of this study.

I. REVIEWERS' CONCLUSIONS: No evidence of infectivity, pathogenicity or toxicity was found from intratracheal administration of 1.0×10^7 spores *Bacillus amyloliquefaciens* strain D747 to rats. There were no mortalities, no clinical effects from intratracheal administration and steady weight gain of treated rats throughout the study duration. Clearance was steady though residual viable cells remained in the lungs and trachea at day 60 on study termination, typical of spore forming bacteria administered to rats. There was no evidence of an increase in viable counts over time that would be indicative of a chronic infection. Since a pattern of clearance was shown it is assumed that the remaining viable cells were spores that take longer to be cleared by healthy immune systems.

DEFICIENCIES: None.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Type	Acute Oral Toxicity – Rats (OCSPP 870.1100).
MRID No.	481657-07.
Test Material	*Bacillus amyloliquefaciens* strain D747 CX-9030.
Study No.	13847-10.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Stillmeadow, Inc.; 12852 Park One Drive; Sugar Land, TX 77478.
Titles of Reports	*Bacillus subtilis* CX-9030 Acute Oral Toxicity Study (UDP) in Rats.
Author	Janice O. Kuhn, Ph.D., DABT.
Study Completed	April 22, 2010.
Study Summary	No evidence of toxicity was found from oral administration of 5000 mg/Kg *Bacillus amyloliquefaciens* strain D747 CX-9030 to rats in a 14 day acute toxicity study.
Classification	**ACCEPTABLE** - oral LD > 5000 mg/Kg – EPA Toxicity Category IV.
Good Laboratory Practice	Signed and dated GLP statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: *Bacillus amyloliquefaciens* strain D747.
   Description: *Bacillus amyloliquefaciens* strain D747 CX-9030.
   Lot/Batch #: 0102-64.
   Purity: $5x10^{10}$ CFU/mL.
   CAS #: n/a
   Storage conditions: Shipped and stored at room temperature.
   Microbiology: Certificate of analysis provided by study sponsor – the laboratory did not perform further characterization.

2. Sample Preparation: The test substance was used mixed at 40% w/v in DI water and administered by oral gavage at 12.5 mL/Kg corresponding to 5,000 mg/Kg.

3. Controls: there were no control groups.

4. Test animals: Rat
   Species: *Rattus norvegicus*
   Strain: Albino Sprague Dawley rats.
   Age/weight at dosing: Approximately 8 weeks old; 160-172 g (females) at dosing; none varied more than 20% from the mean weight.
   Source: Texas Animal Specialties, Humble, TX.
   Housing: Stainless steel cages, 1 rat/cage.
   Diet: PMI Feeds Inc.™ Formulab #5008, ad libitum.
   Water: Municipal tap water, ad libitum.
   Environmental conditions: Temperature: 20-23°C
   Humidity: 30-84%
   Air changes: Not specified.
   Photoperiod: 12 hrs dark / 12 hrs light
   Acclimation period: 5 days

B. STUDY DESIGN and METHODS:

1. In life dates: Start: 23-25 March 2010; End: 06-08 April 2010

2. Preliminary Challenge Assay: Performed on one rat, followed by treatment of remaining two rats.

3. Animal assignment and treatment: All animals were fasted starting the evening prior (16 hours) to the day of dosing. Food, but not water, was withheld, and rats were fed after dosing. A test substance dose group of three females were treated once with the test substance (5000 mg/Kg) administered by oral gavage.
4. Clinical Observations and Body Weights: Observations were made periodically on the day of dosing (at least 3x), then daily for 14 days.
5. Feed Consumption: Feed consumption was not measured.
6. Necropsy and Organ Weight Determination: At necropsy animals were examined grossly.
7. Microbial Enumeration: This component was not measured.
8. Sensitivity of Detection: n/a.
9. Statistics: There were no clinical signs or treatment-related mortalities, so statistics were not required to calculate the LD_{50}.

II. RESULTS AND DISCUSSION:
A. MORTALITY: There were no mortalities. The oral LD > 5000 mg/Kg.
B. CLINICAL OBSERVATIONS: No adverse clinical signs were observed during the 14 day observation period.
C. BODY WEIGHT: All animals gained weight during the study. Body weights are presented in Table 1.

Table 1. Body weight gain in rats treated with *Bacillus amyloliquefaciens* strain D747 CX-9030.

Group	Dose	Sex	Animal	Body weight (g)		
				Day 0	Day 7	Day 14
Live test substance	5000 mg/Kg	Female	261	172	196	211
			262	160	199	216
			263	165	202	227

D. FEED CONSUMPTION: Feed consumption was not measured.
E. NECROPSY: No abnormalities noted.
F. ORGAN WEIGHTS: Not measured.
G. MICROBIAL ENUMERATION: Not measured.
H. STUDY AUTHORS' CONCLUSIONS: The test substance, *Bacillus subtilis* CX-9030, was evaluated for its acute toxicity potential when administered to albino rats. The acute oral LD_{50} is estimated to be greater than 5000 mg/Kg in females.
I. REVIEWERS' CONCLUSIONS: No evidence of toxicity was found from oral administration of 5000 mg/Kg *Bacillus amyloliquefaciens* strain D747 CX-9030 to rats in a 14 day acute toxicity study.

DEFICIENCIES: None.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Type	Acute Dermal Toxicity – Rats (OCSPP 870.1200).
MRID No.	481657-08.
Test Material	*Bacillus amyloliquefaciens* strain D747 CX-9030.
Study No.	13848-10.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Stillmeadow, Inc.; 12852 Park One Drive; Sugar Land, TX 77478.
Titles of Reports	*Bacillus subtilis* CX-9030 Acute Dermal Toxicity Study in Rats.
Author	Janice O. Kuhn, Ph.D., DABT.
Study Completed	April 20, 2010.
Study Summary	No evidence of toxicity was found from dermal administration of 5050 mg/Kg *Bacillus amyloliquefaciens* strain D747 CX-9030 to rats in a 14 day acute toxicity study.
Classification	**ACCEPTABLE** - dermal LD > 5050 mg/Kg – EPA Toxicity Category IV.
Good Laboratory Practice	Signed and dated GLP statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: *Bacillus amyloliquefaciens* strain D747.
   Description: *Bacillus amyloliquefaciens* strain D747 CX-9030.
   Lot/Batch #: 0102-64.
   Purity: $5x10^{10}$ CFU/mL.
   CAS #: n/a
   Storage conditions: Shipped and stored at room temperature.
   Microbiology: Certificate of analysis provided by study sponsor – the laboratory did not perform further characterization.

2. Sample Preparation: The test substance was used mixed at 40% w/v in DI water and administered by oral gavage at 12.5 mL/Kg corresponding to 5,000 mg/Kg.

3. Controls: there were no control groups.

4. Test animals: Rat
   Species: *Rattus norvegicus*
   Strain: Albino Sprague Dawley rats.
   Age/weight at dosing: Approximately 8 weeks old; 275-295 g (males) and 183-204 g (females) at dosing; none varied more than 20% from the mean weight.
   Source: Texas Animal Specialties, Humble, TX.
   Housing: Stainless steel cages, 1 rat/cage.
   Diet: PMI Feeds Inc.™ Formulab #5008, ad libitum.
   Water: Municipal tap water, ad libitum.
   Environmental conditions: Temperature: 20-23°C; Humidity: 30-78%; Air changes: Not specified.; Photoperiod: 12 hrs dark / 12 hrs light
   Acclimation period: 5 days

B. STUDY DESIGN and METHODS:

1. In life dates: Start: 18 March 2010; End: 01 April 2010

2. Preliminary Challenge Assay: not done.

3. Animal assignment and treatment: All animals were fasted starting the evening prior (16 hours) to the day of dosing. Food, but not water, was withheld, and rats were fed after dosing. The dorsal surface of the trunk was clipped of hair to not less than 10% of surface area and animals were examined for pre-existing skin irritation or defects. A test substance dose group of ten rats (5/sex) were treated once with the test substance (5050 mg/Kg) of diluted test substance (1.0 mL/g) spread over the skin in a thin layer, then covered with a 2x4" gauze with tape wrap. The gauze was removed after 24 hours and the test sites washed with room temperature water.
4. Clinical Observations and Body Weights: Observations were made periodically on the day of dosing (at least 3x), then daily for 14 days.
5. Feed Consumption: Feed consumption was not measured.
6. Necropsy and Organ Weight Determination: At necropsy animals were examined grossly.
7. Microbial Enumeration: This component was not measured.
8. Sensitivity of Detection: n/a.
9. Statistics: There were no clinical signs or treatment-related mortalities, so statistics were not required to calculate the LD_{50}.

II. RESULTS AND DISCUSSION:
A. MORTALITY: There were no mortalities. The oral LD > 5050 mg/Kg.
B. CLINICAL OBSERVATIONS: No adverse clinical signs were observed during the 14 day observation period.
C. BODY WEIGHT: All animals gained weight during the study. Body weights are presented in Table 1.

Table 1. Body weight gain in rats treated with *Bacillus amyloliquefaciens* strain D747 CX-9030.

Group	Dose	Sex	Animal	Body weight (g)		
				Day 0	Day 7	Day 14
Live test substance	5050 mg/Kg	Male	221	289	312	328
			222	275	294	320
			223	295	316	331
			224	292	325	338
			225	279	298	322
		Female	226	185	193	211
			227	187	197	214
			228	204	212	226
			229	183	194	218
			230	193	189	210

D. FEED CONSUMPTION: Feed consumption was not measured.
E. NECROPSY: No abnormalities noted.
F. ORGAN WEIGHTS: Not measured.
G. MICROBIAL ENUMERATION: Not measured.
H. STUDY AUTHORS' CONCLUSIONS: The test substance, *Bacillus subtilis* CX-9030, was evaluated for its acute dermal toxicity potential and relative skin irritancy when administered to albino rats. The acute oral LD_{50}, as indicated by the data, is greater than 5050 mg/Kg in males and females.
I. REVIEWERS' CONCLUSIONS: No evidence of toxicity was found from dermal administration of 5050 mg/Kg *Bacillus amyloliquefaciens* strain D747 CX-9030 to rats in a 14 day acute toxicity study.

DEFICIENCIES: None.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Type	Acute Inhalation Toxicity – Rats (OCSPP 870.1300).
MRID No.	481657-09.
Test Material	*Bacillus amyloliquefaciens* strain D747 CX-9030.
Study No.	13820-10.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Stillmeadow, Inc.; 12852 Park One Drive; Sugar Land, TX 77478.
Titles of Reports	*Bacillus subtilis* CX-9030 Acute Inhalation Toxicity Study in Rats.
Author	Andrew Doig, M.S.
Study Completed	May 11, 2010.
Study Summary	Slight toxicity lasting two days from 4-hour aerosol inhalation administration of 2.18 mg/L *Bacillus amyloliquefaciens* strain D747 CX-9030 was noted to rats in a 14 day acute toxicity study.
Classification	**ACCEPTABLE** - inhalation LC > 2.18 mg/L – EPA Toxicity Category IV.
Good Laboratory Practice	Signed and dated GLP statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: *Bacillus amyloliquefaciens* strain D747.
   Description: *Bacillus amyloliquefaciens* strain D747 CX-9030.
   Lot/Batch #: 0102-64.
   Purity: $5x10^{10}$ CFU/mL.
   CAS #: n/a
   Storage conditions: Shipped and stored at room temperature.
   Microbiology: Certificate of analysis provided by study sponsor – the laboratory did not perform further characterization.
2. Sample Preparation: The test substance was ground for 6 hours in a U.S. Stonewear grinder to a fine powder.
3. Controls: there were no control groups.
4. Test animals: Rat
   Species: *Rattus norvegicus*
   Strain: Albino Sprague Dawley rats.
   Age/weight at dosing: Approximately 8 weeks old; 290-338 g (males) and 170-210 g (females) at dosing; none varied more than 20% from the mean weight.
   Source: Texas Animal Specialties, Humble, TX.
   Housing: Stainless steel cages, 1 rat/cage.
   Diet: PMI Feeds Inc.™ Formulab #5008, ad libitum.
   Water: Municipal tap water, ad libitum.
   Environmental conditions: Temperature: 20-23°C; Humidity: 30-78%; Air changes: 26.2 in the test chamber.; Photoperiod: 12 hrs dark / 12 hrs light
   Acclimation period: 5 days

B. STUDY DESIGN and METHODS:

1. In life dates: Start: 18 March 2010; End: 01 April 2010
2. Preliminary Challenge Assay: performed to determine the method that works best to aerosolize test substance.
3. Animal assignment and treatment: All animals were fasted starting the evening prior (16 hours) to the day of dosing. Food, but not water, was withheld, and rats were fed after dosing. A test substance dose group of ten rats

(5/sex) were treated with the test substance for four hours until a 99% concentration of test substance (2.18 mg/L) was obtained.
4. Clinical Observations and Body Weights: Observations were made periodically on the day of dosing, then daily for 14 days.
5. Feed Consumption: Feed consumption was not measured.
6. Necropsy and Organ Weight Determination: At necropsy animals were examined grossly.
7. Microbial Enumeration: This component was not measured.
8. Sensitivity of Detection: n/a.
9. Statistics: There were treatment-related mortalities, so statistics were not required to calculate the LD_{50}.

II. RESULTS AND DISCUSSION:
A. MORTALITY: There were no mortalities. The oral LD > 5050 mg/Kg.
B. CLINICAL OBSERVATIONS: Piloerection and decreased activity were noted in all animals 4.5 hours after exposure began lasting through day 2, with recovery by day 3.
C. BODY WEIGHT: All animals gained weight during the study. Body weights are presented in Table 1.

Table 1. Body weight gain in rats treated with *Bacillus amyloliquefaciens* strain D747 CX-9030.

Group	Dose	Sex	Animal	Body weight (g)		
				Day 0	Day 7	Day 14
Live test substance	2.18 mg/L	Male	191	315	334	350
			192	338	345	363
			193	299	316	335
			194	323	327	341
			195	290	311	349
		Female	196	170	188	222
			197	188	196	217
			198	189	201	209
			199	206	217	229
			200	210	219	234

D. FEED CONSUMPTION: Feed consumption was not measured.
E. NECROPSY: No abnormalities noted.
F. ORGAN WEIGHTS: Not measured.
G. MICROBIAL ENUMERATION: Not measured.
H. STUDY AUTHORS' CONCLUSIONS: *Bacillus subtilis* CX-9030 was evaluated for its acute inhalation toxicity potential in albino rats. As indicated by the data, the acute inhalation LC_{50} is greater than 2.18 mg/L in males and females.
I. REVIEWERS' CONCLUSIONS: Slight toxicity lasting two days from 4-hour aerosol inhalation administration of 2.18 mg/L *Bacillus amyloliquefaciens* strain D747 CX-9030 was noted to rats in a 14 day acute toxicity study.
DEFICIENCIES: None.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Type	Acute Eye Irritation – Rabbit (OCSPP 870.2400).
MRID No.	481657-10.
Test Material	*Bacillus amyloliquefaciens* strain D747 CX-9030.
Study No.	13821-10.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Stillmeadow, Inc.; 12852 Park One Drive; Sugar Land, TX 77478.
Titles of Reports	Bacillus subtilis CX-9030 Acute Eye Irritation Study in Rabbits.
Author	Janice O. Kuhn, Ph.D., DABT.
Study Completed	April 8, 2010.
Study Summary	The maximum average irritation score of 18.3 obtained 1 hour after treatment declined to 17.33 after 24 hours, 2 after 48 hours and 0 after 72 hours following ocular administration of 0.1 mL *Bacillus amyloliquefaciens* strain D747 to New Zealand White rabbits in a 72 hour observation period.
Classification	**ACCEPTABLE** – mildly-irritating – EPA Toxicity Category III.
Good Laboratory Practice	Signed and dated GLP statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: *Bacillus amyloliquefaciens* strain D747.
   - Description: *Bacillus amyloliquefaciens* strain D747 CX-9030.
   - Lot/Batch #: 0102-64.
   - Purity: $5x10^{10}$ CFU/mL.
   - CAS #: n/a
   - Storage conditions: Shipped and stored at room temperature.
   - Microbiology: Certificate of analysis provided by study sponsor – the laboratory did not perform further characterization.

2. Sample Preparation: The test substance was used as supplied by the study sponsor: 88.3 mg equivalent to 0.1 mL was used for dosing.

3. Controls: A naive control group was not included.

4. Test animals: Rabbit
   - Species: Not stated (*Oryctolagus cuniculus*)
   - Strain: New Zealand White albino rabbits.
   - Age/weight at dosing: Rabbits were approximately 4 months old; 2.975 Kg (male) and 2.400-2.725 Kg (females).
   - Source: Myrtle's Rabbitry, Inc., Thompson Station, TN.
   - Housing: Stainless steel cages, 1 rabbit/cage.
   - Diet: PMI Feeds, Inc.™ Lab Rabbit Diet #5321, ~8 oz. daily.
   - Water: Municipal water, ad libitum.
   - Environmental conditions:
     - Temperature: 19-23°C
     - Humidity: 25-83%
     - Air changes: 10-12 per hour.
     - Photoperiod: 12 hrs dark / 12 hrs light
   - Acclimation period: 5 days

B. STUDY DESIGN and METHODS:

1. In life dates: Start: 22 March 2010; End: 25 March 2010
2. Preliminary Challenge Assay: Not performed.

3. Animal assignment and treatment: Live test substance was applied at 0.1 mL undiluted to the conjunctival sac of the right eye to three animals (one male and two female rabbits); the untreated left eye served as a control. The treated eye was rinsed after 24 hours for approximately 60 seconds using room temperature water.
4. Clinical Observations and Body Weights: Observations were made at 1 hour then daily following dosing; fluorescein was used and the eyes scored for lesions and opacity.
5. Feed Consumption: Feed consumption was not measured.
6. Necropsy and Organ Weight Determination: Necropsy was not performed.
7. Microbial Enumeration: This component was not measured.
8. Sensitivity of Detection: n/a.
9. Statistics: There were no treatment-related mortalities, so statistics were not required to calculate the LD_{50}.

II. RESULTS AND DISCUSSION:
A. MORTALITY: There were no mortalities. The ocular LD > 0.1 mL.
B. CLINICAL OBSERVATIONS: Ocular or non-ocular adverse effects were noted.
C. BODY WEIGHT: Not measured.

TABLE 1. Individual Male (M) and Female (F) Eye Scores w/ Time: Cornea (A=Density of Opacity, B=Area of Opacity)

Animal No.		1 hour		24 hours		48 hours		72 hours		4 days		7 days		10 days		14 days		17 days		21 days	
		A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B
Non-washed eyes																					
M	4732	+	1	1	1	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
F	4727	+	1	1	1	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
	4733	+	1	1	2	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
Washed eyes																					
M	4732	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
F	4727	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
	4733	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd

TABLE 2. Summary of Eye Irritation Scores with Time: Conjunctiva and Iris

Score Conditions	1 hour	24 hours	48 hours	72 hours	4 days	7 days	10 days	14 days	17 days	21 days
Non-washed eyes										
Conjunctiva										
Erythema	6	7	3	0	nd	nd	nd	nd	nd	nd
Chemosis	8	5	0	0	nd	nd	nd	nd	nd	nd
Discharge	6	4	0	0	nd	nd	nd	nd	nd	nd
Iris	3	0	0	0	nd	nd	nd	nd	nd	nd
Washed eyes										
Conjunctiva										
Erythema	0	0	0	0	nd	nd	nd	nd	nd	nd
Chemosis	0	0	0	0	nd	nd	nd	nd	nd	nd
Discharge	0	0	0	0	nd	nd	nd	nd	nd	nd
Iris	0	0	0	0	nd	nd	nd	nd	nd	nd

Irritation score is based on the Draize Method (1959); nd = not done.

TABLE 3. Summary of Average and Primary Eye Irritation Scores with Time

Animal #		1 hour	24 hour	48 hour	72 hour	4 day	7 day	10 day	14 day	17 day	21 day
Non-washed eyes											
M	4732	19	17	2	0	nd	nd	nd	nd	nd	nd
F	4727	17	13	2	0	nd	nd	nd	nd	nd	nd
	4733	19	22	2	0	nd	nd	nd	nd	nd	nd
Average		18.33	17.33	2	0	nd	nd	nd	nd	nd	nd
Washed eyes											
M	4732	0	0	0	0	nd	nd	nd	nd	nd	nd
F	4727	0	0	0	0	nd	nd	nd	nd	nd	nd
	4733	0	0	0	0	nd	nd	nd	nd	nd	nd
Average		0	0	0	0	nd	nd	nd	nd	nd	nd

D. FEED CONSUMPTION: Feed consumption was not measured.
E. NECROPSY: Not performed.
F. ORGAN WEIGHTS: Not measured.
G. MICROBIAL ENUMERATION: Not measured.
H. STUDY AUTHORS' CONCLUSIONS: The maximum average irritation score of 18.3 obtained 1 hour after treatment was used to rate *Bacillus subtilis* CX-9030 mildly irritating. Fluorescein staining was observed in three eyes at 24 hours after treatment and was not observed in any eyes at 48 hours after treatment. Toxicity categories are determined by the presence and duration of corneal involvement, iridic irritation, and positive conjunctival irritation. Any corneal involvement or iridic irritation with a score of 1 or more is considered positive. Any conjunctival irritation (redness or chemosis) with a score of 2 or more is considered positive.
I. REVIEWERS' CONCLUSIONS: The maximum average irritation score of 18.3 obtained 1 hour after treatment declined to 17.33 after 24 hours, 2 after 48 hours and 0 after 72 hours following ocular administration of 0.1 mL *Bacillus amyloliquefaciens* strain D747 to New Zealand White rabbits in a 72 hour observation period.

DEFICIENCIES: None.

TABLE 4: Grading Ocular Lesions based on the Draize Method.

CORNEA	Opacity - degree of density	None	0	
		Scattered or diffuse area; details of iris are clearly visible	* 1	+
		Easily discernible translucent areas; details of iris slightly obscured	* 2	
		Opalescent areas; no details of iris visible, size of pupil barely discernible	* 3	
		Opaque; iris invisible	* 4	
	Area of cornea involved	None	0	
		1-25 %	1	
		26-50 %	2	
		51-75 %	3	
		76-100 %	4	
	The opacity reading is taken at the most dense area.			
	Cornea score = (Opacity points) * (Area of cornea involved points) * 5; minimum 0, maximum 80.			
IRIS	No change from normal		0	
	Iris still reacts to light (sluggish response is positive). Any or all of the following or any combination: - Folds above normal - Congestion - Swelling - Circumcorneal injection		* 1	
	Any or all of the following: - No reaction to light - Hemorrhage - Gross destruction		* 2	
	Iris score = (Iris points) * 5; minimum 0, maximum 10.			
CONJUNCTIVAE	Redness / Erythema	Normal	0	
		Vessels definitely injected above normal	1	
		More diffuse deeper crimson red individual vessels not easily discernible	* 2	
		Diffuse beefy red	* 3	
	Chemosis	Normal	0	
		Any swelling above normal including the nictitating membrane	1	
		Obvious swelling with partial eversion of lids	* 2	
		Swelling with lids about half closed	* 3	
		Swelling with lids about half closed to completely closed	* 4	
	Discharge	Normal	0	
		Any amount different from normal (does not include the small amount observed in inner canthus of normal animals)	1	
		Discharge with moistening of the lids and hairs just adjacent to the lids	2	
		Discharge with moistening of the lids and considerable area around the eyes	3	
	Redness refers to palpebral conjunctivae only (The palpebral conjunctiva covers the posterior surface of the eyelid).			
	Conjunctivae score = (Redness points) + (Chemosis points) + (Discharge points) * 2; minimum 0, maximum 20.			
Total score = (Corneal score) + (Iris score) + (Conjunctivae score); minimum 0, maximum 110.				

* Significant or notable irritation per OCSPP Guideline 870.2400.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Type	Acute Dermal Irritation – Rabbits (OCSPP 870.2500).
MRID No.	481657-11.
Test Material	*Bacillus amyloliquefaciens* strain D747 CX-9030.
Study No.	13822-10.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Stillmeadow, Inc.; 12852 Park One Drive; Sugar Land, TX 77478.
Titles of Reports	*Bacillus subtilis* CX-9030 Acute Dermal Irritation Study in Rabbits.
Author	Janice O. Kuhn, Ph.D., DABT.
Study Completed	April 19, 2010.
Study Summary	No evidence of irritation was found from dermal administration of 500 mg *Bacillus amyloliquefaciens* strain D747 CX-9030 to rabbits during a 72 hour exposure and observation period. The dermal irritation score for *Bacillus amyloliquefaciens* strain D747 CX-9030 was 0.00.
Classification	**ACCEPTABLE** – essentially non-irritating – EPA Toxicity Category IV.
Good Laboratory Practice	Signed and dated GLP statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: *Bacillus amyloliquefaciens* strain D747.
   - Description: *Bacillus amyloliquefaciens* strain D747 CX-9030.
   - Lot/Batch #: 0102-64.
   - Purity: $5x10^{10}$ CFU/mL.
   - CAS #: n/a
   - Storage conditions: Shipped and stored at room temperature.
   - Microbiology: Certificate of analysis provided by study sponsor – the laboratory did not perform further characterization.
2. Sample Preparation: 500 mg test substance moistened in 0.5 mL DI water was used for dosing.
3. Controls: A naive control group was not included.
4. Test animals: Rabbit
   - Species: Not stated (*Oryctolagus cuniculus*)
   - Strain: New Zealand White albino rabbits.
   - Age/weight at dosing: Rabbits were approximately 4 months old; 2.450 Kg (male) and 2.675-2.700 Kg (females).
   - Source: Myrtle's Rabbitry, Inc., Thompson Station, TN.
   - Housing: Stainless steel cages, 1 rabbit/cage.
   - Diet: PMI Feeds, Inc.™ Lab Rabbit Diet #5321, ~8 oz. daily.
   - Water: Municipal water, ad libitum.
   - Environmental conditions: Temperature: 19-23°C; Humidity: 25-83%; Air changes: 10-12 per hour.; Photoperiod: 12 hrs dark / 12 hrs light
   - Acclimation period: 5 days

B. STUDY DESIGN and METHODS:

1. In life dates: Start: 15-16 March 2010; End: 19 March 2010
2. Preliminary Challenge Assay: performed on one animal 24 hours prior to treating other animals.

3. Animal assignment and treatment: All animals had fur shaved from the dorsal trunk in an area 8 cm^2 the day of dosing. Live test substance was applied as 500 mg in 0.5 mL water to three animals (one male and two female rabbits) and the area was wrapped with 2.5 cm^2 gauze dressing and elastic adhesive bandage for 4 hours, after which the dressing and bandage were removed, the area rinsed with water then wiped to remove residues.
4. Clinical Observations and Body Weights: Observations made before the first hour then daily after dosing.
5. Feed Consumption: Feed consumption was not measured.
6. Necropsy and Organ Weight Determination: not performed.
7. Microbial Enumeration: This component was not measured.
8. Sensitivity of Detection: n/a.
9. Statistics: There were no clinical signs or treatment-related mortalities, so statistics were not required to calculate the LD_{50} though they were used to report differences in organ and body weights.

II. RESULTS AND DISCUSSION:
A. MORTALITY: There were no mortalities; dermal LD > 500 mg.
B. CLINICAL OBSERVATIONS: No signs of dermal irritation, edema or eschar were observed.
C. BODY WEIGHT: Not measured.
D. FEED CONSUMPTION: Feed consumption was not measured.
E. NECROPSY: Not performed.
F. ORGAN WEIGHTS: Not measured.
G. MICROBIAL ENUMERATION: Not measured.
H. STUDY AUTHORS' CONCLUSIONS: The primary irritation index of 0.0 out of a possible 8.0 was obtained from the observations at 1, 24, 48 and 72 hours, and was used to give *Bacillus subtilis* CX-9030 a descriptive rating of non-irritating. Based on the 72-hour observations only, *Bacillus subtilis* CX-9030 is assigned to toxicity category IV.
I. REVIEWERS' CONCLUSIONS: No evidence of irritation was found from dermal administration of 500 mg *Bacillus amyloliquefaciens* strain D747 CX-9030 to rabbits during a 72 hour exposure and observation period. The dermal irritation score for *Bacillus amyloliquefaciens* strain D747 CX-9030 was 0.00.

DEFICIENCIES: None.

Appendix I: Description of Skin Reactions

Evaluation of Skin Reactions Score

Erythema and eschar formation
No erythema 0
Very slight erythema (barely perceptible) 1
Well-defined erythema 2
Moderate to severe erythema 3
Severe erythema (beet redness) to slight eschar formation (injuries in depth) 4

Edema Formation
No edema 0
Very slight edema (barely perceptible) 1
Slight edema (edges of area well-defined by definite raising) 2
Moderate edema (raised approximately 1 mm) 3
Severe edema (raised more than 1 mm and extending beyond the area of exposure) 4

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Type	Acute Eye Irritation – Rabbit (OCSPP 870.2400).
MRID No.	481655-05.
Test Material	*Bacillus amyloliquefaciens* strain D747 CX-9032.
Study No.	14046-10.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Stillmeadow, Inc.; 12852 Park One Drive; Sugar Land, TX 77478.
Titles of Reports	*Bacillus subtilis* CX-9030 Acute Eye Irritation Study in Rabbits.
Author	Janice O. Kuhn, Ph.D., DABT.
Study Completed	June 22, 2010.
Study Summary	The maximum average irritation score of 0.667 obtained 1 hour after treatment declined to 0 after 24 hours following ocular administration of 0.1 mL *Bacillus amyloliquefaciens* strain D747 CX-9032 to New Zealand White rabbits in a 72 hour observation period.
Classification	**SUPPLEMENTAL but upgradeable** – potentially practically non-irritating – EPA Toxicity Category IV; the test material described here as 7% ai should be clarified how it differs from the CSF provided.
Good Laboratory Practice	Signed and dated GLP statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: *Bacillus amyloliquefaciens* strain D747 CX-9025.
   Description: *Bacillus amyloliquefaciens* strain D747 CX-9032.
   Lot/Batch #: 0104-23-8.
   Purity: 7% active ingredient.
   CAS #: n/a
   Storage conditions: Shipped and stored at room temperature.
   Microbiology: Certificate of analysis provided by study sponsor – the laboratory did not perform further characterization.
2. Sample Preparation: 88.3 mg equivalent to 0.1 mL was used for dosing.
3. Controls: A naive control group was not included.
4. Test animals: Rabbit
   Species: Not stated (*Oryctolagus cuniculus*)
   Strain: New Zealand White albino rabbits.
   Age/weight at dosing: Rabbits were approximately 4 months old; 2.550-3.175 Kg (1 male and 2 females).
   Source: Myrtle's Rabbitry, Inc., Thompson Station, TN.
   Housing: Stainless steel cages, 1 rabbit/cage.
   Diet: PMI Feeds, Inc.™ Lab Rabbit Diet #5321, ~8 oz. daily.
   Water: Municipal water, ad libitum.
   Environmental conditions: Temperature: 19-23°C
   Humidity: 59-95%
   Air changes: 10-12 per hour.
   Photoperiod: 12 hrs dark / 12 hrs light
   Acclimation period: 5 days

B. STUDY DESIGN and METHODS:

1. In life dates: Start: 22 March 2010; End: 25 March 2010
2. Preliminary Challenge Assay: Not performed.

3. Animal assignment and treatment: Test substance was applied at 0.1 mL (pH 4.29) undiluted to the conjunctival sac of the right eye to three animals (one male and two female rabbits).
4. Clinical Observations and Body Weights: Observations were made at 1 hour then daily following dosing; fluorescein was used and the eyes scored for lesions and opacity.
5. Feed Consumption: Feed consumption was not measured.
6. Necropsy and Organ Weight Determination: Necropsy was not performed.
7. Microbial Enumeration: This component was not measured.
8. Sensitivity of Detection: n/a.
9. Statistics: There were no treatment-related mortalities, so statistics were not required to calculate the LD_{50}.

II. RESULTS AND DISCUSSION:
A. MORTALITY: There were no mortalities. The ocular LD > 0.1 mL.
B. CLINICAL OBSERVATIONS: Ocular or non-ocular adverse effects were noted.
C. BODY WEIGHT: Not measured.

TABLE 1. Individual Male (M) and Female (F) Eye Scores w/ Time: Cornea (A=Density of Opacity, B=Area of Opacity)

Animal No.		1 hour		24 hours		48 hours		72 hours		4 days		7 days		10 days		14 days		17 days		21 days	
		A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B
Non-washed eyes																					
M	4872	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
F	4873	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
	4877	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
Washed eyes																					
M	4872	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
F	4873	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd
	4877	0	0	0	0	0	0	0	0	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd	nd

TABLE 2. Summary of Eye Irritation Scores with Time: Conjunctiva and Iris

Score Conditions	1 hour	24 hours	48 hours	72 hours	4 days	7 days	10 days	14 days	17 days	21 days
Non-washed eyes										
Conjunctiva										
Erythema	0	0	0	0	nd	nd	nd	nd	nd	nd
Chemosis	0	0	0	0	nd	nd	nd	nd	nd	nd
Discharge	1	0	0	0	nd	nd	nd	nd	nd	nd
Iris	0	0	0	0	nd	nd	nd	nd	nd	nd
Washed eyes										
Conjunctiva										
Erythema	0	0	0	0	nd	nd	nd	nd	nd	nd
Chemosis	0	0	0	0	nd	nd	nd	nd	nd	nd
Discharge	0	0	0	0	nd	nd	nd	nd	nd	nd
Iris	0	0	0	0	nd	nd	nd	nd	nd	nd

Irritation score is based on the Draize Method (1959); nd = not done.

TABLE 3. Summary of Average and Primary Eye Irritation Scores with Time

Animal #		1 hour	24 hour	48 hour	72 hour	4 day	7 day	10 day	14 day	17 day	21 day
Non-washed eyes											
M	4872	0	0	0	0	nd	nd	nd	nd	nd	nd
F	4873	2	0	0	0	nd	nd	nd	nd	nd	nd
	4877	0	0	0	0	nd	nd	nd	nd	nd	nd
Average		0.667	0	0	0	nd	nd	nd	nd	nd	nd
Washed eyes											
M	4872	0	0	0	0	nd	nd	nd	nd	nd	nd
F	4873	0	0	0	0	nd	nd	nd	nd	nd	nd
	4877	0	0	0	0	nd	nd	nd	nd	nd	nd
Average		0	0	0	0	nd	nd	nd	nd	nd	nd

D. FEED CONSUMPTION: Feed consumption was not measured.

E. NECROPSY: Not performed.
F. ORGAN WEIGHTS: Not measured.
G. MICROBIAL ENUMERATION: Not measured.
H. STUDY AUTHORS' CONCLUSIONS: The maximum average irritation score of 0.7, obtained 1 hour after treatment, was used to rate *Bacillus subtilis* CX-9032 practically non-irritating. Fluorescein staining did not occur in any eyes. Toxicity categories are determined by the presence and duration of corneal involvement, iridic irritation, and positive conjunctival irritation. Any corneal involvement or iridic irritation with a score of 1 or more is considered positive. Any conjunctival irritation (redness or chemosis) with a score of 2 or more is considered positive.
I. REVIEWERS' CONCLUSIONS: The maximum average irritation score of 0.667 obtained 1 hour after treatment declined to 0 after 24 hours following ocular administration of 0.1 mL *Bacillus amyloliquefaciens* strain D747 CX-9032 to New Zealand White rabbits in a 72 hour observation period.

DEFICIENCIES: None.

TABLE 4: Grading Ocular Lesions based on the Draize Method.

CORNEA	Opacity - degree of density	None	0
		Scattered or diffuse area; details of iris are clearly visible	* 1 +
		Easily discernible translucent areas; details of iris slightly obscured	* 2
		Opalescent areas; no details of iris visible, size of pupil barely discernible	* 3
		Opaque; iris invisible	* 4
	Area of cornea involved	None	0
		1-25 %	1
		26-50 %	2
		51-75 %	3
		76-100 %	4
	The opacity reading is taken at the most dense area.		
	Cornea score = (Opacity points) * (Area of cornea involved points) * 5; minimum 0, maximum 80.		
IRIS	No change from normal		0
	Iris still reacts to light (sluggish response is positive). Any or all of the following or any combination: ~ Folds above normal ~ Congestion ~ Swelling ~ Circumcorneal injection		* 1
	Any or all of the following: ~ No reaction to light ~ Hemorrhage ~ Gross destruction		* 2
	Iris score = (Iris points) * 5; minimum 0, maximum 10.		
CONJUNCTIVAE	Redness / Erythema	Normal	0
		Vessels definitely injected above normal	1
		More diffuse deeper crimson red individual vessels not easily discernible	* 2
		Diffuse beety red	* 3
	Chemosis	Normal	0
		Any swelling above normal including the nictitating membrane	1
		Obvious swelling with partial eversion of lids	* 2
		Swelling with lids about half closed	* 3
		Swelling with lids about half closed to completely closed	* 4
	Discharge	Normal	0
		Any amount different from normal (does not include the small amount observed in inner canthus of normal animals)	1
		Discharge with moistening of the lids and hairs just adjacent to the lids	2
		Discharge with moistening of the lids and considerable area around the eyes	3
	Redness refers to palpebral conjunctivae only (The palpebral conjunctiva covers the posterior surface of the eyelid).		
	Conjunctivae score = (Redness points) + (Chemosis points) + (Discharge points) * 2; minimum 0, maximum 20.		
Total score = (Corneal score) + (Iris score) + (Conjunctivae score); minimum 0, maximum 110.			

* Significant or notable irritation per OCSPP Guideline 870.2400.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Type	Acute Dermal Irritation – Rabbits (OCSPP 870.2500).
MRID No.	481655-06.
Test Material	*Bacillus amyloliquefaciens* strain D747 CX-9032.
Study No.	14047-10.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Stillmeadow, Inc.; 12852 Park One Drive; Sugar Land, TX 77478.
Titles of Reports	*Bacillus subtilis* CX-9032 Acute Dermal Irritation Study in Rabbits.
Author	Janice O. Kuhn, Ph.D., DABT.
Study Completed	June 15, 2010.
Study Summary	No evidence of irritation was found from dermal administration of 0.5 mL undiluted *Bacillus amyloliquefaciens* strain D747 CX-9032 to rabbits during a 72 hour exposure and observation period. The dermal irritation score for *Bacillus amyloliquefaciens* strain D747 CX-9032 was 0.00.
Classification	**SUPPLEMENTAL but upgradeable** – potentially essentially non-irritating – EPA Toxicity Category IV; the test material described here as 7% ai should be clarified how it differs from the CSF provided.
Good Laboratory Practice	Signed and dated GLP statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: *Bacillus amyloliquefaciens* strain D747.
   - Description: *Bacillus amyloliquefaciens* strain D747 CX-9032.
   - Lot/Batch #: 0104-23-8.
   - Purity: 7% active ingredient.
   - CAS #: n/a
   - Storage conditions: Shipped and stored at room temperature.
   - Microbiology: Certificate of analysis provided by study sponsor – the laboratory did not perform further characterization.
2. Sample Preparation: 0.5 mL was used for dosing.
3. Controls: A naive control group was not included.
4. Test animals: Rabbit
   - Species: Not stated (*Oryctolagus cuniculus*)
   - Strain: New Zealand White albino rabbits.
   - Age/weight at dosing: Rabbits were approximately 4 months old; 3.150-3.200 Kg (1 male and 2 females).
   - Source: Myrtle's Rabbitry, Inc., Thompson Station, TN.
   - Housing: Stainless steel cages, 1 rabbit/cage.
   - Diet: PMI Feeds, Inc.™ Lab Rabbit Diet #5321, ~8 oz. daily.
   - Water: Municipal water, ad libitum.
   - Environmental conditions:
     - Temperature: 19-23°C
     - Humidity: 55-95%
     - Air changes: 10-12 per hour.
     - Photoperiod: 12 hrs dark / 12 hrs light
   - Acclimation period: 5 days

B. STUDY DESIGN and METHODS:

1. In life dates: Start: 24 May 2010; End: 28 May 2010
2. Preliminary Challenge Assay: performed on one animal 24 hours prior to treating other animals.

3. Animal assignment and treatment: All animals had fur shaved from the dorsal trunk in an area 8 cm^2 the day of dosing. Live test substance was applied at 0.5 mL undiluted (pH 4.29) to three animals (one male and two female rabbits) and the area was wrapped with 2.5 cm^2 gauze dressing and elastic adhesive bandage for 4 hours, after which the dressing and bandage were removed, the area rinsed with water then wiped to remove residues.
4. Clinical Observations and Body Weights: Observations made before the first hour then daily after dosing.
5. Feed Consumption: Feed consumption was not measured.
6. Necropsy and Organ Weight Determination: not performed.
7. Microbial Enumeration: This component was not measured.
8. Sensitivity of Detection: n/a.
9. Statistics: There were no clinical signs or treatment-related mortalities, so statistics were not required to calculate the LD_{50} though they were used to report differences in organ and body weights.

II. RESULTS AND DISCUSSION:
A. MORTALITY: There were no mortalities; dermal LD > 0.5 mL.
B. CLINICAL OBSERVATIONS: No signs of dermal irritation, edema or eschar were observed.
C. BODY WEIGHT: Not measured.
D. FEED CONSUMPTION: Feed consumption was not measured.
E. NECROPSY: Not performed.
F. ORGAN WEIGHTS: Not measured.
G. MICROBIAL ENUMERATION: Not measured.
H. STUDY AUTHORS' CONCLUSIONS: The primary irritation index of 0.0 out of a possible 8.0 was obtained from the observations at 1, 24, 48 and 72 hours, and was used to give *Bacillus subtilis* CX-9032 a descriptive rating of non-irritating. Based on the 72-hour observations only, *Bacillus subtilis* CX-9032 is assigned to toxicity category IV.
I. REVIEWERS' CONCLUSIONS: No evidence of irritation was found from dermal administration of 0.5 mL undiluted *Bacillus amyloliquefaciens* strain D747 CX-9032 to rabbits during a 72 hour exposure and observation period. The dermal irritation score for *Bacillus amyloliquefaciens* strain D747 CX-9032 was 0.00.

DEFICIENCIES: None.

Appendix I: Description of Skin Reactions

Evaluation of Skin Reactions Score

Erythema and eschar formation
No erythema 0
Very slight erythema (barely perceptible) 1
Well-defined erythema 2
Moderate to severe erythema 3
Severe erythema (beet redness) to slight eschar formation (injuries in depth) 4

Edema Formation
No edema 0
Very slight edema (barely perceptible) 1
Slight edema (edges of area well-defined by definite raising) 2
Moderate edema (raised approximately 1 mm) 3
Severe edema (raised more than 1 mm and extending beyond the area of exposure) 4

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Type	Waiver requests for: Acute Oral Toxicity (OCSPP 870.1100); Acute Dermal Toxicity (OCSPP 870.1200); Acute Inhalation Toxicity (OCSPP 870.1300); Hypersensitivity (OCSPP 885.3400).
MRID No.	481655-04.
Test Material	*Bacillus amyloliquefaciens* strain D747 CX-9032.
Study No.	None.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Titles of Reports	Request for no further testing.
Author	Christine A. Dively.
Studies Completed	June 16, 2010.
Study Summary	Oral exposure to the manufacturing use product showed no adverse effects including infectivity, pathogenicity and toxicity up to the limit dose. Dermal toxicity and irritation testing for the end-use products showed no adverse effects up to the limit doses. Pulmonary exposure to the manufacturing use product showed no adverse effects including infectivity, pathogenicity and toxicity though slight toxicity lasting 2 days from 4-hour aerosol inhalation administration of 2.18 mg/L, where inert ingredients were also present, was noted in another study. Inert ingredients all have existing appropriate food tolerance exemptions and most are listed as 40 CFR 180.950 minimal risk; no additional toxicity for oral, dermal or inhalation exposure is expected from the incremental testing of formulations with these inert ingredients added.
Classification	Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity – **ACCEPTABLE**; Hypersensitivity – **SUPPLEMENTAL** – not a required study.
Good Laboratory Practice	Study does not meet the requirements for 40 CFR Part 160 – waiver request, not a scientific study.

DISCUSSION: Oral exposure to the manufacturing use product showed no adverse effects including infectivity, pathogenicity and toxicity up to the limit dose. Dermal toxicity and irritation testing for the end-use products showed no adverse effects up to the limit doses. Pulmonary exposure to the manufacturing use product showed no adverse effects including infectivity, pathogenicity and toxicity though slight toxicity lasting 2 days from 4-hour aerosol inhalation administration of 2.18 mg/L, where inert ingredients were also present, was noted in another study. Inert ingredients all have existing appropriate food tolerance exemptions and most are listed as 40 CFR 180.950 minimal risk; no additional toxicity for oral, dermal or inhalation exposure is expected from the incremental testing of formulations with these inert ingredients added.

SUMMARY OF REVIEWED DATA:
STUDY TYPE: Acute Oral Toxicity / Pathogenicity – Rat.
OCSPP Guideline: 885.3050.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747.
MRID NO.: 481657-04.
DISCUSSION: No evidence of infectivity, pathogenicity or toxicity was found from oral administration of 1.0×10^8 CFU *Bacillus amyloliquefaciens* strain D747 to rats. Clearance from fecal material occurred by day 14 and no viable organisms were recovered from blood or any other organ or tissue.
CLASSIFICATION: ACCEPTABLE – oral LD > 1.0×10^8 CFU/rat – not infective, pathogenic or toxic.

STUDY TYPE: Acute Injection Toxicity / Pathogenicity – Rat.

OCSPP Guideline: 885.3200.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747.
MRID NO.: 481657-05.
DISCUSSION: No evidence of infectivity, pathogenicity or toxicity was found from intravenous administration of $1.0x10^7$ spores *Bacillus amyloliquefaciens* strain D747 to rats. There were no mortalities, no clinical effects from intravenous administration and steady weight gain of treated rats throughout the study duration. Clearance was steady though residual viable cells remained in the liver and spleen at day 60 on study termination, typical of spore forming bacteria administered to rats. There was no evidence of an increase in viable counts over time that would be indicative of a chronic infection. Since a pattern of clearance was shown it is assumed that the remaining viable cells were spores that take longer to be cleared by healthy immune systems.
CLASSIFICATION: ACCEPTABLE – intravenous LD > $1.0x10^7$ CFU/rat – not infective, pathogenic or toxic.

STUDY TYPE: Acute Pulmonary Toxicity / Pathogenicity – Rat.
OCSPP Guideline: 885.3150.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747.
MRID NO.: 481657-06.
DISCUSSION: No evidence of infectivity, pathogenicity or toxicity was found from intratracheal administration of $1.0x10^7$ spores *Bacillus amyloliquefaciens* strain D747 to rats. There were no mortalities, no clinical effects from intratracheal administration and steady weight gain of treated rats throughout the study duration. Clearance was steady though residual viable cells remained in the lungs and trachea at day 60 on study termination, typical of spore forming bacteria administered to rats. There was no evidence of an increase in viable counts over time that would be indicative of a chronic infection. Since a pattern of clearance was shown it is assumed that the remaining viable cells were spores that take longer to be cleared by healthy immune systems.
CLASSIFICATION: ACCEPTABLE – pulmonary LD > $1.0x10^7$ CFU/rat - not infective, pathogenic or toxic.

STUDY TYPE: Acute Oral Toxicity – Rats.
OCSPP Guideline: 870.1100.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9030.
MRID NO.: 481657-07.
DISCUSSION: No evidence of toxicity was found from oral administration of 5000 mg/Kg *Bacillus amyloliquefaciens* strain D747 CX-9030 to rats in a 14 day acute toxicity study.
CLASSIFICATION: ACCEPTABLE - oral LD > 5000 mg/Kg – EPA Toxicity Category IV.

STUDY TYPE: Acute Dermal Toxicity – Rabbits.
OCSPP Guideline: 870.1200.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9030.
MRID NO.: 481657-08.
DISCUSSION: No evidence of toxicity was found from dermal administration of 5050 mg/Kg *Bacillus amyloliquefaciens* strain D747 CX-9030 to rats in a 14 day acute toxicity study.
CLASSIFICATION: ACCEPTABLE - dermal LD > 5050 mg/Kg – EPA Toxicity Category IV.

STUDY TYPE: Acute Inhalation Toxicity – Rats.
OCSPP Guideline: 870.1300.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9030.
MRID NO.: 481657-09.
DISCUSSION: Slight toxicity lasting two days from 4-hour aerosol inhalation administration of 2.18 mg/L *Bacillus amyloliquefaciens* strain D747 CX-9030 was noted to rats in a 14 day acute toxicity study.
CLASSIFICATION: ACCEPTABLE - inhalation LC > 2.18 mg/L – EPA Toxicity Category IV.

STUDY TYPE: Acute Eye Irritation – Rabbit.
OCSPP Guideline: 870.2400.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9032.
MRID NO.: 481655-05.
DISCUSSION: The maximum average irritation score of 0.667 obtained 1 hour after treatment declined to 0 after 24 hours following ocular administration of 0.1 mL *Bacillus amyloliquefaciens* strain D747 CX-9032 to New Zealand White rabbits in a 72 hour observation period.
CLASSIFICATION: SUPPLEMENTAL but upgradeable – practically non-irritating – EPA Toxicity Category IV; the test material described here as 7% ai should be clarified how it differs from the CSF provided.

STUDY TYPE: Acute Dermal Irritation.
OCSPP Guideline: 870.2500.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9032.
MRID NO.: 481655-06.
DISCUSSION: No evidence of irritation was found from dermal administration of 0.5 mL undiluted *Bacillus amyloliquefaciens* strain D747 CX-9032 to rabbits during a 72 hour exposure and observation period. The dermal irritation score for *Bacillus amyloliquefaciens* strain D747 CX-9032 was 0.00.
CLASSIFICATION: SUPPLEMENTAL but upgradeable – essentially non-irritating – EPA Toxicity Category IV; the test material described here as 7% ai should be clarified how it differs from the CSF provided.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.
Secondary Review by: John L. Kough, Ph.D.

Study Types	FOOD TOLERANCE EXEMPTION PETITION.
MRID No.	None.
Test Material	*Bacillus amyloliquefaciens* strain D747.
Study No.	None.
Sponsor	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Testing Facility	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Title of Report	Notice of Filing Template.
Authors	Certis U.S.A., L.L.C.; 9145 Guilford Road, Suite 175; Columbia, MD 21046.
Study Completed	Unknown.
Study Summary	Based on extensive testing of the manufacturing use product and of end-use products containing the active ingredient, no toxicity, infectivity, pathogenicity or other adverse effects from dietary exposure to *Bacillus amyloliquefaciens* strain D747 are expected. *Bacillus* spp. including *Bacillus amyloliquefaciens* are commonly found in agricultural settings (i.e. soils) and are present on fresh produce of all kinds with no known adverse effects. The Manual of Clinical Microbiology (9th edition) mentions that dried food such as spices, milk powder and grains often contain large amounts of *Bacillus* spores. *Bacillus amyloliquefaciens* is not known to produce any mammalian toxins and no foodborne disease outbreaks associated with *Bacillus amyloliquefaciens* or toxin production from *Bacillus amyloliquefaciens* have been reported. Since *Bacillus amyloliquefaciens* is naturally present in soils, exposure to *Bacillus amyloliquefaciens* from surface and possibly groundwater can be expected. Water treatment processes should remove any *Bacillus amyloliquefaciens* present. No adverse effects are expected or have been reported from exposure to *Bacillus amyloliquefaciens* through drinking water.
Classification	**ACCEPTABLE.**
Good Laboratory Practice	Not applicable.

Toxicological Profile

Based on extensive testing of the manufacturing use product and of end-use products containing the active ingredient, no toxicity, infectivity, pathogenicity or other adverse effects from dietary exposure to *Bacillus amyloliquefaciens* strain D747 are expected. *Bacillus* spp. including *Bacillus amyloliquefaciens* are commonly found in agricultural settings (i.e. soils) and are present on fresh produce of all kinds with no known adverse effects. The Manual of Clinical Microbiology (9th edition) mentions that dried food such as spices, milk powder and grains often contain large amounts of *Bacillus* spores. *Bacillus amyloliquefaciens* is not known to produce any mammalian toxins and no foodborne disease outbreaks associated with *Bacillus amyloliquefaciens* or toxin production from *Bacillus amyloliquefaciens* have been reported. Since *Bacillus amyloliquefaciens* is naturally present in soils, exposure to *Bacillus amyloliquefaciens* from surface and possibly groundwater can be expected. Water treatment processes should remove any *Bacillus amyloliquefaciens* present. No adverse effects are expected or have been reported from exposure to *Bacillus amyloliquefaciens* through drinking water.

Intravenous LD > 1.0×10^7 CFU/rat – not infective, pathogenic or toxic.
Pulmonary LD > 1.0×10^7 CFU/rat - not infective, pathogenic or toxic.
Oral LD > 5000 mg/Kg – EPA Toxicity Category IV.
Dermal LD > 5050 mg/Kg – EPA Toxicity Category IV.
Inhalation LC > 2.18 mg/L – EPA Toxicity Category III.
Mildly-irritating to the eye – EPA Toxicity Category III.
Essentially non-irritating dermally – EPA Toxicity Category IV.

Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Due to the biological nature of *Bacillus amyloliquefaciens* strain D747 it is not expected to persist in the environment or accumulate in any reservoirs, rather it will naturally degrade due to predation by other biological organisms and exposure to heat, cold, sunlight, etc.

A. Dietary Exposure

1. *Food. Bacillus* spp. including *Bacillus amyloliquefaciens* are commonly found in agricultural settings (i.e. soils) and are present on fresh produce of all kinds with no known adverse effects. *Bacillus amyloliquefaciens* is not known to produce any mammalian toxins and no foodborne disease outbreaks associated with *Bacillus amyloliquefaciens* or toxin production from *Bacillus amyloliquefaciens* have been reported.

2. *Drinking water exposure*. Since *Bacillus amyloliquefaciens* is naturally present in soils exposure to *Bacillus amyloliquefaciens* from surface and possibly groundwater can be expected. Water treatment processes should remove any *Bacillus amyloliquefaciens* present. No adverse effects are expected or have been reported from exposure to *Bacillus amyloliquefaciens* through drinking water.

B. Other Non-Occupational Exposure

Exposures other than those to workers, mitigated by label language for use patterns and PPE, are not expected.

1. *Dermal exposure. Bacillus amyloliquefaciens* strain D747 was shown to be non-toxic and non-irritating by dermal exposure; dermal LD > 5050 mg/Kg – EPA Toxicity Category IV.

2. *Inhalation exposure*. Pulmonary exposure to the manufacturing use product showed no adverse effects including infectivity, pathogenicity and toxicity though slight toxicity lasting 2 days from 4-hour aerosol inhalation administration of 2.18 mg/L, where inert ingredients were also present, was noted in another study. Respiratory protection is routinely required for applicators of microbial pesticides to prevent allergic sensitization; in this case respirators are also required PPE.

V. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has not found *Bacillus amyloliquefaciens* strain D747 to share a common mechanism of toxicity with any other substances, and *Bacillus amyloliquefaciens* strain D747 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that *Bacillus amyloliquefaciens* strain D747 does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

Determination of Safety for U.S. Population, Infants and Children

No toxicological, sensitization, irritation, infectious or pathogenic endpoints were noted in mammalian testing of *Bacillus amyloliquefaciens* strain D747 and differential effects to infants and children are not expected.

Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

Cited studies:

STUDY TYPE: Acute Oral Toxicity / Pathogenicity – Rat.
OCSPP Guideline: 885.3050.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747.
MRID NO.: 481657-04.

DISCUSSION: No evidence of infectivity, pathogenicity or toxicity was found from oral administration of $1.0x10^8$ CFU *Bacillus amyloliquefaciens* strain D747 to rats. Clearance from fecal material occurred by day 14 and no viable organisms were recovered from blood or any other organ or tissue.
CLASSIFICATION: ACCEPTABLE – oral LD > $1.0x10^8$ CFU/rat – not infective, pathogenic or toxic.

STUDY TYPE: Acute Injection Toxicity / Pathogenicity – Rat.
OCSPP Guideline: 885.3200.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747.
MRID NO.: 481657-05.
DISCUSSION: No evidence of infectivity, pathogenicity or toxicity was found from intravenous administration of $1.0x10^7$ spores *Bacillus amyloliquefaciens* strain D747 to rats. There were no mortalities, no clinical effects from intravenous administration and steady weight gain of treated rats throughout the study duration. Clearance was steady though residual viable cells remained in the liver and spleen at day 60 on study termination, typical of spore forming bacteria administered to rats. There was no evidence of an increase in viable counts over time that would be indicative of a chronic infection. Since a pattern of clearance was shown it is assumed that the remaining viable cells were spores that take longer to be cleared by healthy immune systems.
CLASSIFICATION: ACCEPTABLE – intravenous LD > $1.0x10^7$ CFU/rat – not infective, pathogenic or toxic.

STUDY TYPE: Acute Pulmonary Toxicity / Pathogenicity – Rat.
OCSPP Guideline: 885.3150.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747.
MRID NO.: 481657-06.
DISCUSSION: No evidence of infectivity, pathogenicity or toxicity was found from intratracheal administration of $1.0x10^7$ spores *Bacillus amyloliquefaciens* strain D747 to rats. There were no mortalities, no clinical effects from intratracheal administration and steady weight gain of treated rats throughout the study duration. Clearance was steady though residual viable cells remained in the lungs and trachea at day 60 on study termination, typical of spore forming bacteria administered to rats. There was no evidence of an increase in viable counts over time that would be indicative of a chronic infection. Since a pattern of clearance was shown it is assumed that the remaining viable cells were spores that take longer to be cleared by healthy immune systems.
CLASSIFICATION: ACCEPTABLE – pulmonary LD > $1.0x10^7$ CFU/rat - not infective, pathogenic or toxic.

STUDY TYPE: Acute Oral Toxicity – Rats.
OCSPP Guideline: 870.1100.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9030.
MRID NO.: 481657-07.
DISCUSSION: No evidence of toxicity was found from oral administration of 5000 mg/Kg *Bacillus amyloliquefaciens* strain D747 CX-9030 to rats in a 14 day acute toxicity study.
CLASSIFICATION: ACCEPTABLE - oral LD > 5000 mg/Kg – EPA Toxicity Category IV.

STUDY TYPE: Acute Dermal Toxicity – Rabbits.
OCSPP Guideline: 870.1200.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9030.
MRID NO.: 481657-08.
DISCUSSION: No evidence of toxicity was found from dermal administration of 5050 mg/Kg *Bacillus amyloliquefaciens* strain D747 CX-9030 to rats in a 14 day acute toxicity study.
CLASSIFICATION: ACCEPTABLE - dermal LD > 5050 mg/Kg – EPA Toxicity Category IV.

STUDY TYPE: Acute Inhalation Toxicity – Rats.
OCSPP Guideline: 870.1300.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9030.
MRID NO.: 481657-09.
DISCUSSION: Slight toxicity lasting two days from 4-hour aerosol inhalation administration of 2.18 mg/L *Bacillus amyloliquefaciens* strain D747 CX-9030 was noted to rats in a 14 day acute toxicity study.
CLASSIFICATION: ACCEPTABLE - inhalation LC > 2.18 mg/L – EPA Toxicity Category IV.

STUDY TYPE: Acute Eye Irritation – Rabbit.
OCSPP Guideline: 870.2400.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9030.
MRID NO.: 481657-10.
DISCUSSION: The maximum average irritation score of 18.3 obtained 1 hour after treatment declined to 17.33 after 24 hours, 2 after 48 hours and 0 after 72 hours following ocular administration of 0.1 mL *Bacillus amyloliquefaciens* strain D747 to New Zealand White rabbits in a 72 hour observation period.
CLASSIFICATION: ACCEPTABLE – mildly-irritating – EPA Toxicity Category III.

STUDY TYPE: Acute Dermal Irritation.
OCSPP Guideline: 870.2500.
TEST MATERIAL: *Bacillus amyloliquefaciens* strain D747 CX-9030.
MRID NO.: 481657-11.
DISCUSSION: No evidence of irritation was found from dermal administration of 0.5 mg *Bacillus amyloliquefaciens* strain D747 CX-9030 to rabbits during a 72 hour exposure and observation period. The dermal irritation score for *Bacillus amyloliquefaciens* strain D747 CX-9030 was 0.00.
CLASSIFICATION: ACCEPTABLE – essentially non-irritating – EPA Toxicity Category IV.

RE: 70051-RNI and RNT- Division director requested a more detailed authorization

Dively, Chris to: Susanne Cerrelli 09/15/2011 01:08 PM

Cc: "Dively, Chris"

Susanne,

Certis USA requests a copy of the Data Evaluation Record (DER) dated September 14, 2011, Product Chemistry and Health Effects for Bacillus amyloliquefaciens D747 for EPA File Symbol 70051-RNI and RNT sent by fax to 301-604-7015. Certis USA acknowledges that the DER contains Confidential Business Information; however, Certis USA authorizes EPA to transmit this document to the above listed fax number.

Sincerely,
Christina Dively
Director of Regulatory Affairs
Certis USA

-----Original Message-----
From: Cerrelli.Susanne@epamail.epa.gov [
mailto:Cerrelli.Susanne@epamail.epa.gov]
Sent: Thursday, September 15, 2011 11:38 AM
To: Dively, Chris
Subject: Re: 70051-RNI and RNT- Division director requested a more detailed authorization

I should have been more explicit earlier. I have the materials ready to Fax to you but we need a more explicit authorization email.

It should indicate that
Certis would like a copy of the Data Evaluation Record dated September 14, 2011 Product Chemistry and Health Effects DERs for Bacillus amyloliquiefaciens strain D747
for EPA Reg. No. 70051-RNI and RNT sent by FAX to fax number 301-604-7015.

It also should indicate that:
Certis is acknowledges that the materials requested contain Confidential business information , however, Certis authorizes EPA to transmit this document to the above listed Fax number.

Regards,

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

From: "Dively, Chris" <cdively@certisusa.com>

70051-RNI and RNT
Dively, Chris
to:
Susanne Cerrelli
09/14/2011 04:09 PM
Hide Details
From: "Dively, Chris" <cdively@certisusa.com>

To: Susanne Cerrelli/DC/USEPA/US@EPA

Susanne,

Certis USA authorizes you to fax the Product Chemistry and Health Effects DERs to the fax number 301-604-7015.

Thank you,
Christina Dively
Director of Regulatory Affairs

Re: B. amyloliquefaciens - deficienciesEPA file symbols 70051- RNI and RNT SEE below

Susanne Cerrelli to: Shannon Borges 08/26/2011 03:03 PM

Shannon-

I just got off the phone with Chris Dively to provide an adequate response she will need a copy of the reviews for D747. She wanted to have a better understanding of what deficiencies were identified so she could respond in a complete fashion (and the DERs would help).

She has additional non- target insect studies that were done for Annex 1 registration in Europe. She says they were deemed acceptable and that she could submit a copy Monday. I asked her what insects were tested and she said she will email us a list. I will forward Dively's list of tested insects when I get it . Her understanding is that this is not registered in Europe yet, but she mentioned the insect studies were deemed acceptable by the Europeans.

I 1ried to explain to her that the eco- assessment is complete but that we wanted to give her an opportunity to address the guidelines that were found deficient to improve the registration decision for their company.

Could I get the signed reviews on Tuesday for D747?

When I give you the list of available insect studies that were not submitted yet , can you give me an indication if the studies should be submitted.? or should she just submit whatever she has and if it isn't helpful you don't review it? Please let me know your preference, and any other comments/ suggestions on the matter.

I am going to go ahead and see if I can get approval to fax the reviews to Dively after you and Gail sign them..

I can stop by in personTuesday but am working at home Monday.

THANKS!

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

Shannon Borges Hi Susanne, Gail and I went through the studies... 08/24/2011 02:26:03 PM

From: Shannon Borges/DC/USEPA/US
To: Susanne Cerrelli/DC/USEPA/US@EPA
Date: 08/24/2011 02:26 PM
Subject: B. amyloliquefaciens - deficiencies

Hi Susanne,

Gail and I went through the studies for Bacillus subtilis var. amyloliquefaciens D747, and we have noted some deficiencies. The nontarget insect studies were all determined to be unacceptable, and both honeybee studies, the avian oral, and the nontarget plant study were supplemental. Since B.

Fw: B. amyloliquefaciens -D747 EPA File Symbols 70051-RNI and RNT
Susanne Cerrelli to: Dively, Chris 08/25/2011 10:54 AM
Bcc: Shannon Borges, Alan Reynolds

Dear Ms. Dively

The science reviewers evaluated the ecological hazard evaluation studies for Bacillus subtilis var. amyloliquefaciens D747, and have noted some deficiencies. The nontarget insect studies were all determined to be unacceptable, and both honeybee studies, the avian oral, and the nontarget plant study were supplemental. Since B. amyloliquefaciens is not related to a known plant pathogen, the nontarget plant study is not required. However, the nontarget insect, honeybee, and bird studies need to be re-addressed, either with additional studies or with adequate rationales to justify a finding of no toxicity or pathogenicity to these non-target organisms. We wanted to alert you before sending a letter with the reviews in hopes that this could help expedite your preparation of a response, for our assessments.

Please, let me know if you have any questions.

Regards,

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

Biopesticides and Pollution Prevention Division

FAX

August 30, 2011

Pages: 48 including Cover

TO: Chris Dively
FAX Phone:301-604-7015

FROM: Susanne Cerrelli
US Environmental Protection Agency.
Office of Pesticide Programs
Biopesticides & Pollution Prevention Division (7511c)

Phone 703-308-8077 (FAX 703-308-7026)
Email: CERRELLI.SUSANNE@ epa.gov

Subject: Data evaluation records for B. subtilis Var Amyloliquefaciens –D747 EPA Reg. No. 70051-RNI and RNT

The evaluators strongly suggest that the most expeditious manner to address the unsatisfied guidelines is with waiver rationale for each of those guidelines. An evaluation of new data would require more time and very likely would affect PRIA dates.

If you have any questions, please contact me.

Sincerely,

Susanne Cerrelli

RE: B. amyloliquefaciens -D747 EPA File Symbols 70051-RNI and RNT
Dively, Chris to: Susanne Cerrelli 08/29/2011 12:32 PM
Cc: "Dively, Chris"

Dear Susanne,

Certis USA authorizes BPPD (Susanne Cerelli) to fax data evaluation records for pending Registration File Symbol: 70051-RNI and 70051-RNT. The Certis Fax Number is 301-604-7015.

Thank you,
Chris Dively
Director of Regulatory Affairs
Certis USA

-----Original Message-----
From: Cerrelli.Susanne@epamail.epa.gov [
mailto:Cerrelli.Susanne@epamail.epa.gov]
Sent: Friday, August 26, 2011 3:40 PM
To: Dively, Chris
Cc: Borges.Shannon@epamail.epa.gov
Subject: RE: B. amyloliquefaciens -D747 EPA File Symbols 70051-RNI and RNT

I will not be able ot get a copy of the reviews until next week. It may be Tuesday or Wednesday before I can get a signed copy to you. Can you please confirm with an email that you authorize me to FAX you the data evaluation records, and provide the FAX number to use ?

Also the reviewers need to know- what is the duration of the studies listed below? If the duration is short it is difficult to assess potential pathogenicity to insects.

If you have questions about generating a waiver rationale using available published literature and the submitted studies , please let me know.

Regards,

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

From: "Dively, Chris" <cdively@certisusa.com>
To: Susanne Cerrelli/DC/USEPA/US@EPA
Cc: "Dively, Chris" <cdively@certisusa.com>
Date: 08/26/2011 03:24 PM
Subject: RE: B. amyloliquefaciens -D747 EPA File Symbols 70051-RNI and RNT

Hi Susanne,
The non-target insect studies that were submitted to support the inclusion of B.Subtilis var. amyloliwquefaciens in EU Annex I & II of 91/414 are: Toxicity of Predatory Mite Typhlodromus pyri in the laboratory and Toxicity to the Aphid Parasitoid, Aphidius rhopalosiphi in the laboratory. These studies can be made available to your review group immediatedly, if requested. Further there is an assessment summary for the non-target insects, including honeybee as well that can be shared with the eco. reviewer.
Just let me know if you would like to review this information and I will get it to you asap.

Thanks for your email as a "heads-up" in an effort to expedite the additional requested data/information so that the final reviews/assessments may proceed.

Best Regards,
Chris

-----Original Message-----
From: Cerrelli.Susanne@epamail.epa.gov [mailto:Cerrelli.Susanne@epamail.epa.gov]
Sent: Thursday, August 25, 2011 10:55 AM
To: Dively, Chris
Subject: Fw: B. amyloliquefaciens -D747 EPA File Symbols 70051-RNI and RNT

Dear Ms. Dively

The science reviewers evaluated the ecological hazard evaluation studies for Bacill++
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s subtilis var. amyloliquefaciens D747, and have noted some deficiencies. The nontarget insect studies were all determined to be unacceptable, and both honeybee studies, the avian oral, and the nontarget plant study were supplemental. Since B. amyloliquefaciens is not related to a known plant pathogen, the nontarget plant study is not required. However, the nontarget insect, honeybee, and bird studies need to be re-addressed, either with additional studies or with adequate rationales to justify a finding of no toxicity or pathogenicity to these non-target organisms. We wanted to alert you before sending a letter with the reviews in hopes that this could help expedite your preparation of a response, for our assessments.

Please, let me know if you have any questions.

Regards,

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

Terrestrial Arthropods - Honey Bees (*Apis mellifera*) – *Bacillus subtilis* var. *amyloliquefaciens* Strain D747 – Study Review

Sub. No. 879171/ Company code: 70051/MRID not assigned at time of review
TECHNICAL / PC Code 016482

Primary Reviewer:	Shannon Borges	**Date:** 8/29/11
	Biologist, BPPD	
Secondary Reviewer:	Gail Tomimatsu	**Date:** 8/30/11
	Plant Pathologist, BPPD	

REQUIREMENT: PMRA Data Code: M9.5.1–Terrestrial arthropods
U.S. EPA Requirement: 885.4380
OECD Data Code: IIM 8.7, IIIM 10.3

TEST MATERIAL (PURITY): *Bacillus subtilis* var. amyloliquefaciens D747, 5 x 10^{10} spores/g

SYNONYMS: *Bacillus amyloliquefaciens*, *Bacillus subtilis* var. *amyloliquefaciens*

CITATION: Verge, E. 2010. CX-9030 – Acute oral and contact toxicity to the honeybee *Apis mellifera* L. in the laboratory. Eurofins Agroscience Services GmbH. Study code: S10-02546. Unpublished study dated October 5, 2010. MRID not assigned at time of review.

SPONSOR: Certis USA, 9145 Guilford Road, Suite 175, Columbia, MD 21046.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. The study was conducted in compliance with GLP principles within the following: The Principles of Good Laboratory Practice (GLP), Chemical Act, attachment 1, Germany; The OECD Principles of Good Laboratory Practice. This DER does not contain CBI.

EXECUTIVE SUMMARY:

In a 48-hour oral toxicity study, and another 48-hour contact toxicity study, honey bees (*Apis mellifera*) were exposed to *Bacillus subtilis* CX-9030. Mortality was 0% in both *B. subtilis* CX-9030 and negative control treatment groups in the oral toxicity study, and mortality did not exceed 10% in the acute contact toxicity study in any of the treatment groups. Based on the results, the LD_{50} for oral toxicity was empirically determined to be 446.63 µg/bee and the LD_{50} for acute contact toxicity was determined to be >360 µg/bee.

The study is sufficient to show that *Bacillus subtilis* CX-9030 is not toxic to honey bees. However, the study is not of sufficient duration to determine whether it may be pathogenic to honey bees.

CLASSIFICATION: SUPPLEMENTAL

I. MATERIALS AND METHODS:

A. GUIDELINE FOLLOWED: OECD guidelines No. 213 and 214

B. MATERIALS:

1. **Test Material:** CX-9030 (*Bacillus subtilis* CX-9030); Table 2, page 9 states that the test item was *Bacillus subtilis* CX-9025, which is the technical material. All contain B. s. amyloliquefaciens D747.

   Description: buff colored, small granules, density 0.765 g/cm3

   Lot/Batch #: 0700680, Test item code 2010-001216

   Purity: 5×10^{10} spores/g

   Storage conditions: Cool, dry place.

2. **Test Organism:**

   Species (common and scientific names): Honey bee (*Apis mellifera*)

   Age at test initiation: Young adult worker bees.

   Source: Healthy colony descended from a breeding line of a beekeeper in Rheinland-Pfalz, Germany (name and address provided in the study report)

   Date of collection: One day prior to start of the study.

   Rationale: This is the species of bee required for testing by EPA data requirements.

C. STUDY DESIGN AND METHODS:

An oral toxicity study and a contact toxicity study were both performed with *Bacillus subtilis* CX-9030 on the honey bee (*Apis mellifera*). Five replicate groups of 10 bees were tested at each dose for each of the studies. In each study, bees were assessed at 4, 24, and 48 hours for survival and/or abnormal behavior.

The oral toxicity study was carried out with a limit dose (nominal 400 µg/bee, measured 446.63 µg/bee). CX-9030 was provided in 50% (w/v) aqueous sucrose solution (diet) after the bees were fasted for two hours. A reference (positive control; dimethoate, 0.07 – 0.17 µg/bee) solution was given to another group, and a negative control (50% sucrose solution only) was included as well. A quantity of 250µL of the test or reference solution was provided to the bees for six hours to ensure sufficient consumption of the test or reference material. Bees within a cage shared the test solution and are assumed to have received a similar dose. The amount of test solution consumed by each replicate was determined by weighing the feeders (Eppendorf cups) before and after each feeding. After the six-hour exposure period, the bees were supplied *ad libitum* with untreated 50% aqueous sucrose solution. The same procedure was also carried out with the negative control group.

The contact toxicity study was carried out as a definitive study. *Bacillus subtilis* CX-9030 was tested at nominal concentrations of 20, 40, 80, 160, and 320 µg/bee. These amounts were applied (in 2 µL) directly to the dorsal thorax of each bees after were anesthetization with carbon dioxide. Positive controls (dimethoate) were included at rates of 0.10, 0.15, 0.23, and 0.34 µg/bee, and a negative control (tap water) was also included. After treatment, the bees were returned to the test cages and fed with a 50% aqueous sucrose solution *ad libitum*.

1. **Experimental Methods and Conditions:**

Acclimation:

Duration: One day
Feeding: Not described specifically
Water: Not described specifically
Temperature: Not described specifically
Relative humidity: Not described specifically

The study report states that bees were kept under laboratory conditions until the start of the experimental phase. Bee colonies were inspected periodically according to the rules of bee keeping by and experienced apiarist. An authorized bee specialist also examined the colonies for a reportable bee epidemic, without any findings.

Test chamber - description and size:

Bees were kept in cages made of stainless steel (base: 8.2 cm x 40 cm; height: 6.0 cm). The front side of the cages was equipped with a transparent window so that the bees could be observed. The bottom of the cages consisted of perforated steel, which guaranteed sufficient air supply for the test insects. The test cages were lined with filter paper.

Route(s) of exposure:

Oral (dietary) and contact.

Dose levels / test concentrations:

Oral - Nominal: 400 µg/bee (needs clarification, either 2.5 x 10^6 cfu/bee or 2.0 x 10^6 cfu/bee)
Oral - Measured: 446.63 µg/bee (based on consumption)

Contact – Nominal: 20, 40, 80, 160, 320 µg/bee (1.0 x 10^6, 2.0 x 10^6, 4.0 x 10^6, 8.0 x 10^6, and 1.6 x 10^7 cfu/bee, respectively)
Measured – Not done.

The maximum hazard concentration, based on the maximum rate shown on proposed label for the end-use product, CX-9030, is 1.8 x 10^9 cfu/mL. This is based on an application rate of 3 lbs. of the product diluted in 100 gallons of water. Based on the information given about the preparation of the test substances, the oral toxicity study test material concentration was 1 x 10^9 cfu/mL and the contact toxicity study test material ranged from 5 x 10^8 to 8 x 10^9 cfu/mL. Therefore, the concentrations used in the studies adequately test toxicity at the maximum hazard dose (10 – 100x the EEC).

Preparation of dose or test concentration:

For the oral toxicity study, 2000 mg of CX-9030 were made up to a final volume of 10 mL with tap water. 2.0 mL of this stock solution was added to 50% sucrose solution to make a solution with a final volume of 20.0 mL. This was the test material given to the bees.

For the contact toxicity study, 1600 mg of CX-9030 were made up to a final volume of 10.0 mL with tap water. This was the stock solution that was the 320 µg/bee treatment. 2.5 mL and 1.5 mL of this stock solution was diluted with 5.0 mL of tap water to make the 160 µg/bee and 80 µg/bee treatments, respectively. 1.25 mL of the stock solution was diluted with 10.0 mL tap water to make up the 40 µg/bee treatment, and 2.5 mL of this resulting solution was diluted with 5.0 mL tap water to make the final treatment of 20 µg/bee.

Solvent/vehicle: For contact toxicity, tap water was used as a carrier.

Confirmation of MPCA viability: Not done with the study, no certificate of analysis provided either.

Positive control / reference material: Dimethoate, tested concurrently.

Other controls: Negative controls (50% sucrose solution in the oral toxicity study, tap water in the contact toxicity study)

Number of bees per chamber:

Control(s): 10
Treatment(s): 10

Number of replicates (chambers) per treatment:

Control(s): 5
Treatment(s): 5

Recovery of MPCA from bees: Not done.

Feeding: 50% sucrose was provided *ad libitum*

Test conditions:
Temperature: During the oral toxicity study: 25°C; during the contact toxicity study: 24.5 – 25.5°C
Humidity: Oral study: 64 – 66%; contact study: 60 – 67%
Lighting: Maintained in the dark. Handling was done with neon lighting.

Duration of the study: 48 hours.

Other methods or conditions, if any: N/A

2. <u>Observations</u>:

Parameters measured including sublethal effects/toxicity symptoms: Survival, behavior.

Observation/measurement intervals: 4, 24, and 48 hours.

Testing for infectivity: Not done.

Were raw data included? Raw data were included for the acute oral toxicity study. Raw data were not included for the contact toxicity study.

Other observations, if any: N/A

II. RESULTS:

A. VIABILITY OF DOSING SUSPENSIONS: Not done.

B. MORTALITY: No mortalities were observed in the control group or the *Bacillus subtilis* CX-9030 treatment group. The LD50 was determined empirically to be 400 µg/bee (nominal) or 446.63 µg/bee (nominal, based on food consumption). The LD50 of the reference material, dimethoate, was determined to be 0.12 µg a.i./bee, which is within the acceptable range of 0.10 to 0.35 µg/bee for this reference item. Mortality for the test and reference material is provided in Table 1. No sublethal effects were observed throughout the 48 hour period.

TABLE 1. Effect of *Bacillus subtilis* CX-9030 on honey bees (*Apis mellifera*) in an oral (dietary) toxicity study.

Treatment (Target Dose)	Test item consumed	Mortality (%)	
		24 hours	48 hours
Control (50% sucrose)		0.0	0.0
Test item: CX-9030 (µg/bee)			
400	446.63	0.0	0.0
Reference item: dimethoate (µg a.i./bee)			
0.06	0.07	0.0	2.0
0.08	0.09	14.0	14.0
0.11	0.12	38.0	46.0
0.15	0.17	88.0	96.0

The mortality in the contact toxicity study is given in Table 2. No mortality was observed in the negative control group. A maximum of 10% mortality was observed in the *Bacillus subtilis* CX-9030 test groups, and mortality did not follow a dose-response relationship. The study authors determined the LD50 for the test material to be >320 µg/bee. Mortality in the reference/positive control group did show a dose-response relationship. The acute contact LD50 was determined to be 0.15 µg a.i./bee, which was within the range of validity of 0.10 to 0.30 µg/bee for contact toxicity for this reference material.

At the assessment at 4 hours after application, four bees were observed showing reduced coordination and ability to move at the highest and lowest *Bacillus subtilis* CX-9030 dose levels. No other sublethal effects were observed at the following assessments at 24 and 48 hours.

TABLE 2. Effect of *Bacillus subtilis* CX-9030 on cumulative mortality of honey bees (*Apis mellifera*) in an acute contact toxicity study.

Treatment	Mortality (%)	
	24 hours	48 hours
Control (tap water)	0.0	0.0
Test item: CX-9030 (µg/bee)		
20	0.0	2.0
40	2.0	10.0

80	2.0	2.0
160	4.0	10.0
320	0.0	2.0
Reference item: dimethoate (µg/bee)		
0.10	2.0	6.0
0.15	60.0	70.0
0.23	82.0	86.0
0.34	86.0	92.0

B. **REPORTED STATISTICS:** LD_{50} values with 95% confidence limits for the reference item were calculated by probit analysis using SAS version 9.1.3. LD_{50} values are as reported above. LD50 values for the test item were determined empirically.

D. **VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER:** LD_{50} for acute oral and contact toxicity of the reference were confirmed with EPA's Toxanal program. The LD_{50} for oral toxicity of the dimethoate was determined to be 0.11 (95% CI – 0.10 – 0.12). The LD_{50} for contact toxicity was determined to be the same as reported, although given the response curve, a probit analysis is not necessarily the most appropriate. These results do show, however, that the test system did expose the bees to the test material, which is the point of inclusion of the positive control.

Raw data were not included for the contact toxicity study, but since none of the treatments led to mortality of 50% or greater, the empirical determination is correct.

III. CONCLUSION:

A. **REVIEWER'S CONCLUSIONS:** The study is sufficient to show that *Bacillus subtilis* CX-9030 is not toxic to honey bees. However, the study is not of sufficient duration to determine whether it may be pathogenic to honey bees. Thus the study is classified as **supplemental.**

B. **STUDY DEFICIENCIES:** The study is of too short duration to determine pathogenicity.

Primary Reviewer:	Shannon Borges	**Date:** 8/29/11
	Biologist, BPPD	
Secondary Reviewer:	Gail Tomimatsu	**Date:** 8/30/11
	Plant Pathologist, BPPD	

REQUIREMENT: U.S. EPA Requirement: 885.4340

TEST MATERIAL (PURITY): *Bacillus subtilis* D747
Potency: 1 x 10^{11} cfu/mL

SYNONYMS: N/A

CITATION: Commission of the Japan Plant Protection Association. 2003. *Bacillus subtilis* var. *amyloliquefaciens* Strain D747 Non-target insect testing. Full study – unpublished. Study completed September 2, 2003. MRID 48165716.

SPONSOR: N/A – Submitted by Certis USA, LLC, 9145 Guilford RD, Suite 175, Columbia, MD 21046. Testing site is given as: Japan Plant Protection Association Research Institute, 535 Kessoku-cho, Ushiku-shi, Ibaraki.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. Since Certis is not the sponsor of the study and did not conduct it, Certis does not know whether the study was conducted under GLP. This DER does not contain CBI.

EXECUTIVE SUMMARY:

Fifty immature *Orius strigicollis* were exposed for 24 hours to *Bacillus subtilis* D747 at 10X the expected environmental exposure. After 24 hours, the insects were moved to new vials without the test substance and were observed for seven days for survival. Those that died were tested for the presence of *Bacillus*. The number reaching adulthood was also observed. After 12 days, adults were removed and placed in sealed containers and allowed to mate. Egg-laying was allowed for two days and then the number of eggs per female was observed.

This study may indicate that *Orius* exposed to *B. subtilis* at the described rate for one day are not sensitive to this test material; however, little information is provided about how the insects were exposed. It is assumed that their food source was treated, but this is not clearly described, and a positive control was not included to confirm that the insects were sufficiently exposed. Study duration was 14 days, and mortality of adults after egg laying began was not reported to determine if control mortality was 20%. Based on food consumption, the insects consumed approximately the same amount of diet. Eclosion and egg production were not affected. Assuming that the insects were properly exposed, the one day LD_{50} is >5.0 x 10^8 cfu/mL *Bacillus subtilis* D747. This exposure level is 5X the expected environmental concentration assuming maximum application rate of 3 lbs/100 gallons of water.

The study has the following deficiencies: unknown GLP status and data quality, study duration of 14 days (without confirmation that 20% mortality was reached in the control group), the exposure tested was

not at the maximum hazard rate, exposure route and treatment methods were not adequately described; a positive control was not included to confirm exposure with this test system.

CLASSIFICATION: UNACCEPTABLE

I. MATERIALS AND METHODS:

A. GUIDELINE FOLLOWED: Not identified.

B. MATERIALS:

1. Test Material: *Bacillus subtilis* D747

Description: Not given

Lot/Batch #: Lot no. K3E001

Purity: 1×10^{11} cfu/mL

Storage conditions: Not described.

2. Test Organism:

Species (common and scientific names): Flower bug, *Orius strigicollis* (predaceous hemipteran)

Age at test initiation: 3rd instar

Source: Parents of test animals appear to have been purchased from Arysta Lifescience Corporation (product name "Tairiku")

Rationale: This species is a predaceous hemipteran, which is a preferred test animal according to the OPPTS (OSCPP) guideline for nontarget insect testing with MPCAs.

C. STUDY DESIGN AND METHODS:

Fifty immature *Orius strigicollis* were exposed for 24 hours to *Bacillus subtilis* D747 at 10X the expected environmental exposure. After 24 hours, the insects were moved to new vials without the test substance and were observed for seven days for survival. Those that died were tested for the presence of *Bacillus*. The number reaching adulthood was also observed. After 12 days, adults were removed and placed in sealed containers and allowed to mate. Egg-laying was allowed for two days and then the number of eggs per female was observed.

1. Experimental Methods and Conditions:

Acclimation: Not described.

Test chamber - description and size: Glass vial, diameter 2.5 cm, depth 7 cm; tops of the vials were covered with parafilm after each test vessel were weighed and after 1 test animal added to the vial with the instilled "regulated solution."

Amount of soil per test chamber: None – substrate not described

Route(s) of exposure: Not described; assumed to be via diet, since food consumption was observed. The description only states that 6 µl of the "regulated solution" was instilled by micropipette into the test vessel. Dietary intake by each individual test animal was determined by pre- and post-instillation weights of the vials.

Dose levels / test concentrations: (nominal) 5.0×10^8 cfu/mL – 10X the EEC according to the author. According to the proposed labels, however, this concentration is 5X the concentration of the spray that would be applied when the highest use rate is used (3 lbs/acre in 100 gallons of water).

Preparation of doses or test concentrations: The test substance was diluted 200X with distilled water.

Solvent/vehicle: None

Confirmation of MPCA viability: Not done.

Positive control / reference material: None

Other controls: Negative control (distilled water)

Number of test organisms per chamber:
Control(s): 1
Treatments: 1

Number of replicates (chambers) per treatment:
Control(s): 50
Treatments: 50

Recovery of MPCA from test organisms: Each individual that died was immersed for a few seconds in 70% ethanol solution, and after surface pasteurization was accomplished, the ethanol was removed with distilled water. The insect was ground with 50 µl of distilled water. A nutrient broth growth medium (manufactured by Eiken Chemical Co., Ltd.) was then inoculated with 20 µl of the water containing the ground insect. This was cultured for two days in an incubator at 28°C in total darkness, and the number of colony forming units of the genus *Bacillus* on the growth medium was then surveyed.

Feeding: The diet of the insects during exposure is not described. In the observation period after exposure, the *Orius* was fed *Ephestia kuehniella* eggs.

Test conditions:

Temperature: 22 °C
Humidity: Not described
Lighting: 16L:8D photoperiod

Duration of the study: Survival was measured for up to seven days. After 12 days, the insects were combined and allowed to mate. Egg laying was observed for two days.

2. **Observations:**

Parameters measured including sublethal effects/toxicity symptoms: Egg production 12 days after release from test chambers

Observation/measurement intervals: Daily

Testing for infectivity: Other than described above, no additional testing was done.

Were raw data included? Raw data were included for mortality. Raw data were not included for effects on egg production.

Other observations, if any: N/A

II. **RESULTS:**

A. **VIABILITY OF DOSING SUSPENSIONS:** Not done.

B. **MORTALITY:** Abbot's correction was used due to some mortality in the controls. The corrected rate of mortality in *Orius strigicollis* after seven days of exposure was 8.9%. Food consumption was shown to be 0.003 g (mean) for the control group and 0.004 g (mean) for the *B. subtilis* D747 treated group.

TABLE 1. Effect of *Bacillus subtilis* D747 on cumulative mortality of *Orius strigicollis* larva.

Treatments	No. of Arthropods	Cumulative Mortality						
		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Negative control	50	1	2	3	3	3	9	9
B. subtilis D747 5×10^8 cfu/mL	50	1	1	2	2	2	5	5
LD_{50}	> 5.0×10^8 cfu/mL							

B. **SUB-LETHAL TOXICITY EFFECTS:** Eclosion rate is described as 82% for *Orius* exposed to the *B. subtilis* D747 treatment and 90% for *Orius* in the control treatment. These are the same as uncorrected survival rates. After 10 days all surviving larvae matured to adults.

Raw data were not included for effects on egg production. In the *B. subtilis* treatment group, 20 females were paired with 15 males, and after two days the number of eggs per female per day was determined to be 1.75. For the controls, 22 females were paired with 16 males, and these females each produced an average of 1.09 eggs per day. Statistical analyses were not described, but it is evident that exposure to *B. subtilis* for one day as larvae did not affect egg production in later life stages.

C. **RECOVERY OF BACILLUS FROM INSECTS:** Based on the information provided in the report, a mean of 2.1 *Bacillus* cfu's were recovered from dead *Orius* larvae exposed to *B. subtilis* D747 for one day, and a mean of 1.6 *Bacillus* cfu's were recovered from control *Orius*. These are not significantly different ($t_{11} = 0.41$; $p = 0.69$). It is unclear, however, whether this is the result of lack of exposure or the inability of *Bacillus* to survive within the insect. Greater assurance is needed that the insects were properly exposed.

C. **REPORTED STATISTICS:** N/A. One-day LD_{50} was empirically determined to be $>5.0 \times 10^8$ cfu/mL and NOEC determined to be 5.0×10^8 cfu/mL.

III. CONCLUSION:

A. **REVIEWER'S CONCLUSIONS:** This study may indicate that *Orius* exposed to *B. subtilis* at the described rate for one day are not sensitive to this test material; however, little information is provided about how the insects were exposed. It is assumed that their food source was treated, but this is not clearly described, and a positive control was not included to confirm that the insects were sufficiently exposed. Study duration was 14 days, and mortality of adults after egg laying began was not reported to determine if control mortality was 20%. Based on food consumption, the insects consumed approximately the same amount of diet. Eclosion and egg production were not affected. Assuming that the insects were exposed, the one day LD_{50} would be $>5.0 \times 10^8$ cfu/mL *Bacillus subtilis* D747; however, this is difficult to prove because exposure was not of sufficient duration. This exposure level is 5X the expected environmental concentration assuming maximum application rate of 3 lbs/100 gallons of water.

The cumulative mortality of *Orius strigicollis* in the negative control (Table 1) is nearly twice that in the bacterial treatment, which may indicate the lack of protein in the negative control may have contributed to mortality. The test is of insufficient duration to determine a valid LD50. Furthermore, as the test was not conducted at maximum hazard dose, there is additional uncertainty regarding the NOEC.

This study is classified as **unacceptable** because of the deficiencies below.

B. **STUDY DEFICIENCIES:**

The study has the following deficiencies:

- Unknown GLP status
- Study duration of 14 days led to a premature conclusion of the test (without confirmation that 20% mortality was reached in the control group)
- The exposure tested was not at the maximum hazard rate
- Exposure route and treatment methods were not adequately described; a positive control was not included to confirm exposure with this test system.
- Raw data were not included to verify results with statistical analysis, though in this case it is a minor deficiency.

Primary Reviewer:	Shannon Borges	**Date:** 8/29/11
	Biologist, BPPD	
Secondary Reviewer:	Gail Tomimatsu	**Date:** 8/30/11
	Plant Pathologist, BPPD	

REQUIREMENT: U.S. EPA Requirement: 885.4340

TEST MATERIAL (PURITY): *Bacillus subtilis* D747
Potency: 1 x 10^{11} cfu/mL

SYNONYMS: N/A

CITATION: Commission of the Japan Plant Protection Association. 2003. *Bacillus subtilis* var. *amyloliquefaciens* Strain D747 Non-target insect testing. Full study – unpublished. Study completed September 2, 2003. MRID 28165716.

SPONSOR: N/A – Submitted by Certis USA, LLC, 9145 Guilford RD, Suite 175, Columbia, MD 21046. Testing site is given as: Japan Plant Protection Association Research Institute, 535 Kessoku-cho, Ushiku-shi, Ibaraki.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. Since Certis is not the sponsor of the study and did not conduct it, Certis does not know whether the study was conducted under GLP. This DER does not contain CBI.

EXECUTIVE SUMMARY:

Fifty immature *Phytoseiulus persimilis* were exposed for six days to *Bacillus subtilis* D747 at 10X the expected environmental exposure. Exposure occurred through treated food and substrate. The mites were observed for survival and reproduction.

This study showed no effects on *Phytoseiulus persimulus*; however, untreated prey was provided after the initial exposure and food consumption was not measured. Positive controls were also not included. Therefore, it is not possible to determine the exposure period or confirm exposure. Assuming the insects were sufficiently exposed, the LD_{50} is >5.0 x 10^8 cfu/mL *Bacillus subtilis* D747, and the NOEC for reproduction is 5.0 x10^8 cfu/mL.

The study has the following deficiencies: unknown GLP status, study duration was too short, exposure was not at the maximum hazard rate, exposure duration was not specified and exposure was not confirmed.

CLASSIFICATION: UNACCEPTABLE

I. MATERIALS AND METHODS:

A. GUIDELINE FOLLOWED: Not identified.

B. MATERIALS:

1. Test Material: *Bacillus subtilis* D747

Description: Not given

Lot/Batch #: Lot no. K3E001

Purity: 1×10^{11} cfu/mL

Storage conditions: Not described.

2. Test Organism:

Species (common and scientific names): Predatory mite, *Phytoseiulus persimilis*

Age at test initiation: 1-2 days post hatching

Source: Parents of test animals were purchased from Arysta Lifescience Corporation (product name "SpidEX")

Rationale: This species is a predatory mite, which is a preferred test animal according to the OPPTS (OSCPP) guideline for nontarget insect testing with MPCAs.

C. STUDY DESIGN AND METHODS:

Fifty immature *Phytoseiulus persimilis* were exposed for six days to *Bacillus subtilis* D747 at 10X the expected environmental exposure. Exposure occurred through treated food and substrate. The mites were observed for survival and reproduction.

1. Experimental Methods and Conditions:

Acclimation: Not described.

Test chamber - description and size: Plastic petri dish (9 cm diameter, 2 cm depth) containing a sponge soaked in water covered by a bed of tissue.

Amount of soil per test chamber: No soil used. Substrate was a sponge soaked in water, covered with tissue; bean leaves.

Route(s) of exposure: Diet and substrate were sprayed with 2 mL of test solution.

Dose levels / test concentrations: (nominal) 5.0×10^8 cfu/mL – 10X the EEC according to the author. According to the proposed labels, however, this concentration is 5X the concentration of the spray that would be applied when the highest use rate is used (3 lbs/acre in 100 gallons of water).

Preparation of doses or test concentrations: The test substance was diluted 200X with distilled water.

Solvent/vehicle: None

Confirmation of MPCA viability: Not done.

Positive control / reference material: None

Other controls: Negative control (distilled water)

Number of test organisms per chamber:
Control(s): 10
Treatments: 10

Number of replicates (chambers) per treatment:
Control(s): 5
Treatments: 5

Recovery of MPCA from test organisms: Not done.

Feeding: *Tetranychus urticae* were provided as needed.

Test conditions:

Temperature: 25 °C
Humidity: Not described
Lighting: 16L:8D photoperiod

Duration of the study: 6 days.

2. Observations:

Parameters measured including sublethal effects/toxicity symptoms: cumulative mortality and egg production

Observation/measurement intervals: Daily

Testing for infectivity: None.

Were raw data included? Raw data were included for mortality. Raw data were not included for effects on egg production.

Other observations, if any: N/A

II. **RESULTS:**

A. VIABILITY OF DOSING SUSPENSIONS: Not done.

B. MORTALITY: No mortality was observed in the *B. subtilis* D747 test group or in the control group after four days. All mites matured to adulthood. The LD_{50} was empirically determined to be $>5.0 \times 10^8$ cfu/mL.

B. **SUB-LETHAL TOXICITY EFFECTS:** Raw data were not included for effects on egg production. In the *B. subtilis* treatment group, 13 females were paired with 8 males, and after two days the number of eggs per female per day was determined to be 2.31. For the controls, 10 females were paired with 10 males, and these females each produced an average of 2.65 eggs per day. Statistical analyses were not described, and raw data were not included to determine if the difference is significant.

C. **REPORTED STATISTICS:** The LD_{50} was empirically determined to be >5.0 x 10^8 cfu/mL and NOEC determined to be 5.0 x 10^8 cfu/mL.

III. CONCLUSION:

A. **REVIEWER'S CONCLUSIONS:** This study shows that *Phytoseiulus persimulus* is not affected at the exposure tested. Since untreated prey was provided after the initial exposure, and because food consumption was not measured, it is not possible to determine the exposure period or confirm exposure. The study duration is also too short based on the OCSPP guideline. Based on this study, the LD_{50} is >5.0 x 10^8 cfu/mL *Bacillus subtilis* D747, and the NOEC for reproduction is 5.0 x10^8 cfu/mL. This exposure is 5X the expected concentration of the spray used at maximum application rate.

This study is classified as **unacceptable** because of the deficiencies below. The test is of insufficient duration to determine a valid LD50. Furthermore, as the test was not conducted at maximum hazard dose, there is additional uncertainty regarding the NOEC.

B. **STUDY DEFICIENCIES:**

The study has the following deficiencies:

- Unknown GLP status
- Study duration of only six days (without reaching 20% mortality in controls)
- The exposure tested was not at the maximum hazard rate
- Exposure duration was not specified.
- A positive control or food consumption data are needed to confirm exposure to the test material
- Raw data were not included to verify results with statistical analysis, though in this case it is a minor deficiency.

Primary Reviewer:	Shannon Borges	**Date:** 8/29/11
	Biologist, BPPD	
Secondary Reviewer:	Gail Tomimatsu	**Date:** 8/30/11
	Plant Pathologist, BPPD	

REQUIREMENT: PMRA Data Code: M9.5.1–Terrestrial arthropods
U.S. EPA Requirement: 885.4380
OECD Data Code: IIM 8.7, IIIM 10.3

TEST MATERIAL (PURITY): *Bacillus subtilis* D747, 1x 10^{11} cfu/mL

SYNONYMS: *Bacillus amyloliquefaciens*

CITATION: Life Science Research Institute. 2003. *Bacillus subtilis* var. *amyloliquefaciens* strain D747: An acute dietary pathogenicity and toxicity study with the honey bee (Apis mellifera). Life Science Research Institute, Kumiai Chemical Industry Co., Ltd., Shizuoka, Japan. Study completed September 2, 2003. MRID 48165717.

SPONSOR: Not given. Submitted by Certis U.S.A., L.L.C., 9145 Guilford Road, Suite 175, Columbia, Maryland 21046

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. Certis states that it did not sponsor of the study and did not conduct it, and does not know whether it was conducted in accordance with 40 CFR Part 160. This DER does not contain CBI.

EXECUTIVE SUMMARY:

Ten test insects were exposed to *Bacillus subtilis* D747 at a concentration of 1 x 10^9 cfu/mL (in 50% sucrose solution) for 48 hours. The diet after 48 hours was changed to 50% sucrose solution, and then the bees were observed for mortality for an additional 20 days.

The study report contains few details about the conduct of the experiment, and the study contains several deficiencies that render it not useful for ecological risk assessment. Deficiencies of the study include: unknown GLP status, positive controls were not used and/or food consumption was not measured to confirm exposure, test material was not characterized and viability was not confirmed, feeding and other conditions of the experiment were not well described, no effort was made to reisolate the test material from the bees, and data were not provided for the entire observation period.

CLASSIFICATION: SUPPLEMENTAL

I. MATERIALS AND METHODS:

A. **GUIDELINE FOLLOWED:** The authors state that the study was carried out in compliance with "Guidelines on Study Reports on Microbial Pesticides for their Safety Evaluation and for Application of Registration. 9 Nousan No. 5090, notified by the Director General of the Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries, August 29,

1997." BPPD was able to locate only a draft copy of the updated version of these guidelines, and the draft did not include the sections on nontarget testing.

B. MATERIALS:

1. Test Material: *Bacillus subtilis* D747

Description: Not given

Lot/Batch #: germ 030716

Purity: 1×10^{11} cfu/mL

Storage conditions: Not described.

2. Test Organism:

Species (common and scientific names): Honey bee (*Apis mellifera*).

Age at test initiation: Worker drones, 3-7 days post emergence

Source: Not given.

Date of collection: Not given.

Rationale: This is the species of bee specified by the OSCPP (OPPTS) guideline.

C. STUDY DESIGN AND METHODS:

Ten test insects were exposed to *Bacillus subtilis* D747 at a concentration of 1×10^9 cfu/mL (in 50% sucrose solution) for 48 hours. Diet after 48 hours was switched to 50% sucrose solution, and then observed for mortality for an additional 20 days.

1. Experimental Methods and Conditions:

Acclimation: Not described.

Test chamber - description and size: Petri dish (9 cm diameter x 7.5 cm height)

Route(s) of exposure: Oral (diet)

Dose levels / test concentrations:

Nominal: 1×10^9 cfu/mL
Measured: Not done.

Preparation of dose or test concentration: The bulk test substance was diluted with 50% sucrose solution to the specified concentration (1×10^9 cfu/mL).

Solvent/vehicle: N/A

Confirmation of MPCA viability: Not done.

Positive control / reference material: Not used.

Other controls: Negative control.

Number of bees per chamber:

Control(s): 10
Treatment(s): 10

Number of replicates (chambers) per treatment:

Control(s): 8
Treatment(s): 8

Recovery of MPCA from bees: Not done.

Feeding: Bees were given 50% sucrose throughout the experiment. The interval at which they were fed is not described, but the amount provided was described as "sufficient."

Test conditions:
Temperature: 20°C
Humidity: Not described
Lighting: Maintained in the dark

Duration of the study: 20 days. After 20 days mortality in the control group was >20%.

Other methods or conditions, if any: No other methods described.

2. Observations:

Parameters measured including sublethal effects/toxicity symptoms: Mortality

Observation/measurement intervals: Daily

Testing for infectivity: Not done.

Were raw data included? Some raw data were provided.

Other observations, if any: None.

II. RESULTS:

A. VIABILITY OF DOSING SUSPENSIONS: Not done.

B. **MORTALITY:** After 17 days, cumulative mortality in the groups fed *Bacillus subtilis* D747 was 16.3%, whereas mortality in the control groups was 10.0% (Table 1). Using Abbott's correction for control mortality, the corrected mortality on Day 17 is 6.9% for the group exposed to *Bacillus subtilis* D747. Data collected on other days were not provided. The authors concluded that the test substance had low toxicity to adult European honey bees.

TABLE 1. Effect of *Bacillus subtilis* D747 on cumulative mortality of honey bees (*Apis mellifera*) in an oral (dietary) test.

Treatments (nominal)	No. of Bees	No. Dead Bees (% Mortality) at Specified Days After Initial Exposure									
		1	2	3	4	5	7	10	14	17	21
Negative control	80	1 (1.3)	1 (1.3)	4 (5.0)	4 (5.0)	4 (5.0)	5 (6.3)	5 (6.3)	5 (6.3)	8 (10.0)	37 (46.3)
B. subtilis 1 x 10^9 cfu/mL	80	0 (0.0)	3 (3.8)	5 (6.3)	5 (6.3)	5 (6.3)	11 (13.8)	11 (13.8)	11 (13.8)	13 (16.3)	39 (48.8)

B. **SUB-LETHAL TOXICITY EFFECTS:** Not observed.

C. **REPORTED STATISTICS:** None reported.

D. **VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER:** Based on the data collected to Day 17, the LD_{50} could be empirically determined to be > 1 x 10^9 cfu/mL.

III. CONCLUSION:

A. **REVIEWER'S CONCLUSIONS:** The study report contains few details about the conduct of the experiment, and the study contains several deficiencies that render it not useful for ecological risk assessment. Deficiencies are listed below.

This study is classified as supplemental.

B. **STUDY DEFICIENCIES:** The study has the following deficiencies:

- The GLP status of the study is not known.
- Positive controls were not used to show that the bees were adequately exposed.
- The test material is not characterized and viability was not confirmed.
- Feeding and other conditions of the experiment were not well described.
- No effort was made to isolate the test material from bees that died.
- Data were not provided for the entire observation period.

Primary Reviewer:	Shannon Borges	**Date:** 8/29/11
	Biologist, BPPD	
Secondary Reviewer:	Gail Tomimatsu	**Date:** 8/30/11
	Plant Pathologist, BPPD	

REQUIREMENT: U.S. EPA Requirement: 885.4340

TEST MATERIAL (PURITY): *Bacillus subtilis* D747
Potency: 1 x 10^{11} cfu/mL

SYNONYMS: N/A

CITATION: Commission of the Japan Plant Protection Association. 2003. *Bacillus subtilis* var. *amyloliquefaciens* Strain D747 Non-target insect testing. Full study – unpublished. Study completed September 2, 2003. MRID 28165716.

SPONSOR: N/A – Submitted by Certis USA, LLC, 9145 Guilford RD, Suite 175, Columbia, MD 21046. Testing site is given as: Japan Plant Protection Association Research Institute, 535 Kessoku-cho, Ushiku-shi, Ibaraki.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. Since Certis is not the sponsor of the study and did not conduct it, Certis does not know whether the study was conducted under GLP. This DER does not contain CBI.

EXECUTIVE SUMMARY:

Thirty immature *Crysoperla carnea* were exposed to *Bacillus subtilis* D747 at 5X the expected environmental exposure and observed for 52 days. Exposure occurred through treated food. The insects were observed for survival, egg production, and egg hatching.

Crysoperla carnea was not significantly affected at the exposure level and duration tested. Feeding rate could not be properly evaluated because raw data were not provided to determine if the difference in feed consumption was significant, but lacewings exposed to the *B. subtilis* D747 consumed 25% less food than controls. This may have affected their exposure to the test substance, and indicates a potential effect of the presence of *B. subtilis* D747 in the diet. There were no apparent effects on egg production, but whether the effect on egg hatching is significant is unknown. Based on this study, the LD_{50} is >5.0 x 10^8 cfu/mL *Bacillus subtilis* D747. It is not clear if the data establish a NOEC for sublethal effects.

Deficiencies include unknown GLP status and study quality controls, testing was not performed at the maximum hazard dose based on the proposed label, and sufficient information was not provided to verify data analysis for food consumption and egg hatching.

CLASSIFICATION: UNACCEPTABLE

I. MATERIALS AND METHODS:

A. GUIDELINE FOLLOWED: Not identified.

B. MATERIALS:

1. Test Material: *Bacillus subtilis* D747

Description: Not given

Lot/Batch #: Lot no. K3E001

Purity: 1×10^{11} cfu/mL

Storage conditions: Not described.

2. Test Organism:

Species (common and scientific names): Green lacewing, *Crysoperla carnea*

Age at test initiation: 2nd instar larvae

Source: Successively bred from insects received from Arysta Lifescience Corporation

Rationale: This species is recommended in the OPPTS (OSCPP) guideline for nontarget insect testing with MPCAs.

C. STUDY DESIGN AND METHODS:

Thirty immature *Crysoperla carnea* were exposed to *Bacillus subtilis* D747 at 10X the expected environmental exposure and observed for 52 days. Exposure occurred through treated food. The insects were observed for survival, egg production, and egg hatching.

1. Experimental Methods and Conditions:

Acclimation: Not described.

Test chamber - description and size: A rectangular acrylic plate (31 cm x 37 cm x 5 mm) with 30 holes (5 cm diameter) drilled in it was placed on top of a glass plate of the same size and fixed in place with acrylic rings. The rings were treated with talc to prevent the insects from climbing up the rings.

Amount of soil per test chamber: N/A

Route(s) of exposure: Diet.

Dose levels / test concentrations: (nominal) 5.0×10^8 cfu/mL – 10X the EEC according to the author. According to the proposed labels, however, this concentration is 5X the concentration of

the spray that would be applied when the highest use rate is used (3 lbs/acre in 100 gallons of water).

Preparation of doses or test concentrations: Powder of juvenile male insects (species not identified) was mixed in a 1:2 weight ratio with distilled water for use as the feed for the experiment. 20 mg of the test substance was mixed into 4 mL of feed and diluted 200 times.

Solvent/vehicle: None

Confirmation of MPCA viability: Dead insects were recovered, and each insect was mixed with 200 microliters of distilled water and ground. 100 microliters of suspension was then cultured on a nutrient broth (2% agar added as plate culture), and incubated for 2 days at 25°C. The number of colony-forming units of the genus *Bacillus* observed was then recorded.

Positive control / reference material: None

Other controls: Negative control (same prepared feed without test material)

Number of test organisms per chamber:
Control(s): 1
Treatments: 1

Number of replicates (chambers) per treatment:
Control(s): 30
Treatments: 30

Recovery of MPCA from test organisms: Not done.

Feeding: Insects were fed with the prepared feed for five days. Afterward, eggs of *Tribolium castaneum* were provided.

Test conditions:

Temperature: 25 °C
Humidity: Not described
Lighting: 16L:8D photoperiod

Duration of the study: 52 days.

2. **Observations:**

Parameters measured including sublethal effects/toxicity symptoms:

Observation/measurement intervals: Every 2-3 days for survival; 3-4 days for egg production

Testing for infectivity: None.

Were raw data included? Yes, for cumulative mortality and egg production. Other raw data were not included.

II. RESULTS:

A. VIABILITY OF DOSING SUSPENSIONS: Not done.

B. MORTALITY: In the control and treated groups, there were only insect deaths recorded on the 4th and 15th day following administration (one on each date), so the corrected death ratio on the 15th day following administration was 0.9% (Abbot's correction was used – uncorrected mortality in the control and treated groups was 6.9% and 7.7%, respectively). Abnormal behavior was not observed in the surviving insects. Colony screening from the dead insects resulted in only 2 and 4 *Bacillus* colonies per individual from the treated and control groups, respectively.

Dietary intake until the 5th day was 1.12 mg/insect in the control group and was 0.830 mg/insect in the treated group. Raw data were not provided, but the author states that the variability was high and that the two groups were not distinct.

B. SUB-LETHAL TOXICITY EFFECTS: There was little difference observed in the number of eggs produced from test insects that had reached adulthood. From the observations, 108.0 eggs were produced per female in the control group and 105.1 eggs were produced per female in the test substance treated group. The eclosion rate was 92.9% in the untreated group and 80.8% in the treated group. Raw data were not provided for eclosion rate, and a statistical analysis could not be performed to determine whether this was significantly different.

C. REPORTED STATISTICS: The LD_{50} was empirically determined to be $>5.0 \times 10^8$ cfu/mL and NOEC determined to be 5.0×10^8 cfu/mL.

III. CONCLUSION:

A. REVIEWER'S CONCLUSIONS: This study shows that survival of *Crysoperla carnea* was not significantly affected at the exposure level and duration tested. Feeding rate could not be properly evaluated because raw data were not provided to determine if the difference in feed consumption was significant. Although the authors state that it is not, lacewings exposed to the *B. subtilis* D747 consumed 25% less food than controls. Inclusion of a positive control would have been helpful in showing that the insects were adequately exposed. This may have affected their exposure to the test substance, and indicates a potential effect of the presence of *B. subtilis* D747 in the diet. There were no apparent effects on egg production, but whether the effect on egg hatching is significant is unknown. Based on this study, the LD_{50} is $>5.0 \times 10^8$ cfu/mL *Bacillus subtilis* D747. It is not clear if the data establish a NOEC for sublethal effects.

This study is classified as **unacceptable** because of the deficiencies below. There is some uncertainty related to the establishment of the LD_{50} because it is unclear whether the food consumption may have been reduced, thus reducing exposure. The study is not upgradeable.

B. STUDY DEFICIENCIES:

The study has the following deficiencies:

- Unknown GLP status
- The exposure tested was not at the maximum hazard rate

- A positive control is not necessary, but would have confirmed exposure to the test material
- Raw data were not included to verify results with statistical analysis

Avian Oral – *Bacillus subtilis* var. *amyloliquefaciens* strain D747 – Review of Guideline Study

MRID 48165712 / Company code 70051, Certis USA, LLC
MPCA / PC Code 016482

EPA Primary Reviewer: _____ **Date:** 8/29/11
Shannon Borges, Biologist
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division, EPA

EPA Secondary Reviewer: _____ **Date:** 8/30/11
Gail Tomimatsu, Plant Pathologist
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division, EPA

REQUIREMENT: PMRA Data Code: M9.2.1–Avian Oral
U.S. EPA Requirement: 885.4050
OECD Data Code: IIM 8.1, IIIM 10.1
Japan MAFF, 11 NohSan Notification No. 6283, Agricultural Production Bureau, 1999

TEST MATERIAL (PURITY): *Bacillus subtilis* CX-9025 (technical product), which contains *B. subtilis amyloliquefaciens* D747, nominal potency 2.0 x 10^{11} spores/g, lot number 0104-18-1. A certificate of analysis was included.

SYNONYMS: N/A

CITATION: Hubbard, P. R., and J. B. Beavers. 2010. Bacillus subtilis CX-9025: An acute oral toxicity study with the Northern bobwhite. Wildlife International, Ltd. Project no: 671-102. Date completed June 23, 2010. MRID 48165712.

SPONSOR: Certis, U.S.A., L.L.C. 9145 Guilford Road, Suite 175, Columbia, MD 21046.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. The study was conducted in compliance with GLP guidelines with the following exceptions as noted by the authors: 1) the test substance characterization and the stability of the test substance under storage conditions at the test site were not determined according to GLP standards, 2) the stability, homogeneity and verification of the test substance concentration in the dosing solution were not determined in accordance with GLP standards, and 3) periodic analyses of feed and water for potential contaminants were not conducted according to GLP standards, but were performed using a certified laboratory and standard USEPA analytical methods. These deviations are not expected to affect the quality of the study. This DER does not contain CBI.

EXECUTIVE SUMMARY:

The acute oral toxicity of Northern bobwhite (approximately 24 weeks of age) was determined to be >2250 mg/kg-bw (>4.5 x 10^{11} spores/kg-bw). This is equivalent to approximately >8.9 x 10^{9} spores per bird based on the average body weight at dosing. No significant differences in body weight or food consumption were observed. No mortalities, abnormal behavior or signs of toxicity were observed.

This study is an acute oral toxicity study, and not an avian oral toxicity/pathogenicity study as required by the data requirements for microbial pesticides. This study is thus rated **supplemental** and does not fulfill the data requirement.

CLASSIFICATION: **SUPPLEMENTAL.** The study is Unacceptable for regulatory risk assessment of microbial pesticides.

I. MATERIALS AND METHODS:

A. GUIDELINE FOLLOWED: OCSPP (OPPTS) 850.2100

B. MATERIALS:

1. **Test Material:** *Bacillus subtilis* CX-9025 (technical product), containing *B. subtilis amyloliquefaciens* D747

Description: Solid (powder), tan color

Lot/Batch #: 0104-18-1

Purity: Nominal potency 2 x 10^{11} spores/g

Storage conditions: Held under ambient conditions in locked storage

2. **Test Organism:**

Species (common and scientific names): Northern bobwhite (*Colinus virginianus*)

Age at study initiation: Approximately 24 weeks at test initiation. This is consistent with OCSPP 850.2100, but according to OCSPP 885.4050, birds should be 14 to 24 days old at testing

Sex: Males and females

Weight at study initiation: 183 – 225 grams.

Source: Buckeye Game Birds, Defiance, OH.

Rationale: The Northern bobwhite is a recommended species for this study.

C. STUDY DESIGN AND METHODS:

A limit dose study was conducted according to the OCSPP 850.2100 guideline for acute oral avian toxicity testing. Birds were assigned to one test group or one control group, and each treatment contained five males and five females. Birds were acclimated to the test pens for approximately four weeks prior to the initiation of the test. Birds were given one dose of either 0 or 2250 mg *Bacillus subtilis* CX-9025 and observed for 14 days. Birds were observed daily for mortality, signs of toxicity, or normal behavior. Body weight and feed consumption measurements were taken on Days 3, 7, and 14. Necropsies were not performed.

1. **Experimental Methods and Conditions:**

Acclimation:

Period: Approximately 4 weeks

Conditions: Same conditions as test
Feeding: *Ad libitum*, except that birds were fasted for approximately 18.5 hours prior to dosing
Water: *Ad libitum*
Health: Birds exhibiting abnormal behavior or injury were not included in the study

Pen size and construction materials:

Test birds were housed indoors by dosage group in batteries of pens manufactured by GQF Manufacturing Co. (Model No. 0010). Each pen's floor space measured approximately 78 x 51 cm. Floors were sloped so that ceiling height ranged from approximately 20 to 25 cm. External walls, ceilings and floors were constructed of wire mesh while side walls were galvanized sheeting.

Method of administration:

A single dose of the test substance in the diluents (reverse osmosis water) was given via oral intubation directly into the crop or proventriculus using a stainless steel 14 gauge cannula.

Dose levels:

Nominal: 0, 2250 mg/kg-bw (0 spores/kg-bw, 4.5×10^{11} cfu/kg-bw)
Measured: N/A

Dose preparation:

The test substance was dispersed in reverse osmosis water. The concentration was adjusted to provide a constant volume to body weight dosage for all treatment birds.

Solvent/vehicle:

Reverse osmosis water

Confirmation of MPCA viability:

Viability was not confirmed, but a certificate of analysis dated 13 days prior to the day of dosing was provided, which confirmed the potency.

Number of feed withholding days before dosing:

18.5 hours

Positive control / reference material:

None.

Other controls:

Negative control (0 mg/kg-bw)

Number of birds per group/treatment:

For negative control: 10 birds
For treated birds: 10 birds

Recovery of MPCA from tissues:

Not performed (According to OCSPP 885. 4050, attempts should be made to re-isolate the MPCA from examined tissues at necropsy)

Feeding:

All birds were fed game bird ration formulated to Wildlife International, Ltd.'s specifications by Cargill Animal Nutrition Company, Shippensbird, PA. Appendix II of the report provides an analysis of the feed provided.

Test conditions:

Temperature: 24.6 ± 0.7°C
Ventilation: Not described
Relative humidity: 57 ± 6%
Lighting: 123 lux
Photoperiod: 8 hours light:16 hours dark

Duration of study:

14 days

Other methods or conditions, if any: None.

2. <u>Observations</u>:

Parameters measured including sublethal effects/toxicity symptoms:

Behavior, signs of toxicity, body weight, food consumption.

Observation/measurement intervals:

Days 3, 7, and 14.

Indicate if the test material was regurgitated:

None was recorded.

Testing for infectivity:

Not performed.

Necropsy:

Not performed.

Were raw data included?

Yes.

Other observations, if any: None.

II. RESULTS:

A. VIABILITY OF DOSING SUSPENSIONS: Not done.

B. MORTALITY: There were no mortalities in the control or test group. Based on these results, the LD_{50} was determined to be >2250 mg/kg-bw.

C. SUBLETHAL TOXICITY ENDPOINTS: When compared to the control group, there were no apparent treatment related effects on mean body weight, mean body weight change or feed consumption among males of females in the 2250 mg/kg-bw test group at any measurement interval. Tables 1and 3 provide additional details.

TABLE 1. Mean body weights of Northern bobwhite exposed to *B. subtilis* CX-9025 in an acute oral limit dose study.

			Mean body weights (g)							
Experimental group	Sex		Day 0	Change	Day 3	Change	Day 7	Change	Day 14	Total Change
0 mg/kg-bw (control)	M	Mean	197	9	206	-4	202	7	209	12
		SD[1]	16	2	18	3	16	4	18	4
	F	Mean	200	7	207	-2	205	5	210	10
		SD	9	2	9	2	9	2	11	4
2250 mg/kg-bw	M	Mean	197	7	204	-4	200	7	207	10
		SD	13	2	13	2	12	1	12	3
	F	Mean	200	6	206	-6	201	7	208	8
		SD	14	2	14	3	16	2	16	3

[1]Standard deviation.

TABLE 2. Feed consumption by Northern bobwhite exposed to *B. subtilis* CX-9025 in an acute oral limit dose study.

		Estimated Mean Feed Consumption Grams/Bird/Day		
Experimental group	Sex	Days 0-3	Days 4-7	Days 8-14
0 mg/kg-bw (control)	M	24	22	21
	F	31	30	25
2250 mg/kg-bw	M	20	18	20
	F	16	17	17

D. REPORTED STATISTICS: The LD_{50} was determined empirically to be >2250 mg/kg-bw *B. subtilis* CX-9025.

E. VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER:

N/A

III. CONCLUSION:

A. **REVIEWER'S CONCLUSIONS:** The reviewer agrees with the conclusions of the study. However, this is an acute oral avian toxicity study, whereas an avian oral toxicity/pathogenicity study is required by the microbial pesticides data requirements. This study is not sufficient to satisfy that data requirement, and the study is classified as supplemental.

B. **DEFICIENCIES:** As noted above, the study was not sufficient to determine pathogenicity.

Primary Reviewer: Shannon Borges, Biologist, BPPD **Date:** 8/29/11

Secondary Reviewer: Gail Tomimatsu, Plant Pathologist, BPPD **Date:** 8/30/11

REQUIREMENT: PMRA Data Code: M9.5.2--Aquatic arthropods
U.S. EPA Requirement: 885.4240, 885.4280
OECD Data Code: IIM 8.3, IIIM 10.2
Japan MAFF Guidelines for Safety Assessments of Microbial Pesticides, 1996

TEST MATERIAL (PURITY): *Bacillus subtilis* D747, nominal purity 5.0 x 10^{10} cfu/mL, batch number KS03L008D.

SYNONYMS: *Bacillus amyloliquefaciens*

CITATION: Cockroft, R. 2004. Prolonged toxicity of microbial pesticides to *Daphnia magna*. Huntingdon Life Sciences, Ltd., UK. Date completed April 5, 2004. Unpublished. MRID 48165714.

SPONSOR: Certis, U.S.A., L.L.C. 9145 Guilford Road, Suite 175, Columbia, MD 21046.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. The study was conducted in compliance with GLP guidelines. This DER does not contain CBI.

EXECUTIVE SUMMARY:

In a 21-day toxicity/pathogenicity study, *Daphnia magna* were exposed to *Bacillus subtilis* D747 under static-renewal conditions. For reproduction and body length, the total number of young for each replicate surviving to the end of the study was calculated. A Williams' test for monotonic trend was used to determine significance. The EC_{10}, EC_{20} and EC_{50} estimates were determined by non-linear regression using nominal concentrations.

The estimated EC_{50} based on mortality was 3.70 x 10^{10} cfu/L based on the lack of significant mortality in any of the test groups. The EC_{50} for mean young per adult and adult body length was determined to be 5.62 x 10^{9} cfu/L. First brood times were significantly delayed in groups exposed at 8.52 x 10^{8} cfu/L and above.

This study is classified as acceptable and satisfies the requirement for freshwater invertebrate testing.

CLASSIFICATION: ACCEPTABLE

I. MATERIALS AND METHODS:

A. GUIDELINE FOLLOWED: OPPTS (OCSPP) 885.4240

B. MATERIALS:

1. **Test Material:** *Bacillus subtilis* D747

Description: Light brown liquid

Lot/Batch #: Batch # KS03L008D

Purity: Nominal potency 5.0 x 10^{10} cfu/mL

Storage conditions: Stored in darkness at approximately 4°C. Viability was confirmed weekly during the study.

2. **Test Organism:**

Species (**common and scientific names**): *Daphnia magna*, water flea

Age at test initiation (mean and range): <24 hours

Sex: Not specified

Source: Cultured in-house; originally obtained from the Institute National de Recherche Chimique Applique, France.

Rationale: None specified. Daphnia are typical test subjects for toxicity/pathogenicity testing, are susceptible to effects of toxic and pathogenic materials, and are representative of animals living in the water column that may be exposed.

C. STUDY DESIGN AND METHODS:

Groups of 20 individually housed *Daphnia magna* were exposed for 21 days under semi-static conditions, to five concentrations of *Bacillus subtilis* D747 dispersed in Elendt M4 culture medium. The nominal test concentrations, selected following preliminary range finding experiments, were 2.84 x 10^8, 8.52 x 10^8, 2.56 x 10^9, 7.67 x 10^9, and 2.3 x 10^{10} cfu/L, equivalent to 1.23, 3.70, 11.1, 33.3, and 100X the predicted environmental concentration (PEC). Twenty control organisms were also tested, housed in Elendt M4 medium without the addition of the *Bacillus subtilis* D747. The *Daphnia* were assessed for adult mortality and the effect of *Bacillus subtilis* D747 on reproduction.

Daily records were maintained for mortality and the general condition of the parental generation. Numbers of live and dead neonates and aborted eggs were recorded daily. *Daphnia* were fed daily with the unicellular green alga, *Chlorella vulgaris*. Test solutions were renewed three times each week and environmental data (pH, dissolved oxygen and temperature) were recorded for fresh and expired solutions on each occasion.

1. **Experimental Methods and Conditions:**

Acclimation: Cultures were maintained in-house and glass vessels containing approximately 500 – 800 mL of Elendt M4 culture medium with 16:8 light:dark cycle at 19 to 20 °C. The day before the start of the study, all juvenile *Daphnia* were removed from the laboratory cultures. The day of the start of the study, juveniles produced by the gravid adult *Daphnia* were removed from the culture vessels and held in a separate holding vessel. These animals were used to initiate the study. Conditions were similar to those of the study; however, because the animals were young, there was no need for an established acclimation period.

Test vessel: Test vessels were 60 mL capacity glass jars. These were loosely covered to prevent evaporation. *Daphnia* were housed individually in each jar, and each jar contained 50 mL of prepared test medium, or diluents medium only. This gave a loading of 50 mL test solution per organism.

Test system:

Static renewal. Medium and test material (prepared fresh) was renewed on days 3, 5, 7, 10, 12, 14, 17, and 19.

Source of dilution water:

The test organisms were maintained and the tests conducted in a reconstituted medium Elendt M4. The medium was prepared using analytical grade reagents and reverse osmosis-deionized water. The hardness of the medium ranged from 227 to 263 mg $CaCO_3$/L, and alkalinity from 42.0 to 56.5 mg/L. The total chlorine of this medium ranged from 0.00 to 0.05, and free chlorine ranged from 0.00 to 0.02 mg/L. The pH of the medium ranged from 7.6 to 8.1 throughout the study.

Water parameters:

Dissolved oxygen: 7.2 mg O_2/L
pH: 7.9
Temperature: 18 - 22°C
Hardness: 227 to 263 mg $CaCO_3$/L
Particulate matter: Not described
Total organic carbon (TOC) or chemical oxygen demand (COD)
Metals: Not described
Pesticides: Not described
Chlorine: total chlorine of this medium ranged from 0.00 to 0.05, and free chlorine ranged from 0.00 to 0.02 mg/L

Water quality measurements were made three times each week.

Aeration: No aeration of test vessels.

Route(s) of exposure:

Daphnia were exposed to the *Bacillus subtilis* D747 in the water column.

Test concentrations:

Nominal: 2.84×10^8, 8.52×10^8, 2.56×10^9, 7.67×10^9, and 2.3×10^{10} cfu/L, equivalent to 1.23, 3.70, 11.1, 33.3, and 100X the predicted environmental concentration (PEC). A control with 0 cfu/L was also tested.

Measured: Not calculated for study, ranged from 8 – 107% of the nominal potency, and were typically about 90% of the nominal potency.

The guideline recommends testing at least 10^6 cfu/mL or 1000X the maximum concentration in a 6-in layer of water, assuming direct application. According to the proposed label, a maximum of three gallons of product (CX-9032) can be applied aerially per acre. The product label states that a minimum of 1×10^{10} cfu/mL is present in the product. Direct application to an acre of water, 6-in (15 cm) deep results in a maximum concentration of 6.2×10^4 cfu/mL, and the maximum hazard dose based on this concentration would be 6.2×10^7 cfu/mL (6.2×10^{10} cfu/L).

These concentrations were established in a 13-day range-finding study in which 0, 2.30×10^8, 2.30×10^9, 2.30×10^{10}, 2.30×10^{11} cfu/L were tested. The results of this study indicated that the reproductive EC_{50} was likely to lie between 10X and 100X PEC, with 100% mortality at 1000 X PEC.

Preparation of test concentrations:

The test substance was dispersed in Elendt M4 to give an initial stock solution with a nominal concentration of 2.30×10^{10} cfu/L (the highest concentration tested). Aliquots of the initial stock solution were further diluted to give the remainder of the nominal test range.

Solvent/vehicle: N/A

Confirmation of MPCA viability:

Single 10 mL aqueous samples of control and each treatment solution were obtained for microbial analysis. Samples of fresh media were taken on Days 0, 5, 10, 14, and 19. Samples of expired test solutions were taken on Days 3, 7, 12, 17, and 21. Prior to quantification of viable test substance concentrations, all samples were heat treated at 75°C for 30 minutest to kill non spore forming bacterial species. Serial ten-fold dilutions of heat treated samples were prepared in sterile phosphate buffered saline (PBS, Oxoid BR0014G) and then 1 mL aliquots were placed into empty Petri-dishes in triplicate and then molten Tryptone Soya Agar (TSA, Oxoid CM 131) added. The agar was allowed to set and then the plates were incubated at 30 - 35°C for a time sufficient to allow development of characteristic colonies of the test organism (1 -3 days). Following incubation, the numbers of colonies of test organism present on the plates were counted and the numbers of viable spores (cfu) per mL in the test sample were calculated.

Positive control / reference material: None.

Other controls: None (no attenuated controls).

Number of replicates/groups:

Control(s): 20
Treatments: 20

Number of organisms per replicate /groups:

Control(s): 1
Treatments: 1

Biomass loading rate: One *Daphnia* per 50 mL dilution water

Recovery of MPCA from tissues: Not done

Feeding: A concentrated solution of *Chlorella vulgaris* was added to each test vessel daily. The Daphnia were fed at a rate of 0.10 mg *Chlorella*/daphnid/day up to Day 5 and at a rate of 0.15 mg *Chlorella*/daphnid/day from Days 6 to 21.

Lighting: Light intensity not described; day length was controlled to give a photoperiod of 16 hours light to 8 hours darkness.

Duration of study: 21 days.

Other methods or conditions, if any: None.

2. Observations:

Parameters measured including sublethal effects/toxicity symptoms:

Daily records were kept of the numbers of dead *Daphnia* of the parental generation, together with general observations of their size and health compared to control animals. Daily records were kept of the numbers of live and dead neonates produced in each vessel and numbers of aborted eggs. (*Daphnia* were considered dead if they were unable to swim within approximately 15 seconds of gentle agitation). Numbers of animals with eggs in the brood pouch were recorded. At the end of the test all surviving *Daphnia* were anaesthetized using carbonated water and their body length measured from the apex of the helmet to the base of the shell spine. Temperature, dissolved oxygen and pH were recorded in the fresh stock solutions and all expired test solutions on each occasion when test solutions were replaced.

Observation/measurement intervals: Daily.

Testing for infectivity: Not done.

Necropsy: N/A

Water quality was acceptable? (Results and Discussion Part A) Yes.

Were raw data included? Yes.

Other observations, if any: None.

II. RESULTS

A. WATER QUALITY PARAMETERS:

Environmental parameters were within acceptable limits throughout the study period. The pH, dissolved oxygen, and temperature were measured in fresh stock solutions and pooled replicates of expired test solutions each time test solutions were renewed. The lowest oxygen concentration was 6.1 mg/L at 21°C, which equates to 68% of the air saturation value. Temperature was also measured in an additional test vessel during the exposure phase. Up to and including Day 7, a thermometer was in use that was subsequently found to be malfunctiononing. From Day 8 to termination, a replacement thermometer was used. The recorded ambient temperatures ranged from 19.2 to 21.1°C and so remained constant to within ±1 °C. Daily records of the water quality parameters are available in the study report. They did not appear to show any anomalies.

B. VIABILITY OF TEST SUSPENSIONS:

Measured concentrations of *Bacillus subtilis* D747 in the test and control solutions is presented in Table 2. With the exception of the two lowest nominal exposure levels at Day 0, measured concentrations of *Bacillus subtilis* D747 ranged from 70 to 109% of nominal. Measured concentrations in expired media ranged from 4.1 to 70% of nominal, with a trend of increasing recoveries with increased nominal concentration. *Daphnia* may have consumed some spores of *Bacillus subtilis* D747, thereby reducing its population. Baishnav and Anderson (1995) showed that the spores of a similar bacterial species (*Bacillus thuringiensis* var. *israelensis*) to be rapidly ingested by *Daphnia magna*.

On Day 0, the measured concentrations of the lowest two test levels were determined to be 8.0 and 23% of nominal, respectively. However, the paired expired measurements for these preparations (Day 3) were consistent with those from later expired sampling occasions. It was considered that the low measured concentrations at Day 0 were likely to have been due to an undetected error in the dilution procedure at microbial counting and were not representative of the actual exposure media.

TABLE 2. Viable count verification of test and control suspension concentrations during a 21-day exposure of *Daphnia* to *Bacillus subtilis* D747; data were excerpted from Table 1, pages 20-22, MRID 48165714

Day	Measured Concentration of Test Suspension (CFU/L)					
	Nominal Concentration of Test Suspension (CFU/L)					
	2.84×10^8	8.52×10^8	2.56×10^9	7.67×10^9	2.30×10^{10}	Negative Control
0 (new)	2.28×10^7	1.97×10^8	2.15×10^9	8.23×10^9	1.65×10^{10}	2.00×10^{3a}
3 (old)	1.17×10^7	1.74×10^8	1.38×10^9	3.07×10^9	9.97×10^9	1.00×10^{3a}
5 (new)	2.40×10^8	7.67×10^8	2.14×10^9	6.80×10^9	1.93×10^{10}	ND
7 (old)	2.22×10^7	1.91×10^8	6.03×10^8	3.87×10^9	1.17×10^{10}	3.00×10^{3a}
10 (new)	2.22×10^8	7.53×10^8	2.14×10^9	6.87×10^9	1.93×10^{10}	ND

Day	Measured Concentration of Test Suspension (CFU/L)					
	Nominal Concentration of Test Suspension (CFU/L)					
	2.84×10^8	8.52×10^8	2.56×10^9	7.67×10^9	2.30×10^{10}	Negative Control
12 (old)	2.46×10^7	1.21×10^8	4.07×10^8	4.37×10^9	1.60×10^{10}	3.83×10^{5a}
14 (new)	2.22×10^8	8.37×10^8	2.03×10^9	7.33×10^9	2.02×10^{10}	1.60×10^{4a}
17 (old)	1.66×10^7	8.37×10^7	2.14×10^8	2.57×10^9	1.42×10^{10}	7.80×10^{4a}
19 (new)	3.10×10^8	8.37×10^8	2.15×10^9	7.87×10^9	1.93×10^{10}	9.00×10^{3a}
21 (old)	6.30×10^7	8.77×10^7	7.20×10^8	3.97×10^9	1.56×10^{10}	9.00×10^{3a}

[a]A small amount of contamination was present, not confirmed as *Bacillus subtilis* D747. Representing <0.01% of the lowest nominal concentration, hence not considered to affect the outcome of validity of the study.

C. **MORTALITY:** No treatments gave significantly lower survival than the control group. Cumulative immobility/mortality is reported in Table 3.

TABLE 3. Cumulative number of immobilized Daphnia exposed to *Bacillus subtilis* D747 for 21-days under semi-static conditions. Data were excerpted from Tables 2 and 3, p 23; and Appendix 2, pp. 28-33, MRID 48165714

Day	Cumulative Number of Immobilized *Daphnia*					
	Measured Concentration of Test Suspension (CFU/L)					
	2.84×10^8	8.52×10^8	2.56×10^9	7.67×10^9	2.30×10^{10}	Negative Control
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	2	0	0	0	0
4	0	2	0	0	0	0
5	0	2	0	0	0	0
6	0	2	0	0	2	0
7	0	2	0	0	3	0
8	0	2	0	0	4	0
9	0	2	0	0	4	0
10	1	2	0	0	5	0
11	1	2	0	0	5	1
12	1	2	0	0	5	1
13	1	3	0	0	5	1
14	2	3	0	0	5	2

Day	Cumulative Number of Immobilized *Daphnia*					
	Measured Concentration of Test Suspension (CFU/L)					
	2.84×10^8	8.52×10^8	2.56×10^9	7.67×10^9	2.30×10^{10}	Negative Control
15	2	3	0	0	5	2
16	2	3	0	0	6	2
17	2	3	0	0	6	2
18	2	3	0	0	6	4
19	3	3	0	1	7	4
20	4	4	0	1	8	4
21	4	4	0	1	8	4
Total immobility	4 (20%)	4 (20%)	0 (0%)	1 (5%)	8 (60%)	4 (80%)

D. **SUBLETHAL TOXICITY ENDPOINTS:** Mean values of sublethal effect measurements are presented in Table 4. Significant reduction in fecundity and timing of first brood release was significantly affected by exposure to *Bacillus subtilis* D747 at concentrations of 8.52×10^8 cfu/L and above. Significant reduction in parental body length was found at concentrations of 7.67×10^9 cfu/L and above.

TABLE 4. Mean cumulative number of offspring produced per female *Daphnia magna* during 21-day exposure to *Bacillus subtilis* D747 under static-renewal conditions. Data were excerpted from Tables 4, 5, and 6, pp 24-25 of MRID 48265714.

Measurement	Mean Measured Concentration (CFU/L)					
	2.84×10^8	8.52×10^8	2.56×10^9	7.67×10^9	2.30×10^{10}	Negative Control
Mean neonate production	111	94	88	41	17	113
Days to first brood	8	10	9	11	12	8
Mean body length (mm)	4.63	4.45	4.48	3.89	3.31	4.53

E. **REPORTED STATISTICS:** Logistic regression was performed to determine the EC50 for mortality/immobility using log nominal concentrations and not assuming zero mortality at the control level. Each group was compared to the control using one-tailed Fisher's exact tests. No description of adjustment for Type I error was described.

For reproduction and body length, the total number of young for each replicate surviving to the end of the study was calculated. A Williams' test for monotonic trend was used to determine significance. The EC_{10}, EC_{20} and EC_{50} estimates were determined by non-linear regression using nominal concentrations.

The estimated EC_{50} based on mortality was 3.70×10^{10} cfu/L based on the lack of significant mortality in any of the test groups. The EC_{50} for mean young per adult and adult body length was determined to be 5.62×10^{9} cfu/L. First brood times were significantly delayed in groups exposed at 8.52×10^{8} cfu/L and above.

III. CONCLUSION

A. **REVIEWER'S CONCLUSIONS:** The reviewer agrees with the findings described in the report.

B. **DEFICIENCIES:** None.

IV. REFERENCES

Vaishnav, D. D., and R. L. Anderson. 1995. Uptake and loss of *Bacillus thuringiensis* var. *israelensis* by Daphnia magna in laboratory exposure. Environmental Toxicology and Chemistry 14: 763-766.

Primary Reviewer:	Shannon Borges	**Date:** 8/29/11
	Biologist, OPP/BPPD	
Secondary Reviewer:	Gail Tomimatsu	**Date:** 8/30/11
	Plant Pathologist, OPP/BPPD	

REQUIREMENT: PMRA Data Code: M9.4.1–Freshwater fish
U.S. EPA Requirement: 885.4200
OECD Data Code: IIM 8.2, IIIM 10.2
Japanese MAFF: Guidelines for Safety Assessments of Microbial Pesticides (Draft 1996).

TEST MATERIAL (PURITY): *Bacillus subtilis* D747, nominal potency 5.0 x 10^{10} cfu/mL

SYNONYMS: N/A

CITATION: Cockroft, B. 2004. *Bacillus subtilis* var. *amyloliquefaciens* strain D747: Prolonged toxicity to microbial pesticides to fish (*Oncorhynchus mykiss*). Huntingdon Life Sciences, Ltd., Cambridgeshire, England. Study completed August 19, 2004. MRID 48165713.

SPONSOR: Certis U.S.A., L.L.C. 9145 Guilford Road, Suite 175, Columbia, MD 21046

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. The study was conducted in compliance with UK and OECD guidelines. This DER does not contain CBI.

EXECUTIVE SUMMARY:

In a definitive 30-day toxicity/pathogenicity study, rainbow trout (*Oncorhynchus mykiss*) were exposed under static-renewal conditions to *Bacillus subtilis* var. *amyloliquefaciens* D747. Test concentrations were 1.14 x 10^{10}, 2.88 x 10^{10}, 5.75 x 10^{10}, 1.15 x 10^{11}, and 2.30 x 10^{11} cfu/L

Treatments of 1.15 x 10^{11} cfu/L and above gave significantly reduced survival compared to the controls. Therefore, based on these data the LC_{50} was determined to be 8.1 x 10^{10} cfu/L. Fish surviving to Day 30 showed significant reduction in body length and weight at test concentrations of 2.88 x 10^{10} cfu/L and above. Based on these data, the LOEC and NOEC for sublethal effects were determined to be 2.88 x 10^{10} cfu/L and 1.44 x 10^{10} cfu/L, respectively.

This study is classified as acceptable and satisfies the guideline requirement for a toxicity/pathogenicity study for freshwater fish.

CLASSIFICATION: ACCEPTABLE

I. MATERIALS AND METHODS:

A. GUIDELINE FOLLOWED: OSCPP (OPPTS) 885.4200

B. MATERIALS:

1. Test Material: *Bacillus subtilis* D747

Description: Light brown liquid

Lot/Batch #: KS03L008D

Purity: Nominal potency 5.0 x 10^{10} cfu/mL

Storage conditions: Kept in darkness at approximately 4°C. Viability confirmed in weekly assessment

2. Test Organism:

Species (common and scientific names): Rainbow trout (*Oncorhynchus mykiss*)

Age at test initiation (mean and range): Juvenile

Weight at test initiation (mean and range): 0.77g

Length at test initiation (mean and range): 4.4 cm

Sex: Not known - juveniles

Source: H.T.F. Rutland, UK

Rationale: The rainbow trout is a species recommended by the guideline.

C. STUDY DESIGN AND METHODS:

Five test concentrations were prepared plus one control (all in duplicate). Ten fish were added to each test vessel. Fish were placed randomly into the test vessel containing prepared test medium or diluents water as appropriate. Fish were exposed to the test or control conditions for a period of 30 days with daily renewal of the test medium to ensure the maintenance of satisfactory environmental conditions and near nominal exposure levels. The quantities of the *B. subtilis* D747 used in the test solutions was adjusted based on the results of weekly viability checks conducted using the same methods as used for confirmation of exposure concentrations. Mortality and sublethal effects were observed on a daily basis. At death or at the end of the experiment, fish were studied for pathological changes compared to the controls.

1. **Experimental Methods and Conditions:**

Acclimation:

Period: 7 days
Conditions: Temp: 15°C, D.O. – 8.8 to 9.9 mgO_2/L, lighting – 16:8 light:dark
Feeding: Fed 2 to 4% f their body weight daily with commercial fry pellet, no medication was given
Water: N/A
Health: No mortalities observed

These were similar to the conditions of the test period.

Test vessel:

Material: Not described
Size: 25 x 46 x 25 cm
Fill volume: Filled to a depth of 19 cm (20L), loading of 0.39 g bw/liter

Test system:

Static renewal, daily renewal

Source of dilution water:

Laboratory tap water that was filtered, dechlorinated, and softened by passage through a Vivendi®, water purification system. The water was passed through a high grade activated carbon filter to remove chlorine and any organic contaminants. A proportion of the supply was then passed through a water sogtener before final reverse osmosis (RO) treatment to produce purified water. These two supplies were then re-mixed in the ratio of approximately 2 parts 'RO' water to 1 part carbon filtered water to give a laboratory supply with the desired water hardness.

Water parameters:

Dissolved oxygen: 6.9 – 8.2 mgO_2/L
pH: 7.6 – 7.9
Temperature: 15°C
Hardness: 157 – 186 mg $CaCO_3/L$
Particulate matter: Not described
Total organic carbon (TOD) or chemical oxygen demand (COD): Not described
Metals: Analysis contained in Appendix I, MRID 48165713, pp. 23-25
Pesticides: Analysis contained in Appendix I, MRID 48165713, pp. 23-25
Chlorine: Analysis contained in Appendix I, MRID 48165713, pp. 23-25

Aeration: Supplemental aeration was provided in this study through narrow bore glass tubes. Justification for this was not provided. The guideline states that gentle aeration of the test vessels used in static systems during the exposure period is permitted only in cases where oxygen levels my fall below 60% saturation. The lowest level measured was approximately 68% of saturation, and test and control water were renewed daily, so it is not clear why this was necessary.

Route(s) of exposure: The test substance was administered as a suspension directly into the water. Treated food was not provided as an additional means of exposure.

Test concentrations:

Nominal: 1.44×10^{10}, 2.88×10^{10}, 5.75×10^{10}, 1.15×10^{11}, and 2.30×10^{11} cfu/L (equivalent to 62, 125, 250, 500, and 1000X the predicted environmental concentration)
Measured: See Table 2 for details. Measured concentrations ranged 68-119% of nominal concentrations, and averaged 97% of nominal concentrations on the day of preparation (fresh). They ranged from 65-113% and averaged 96% of nominal concentrations the following day (expired). Measurements were taken on Days 0 and 1, 7 and 8, 21 and 22, and 29 and 30.

Maximum hazard concentration should be at least 1.12×10^{11} cfu/L. Based on the CX-9030 granular label, a maximum of 3 lbs/acre can be applied. The product contains 5×10^{10} cfu/g, and would result in 1.12×10^{8} cfu/mL if applied directly to a pond 15 cm deep. The nominal test concentrations are sufficient with respect to testing this dose.

The study authors noted that the water in all exposure concentrations were markedly opaque.

These test concentrations were determined based on a preliminary 96-hour range finding study using groups of three fish and concentrations of 0 (control), 2.30×10^{8}, 2.30×10^{9}, 2.30×10^{10}, and 2.30×10^{11} cfu/L. Results of the range finding study indicated that the acute LC_{50} was likely to be $>2.30 \times 10^{11}$ cfu/L. Since a single mortality was observed at this concentration, however, it was determined that the study should be conducted as a definitive study instead of a limit dose study.

Preparation of test concentrations:

Aliquots of the test substance were dispersed directly in diluent water to give the nominal concentrations listed above. Exposure media was prepared separately.

Solvent/vehicle: N/A

Confirmation of MPCA viability:

Single 15 mL aqueous samples of the control and each treatment solution were obtained for microbial analysis. Samples of fresh media were taken on Days 0, 7, 14, 21, and 29. Samples of expired test solutions were takend on Days 1, 8, 15, 22, and 30.

Prior to quantification of viable test substance concentrations, all samples were heat treated at 75°C for 30 minutes to kill non-spore forming bacterial species. Serial ten-fold dilutions of heat treated samles were prepared in sterile phosphate buffered saline (PBS, Oxoid BR0014G) and then 1 mL aliquots were placed into empty Petri dishes in triplicate and then molten Tryptone Soya Agar (TSA, Oxoid CM 131) added. The agar was allowed to set and then the plates were incubated at 30 – 35 °C for a tme sufficient to allow development of characteristic colonies of the test organism (not less than 24 hours). Following incubation, the numbers of colonies of test organism present on the plates were counted and the numbers of viable spores (colony forming units – cfu) per mL in the test sample were calculated.

Positive control / reference material: N/A

Other controls: Negative control

Number of replicates/groups:

Control(s): 2
Treatments: 2

Number of organisms per replicate /groups:

Control(s): 10
Treatments: 10

Biomass loading rate: 0.39 g bodyweight/L

Recovery of MPCA from tissues: Not performed. Animals were examined for physiological changes, but isolation of *B. subtilis* D747 from tissues was not described.

Feeding: Exposure was not provided via the oral route. Fish were fed 3% of their bodyweight daily with commercial fry pellet (Nutra Trout). Fish were re-weighed on Days 9 and 20 for purposes of recalculating the feeding rate.

Lighting: Intensity not reported. Photoperiod was 16h:8h light:dark.

Duration of study: 30 days.

Other methods or conditions, if any:

2. <u>Observations</u>:

Parameters measured including sublethal effects/toxicity symptoms:

Mortality (determined by absence of respiratory movement and absence of response to physical stimulation of the caudal peduncle) was observed and subjective assessments of sublethal effects were also made. From Day 2 onward, the fish were observed to assess whether there was a delayed feeding response compared to controls. Fish that died during the study were inspected internally and externally for signs of pathological changes compared to healthy stock fish. At termination, all surviving fish were examined for pathological changes compared to controls.

Measurements of dissolved oxygen, pH, and temperature were made daily.

Observation/measurement intervals: Daily

Testing for infectivity: Not done. Tissues examined for abnormalities.

Necropsy: Performed on fish that died during the study as well as surviving fish at the end of the study.

Water quality was acceptable? Yes.

Were raw data included? Yes.

II. RESULTS:

A. WATER QUALITY PARAMETERS:

Water quality parameters are summarized in Table 1. Mean values for the experiment are provided here. Raw data for daily measurements are provided in the study report.

TABLE 1. Mean water quality parameters in test suspensions during the 30-day hour exposure of rainbow trout to *Bacillus subtilis* D747.

Parameter	Replicate	1.44×10^{10} cfu/L	2.88×10^{10} cfu/L	5.75×10^{10} cfu/L	1.15×10^{11} cfu/L	2.30×10^{11} cfu/L	Control
Dissolved oxygen (mg/L)	1	8.2	8.1	7.9	7.9	7.9	7.9
	2	8.1	8.0	7.8	8.0	7.7	8.2
Temperature (°C)	1	15	15	15	15	15	15
	2	15	15	15	15	15	15
pH	1	7.7	7.7	7.6	7.6	7.9	7.6
	2	7.7	7.6	7.6	7.9	7.9	7.7

B. VIABILITY OF DOSING SUSPENSIONS:

Measured concentrations ranged 68-119% of nominal concentrations, and averaged 97% of nominal concentrations on the day of preparation (fresh). They ranged from 65-113% and averaged 96% of nominal concentrations the following day (expired).

TABLE 2. Viable count verification of test and control suspension concentrations during a 30-day exposure of rainbow trout to *Bacillus subtilis* D747.

	Fresh		Expired	
Nominal concentration (cfu/L)	**Mean counts of *B. subtilis* D747 (cfu/L)**	**% Nominal**	**Mean counts of *B. subtilis* D747 (cfu/L)**	**% Nominal**
Days 0 (Fresh) and 1 (Expired)				
Control	ND	--	5.27×10^{4} [a]	--
1.44×10^{10}	1.43×10^{10}	99	1.51×10^{10}	105
2.88×10^{10}	2.92×10^{10}	101	2.97×10^{10}	103
5.75×10^{10}	5.81×10^{10}	101	5.90×10^{10}	103
1.15×10^{11}	1.04×10^{11}	90	1.07×10^{11}	93
2.30×10^{11}	1.84×10^{11}	80	2.01×10^{11}	87
Days 7 (Fresh) and 8 (Expired)				
Control	1.00×10^{3}	--	4.6×10^{4} [a]	--
1.44×10^{10}	1.64×10^{10}	114	1.63×10^{10}	113
2.88×10^{10}	2.70×10^{10}	94	3.00×10^{10}	104
5.75×10^{10}	6.82×10^{10}	119	6.69×10^{10}	116
1.15×10^{11}	1.28×10^{11} [b]	111	1.17×10^{11} [b]	102
2.30×10^{11}	N/A [c]	N/A [c]	N/A [c]	N/A [c]

	Fresh		Expired	
Nominal concentration (cfu/L)	Mean counts of *B. subtilis* D747 (cfu/L)	% Nominal	Mean counts of *B. subtilis* D747 (cfu/L)	% Nominal
Days 21 (Fresh) and 22 (Expired)				
Control	6.17×10^{3}[a]	--	6.9×10^{4}[a]	--
1.44×10^{10}	1.40×10^{10}	97	1.33×10^{10}	93
2.88×10^{10}	2.95×10^{10}	102	2.66×10^{10}	93
5.75×10^{10}	6.56×10^{10}	114	6.38×10^{10}	111
1.15×10^{11}	1.30×10^{11}[b]	113	1.18×10^{11}	103
2.30×10^{11}	N/A[c]	N/A[c]	N/A[c]	N/A[c]
Days 29 (Fresh) and 30 (Expired)				
Control	2.45×10^{4}[a]	--	4.45×10^{4}	--
1.44×10^{10}	1.22×10^{10}	85	1.11×10^{10}	77
2.88×10^{10}	1.93×10^{10}	67	1.87×10^{10}	65
5.75×10^{10}	5.34×10^{10}	93	5.10×10^{10}	89
1.15×10^{11}	7.77×10^{6}	68	9.00×10^{10}	78
2.30×10^{11}	N/A[c]	N/A[c]	N/A[c]	N/A[c]

[a]A small amount of contamination was present, not confirmed to be *Bacillus subtilis* D747. The amounts present represented <0.01% of the lowest nominal concentration, and were not considered to affect the outcome of validity of the study.
[b]Not applicable.
[c]Not sampled as all fish were dead.

C. **MORTALITY:** One mortality was observed in the 2.88×10^{10} cfu/L test group, and all fish died in the two highest test groups, 1.15×10^{11} and 2.30×10^{11} cfu/L. Table 3 shows the cumulative mortality over the 30 day period.

TABLE 3. Mortality in rainbow trout during 30-day exposure to *Bacillus subtilis* D747 under static-renewal conditions.

	Cumulative Number of Mortalities Per Day, Days 1-15														
Conc. (cfu/L)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.44×10^{10}	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2.88×10^{10}	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5.75×10^{10}	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.15×10^{11}	0	0	0	10	10	10	19	19	19	19	19	19	19	19	19
2.30×10^{11}	1	1	4	20	20	20	20	20	20	20	20	20	20	20	20
	Cumulative Number of Mortalities Per Day, Days 16-30														
	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.44×10^{10}	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2.88×10^{10}	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1
5.75×10^{10}	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.15×10^{11}	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19
2.30×10^{11}	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20

D. SUBLETHAL TOXICITY ENDPOINTS: Fish surviving to Day 30 showed significant reduction in body length and weight at test concentrations of 2.88 x 10^{10} cfu/L and above (Table 4).

TABLE 4. Mean length and weight of surviving fish at test termination.

Concentration (cfu/L)	Replicate	Mean (SD) Fish Length (cm)	Mean (SD) Fish Weight (g)
Control	1	5.4 (0.4)	2.5 (0.5)
	2	5.4 (0.3)	2.3 (0.4)
1.44 x 10^{10}	1	5.2 (0.3)	2.2 (0.5)
	2	5.3 (0.4)	2.3 (0.5)
2.88 x 10^{10}	1	4.8 (0.4)	1.8 (0.6)
	2	5.0 (0.5)	1.9 (0.6)
5.75 x 10^{10}	1	4.8 (0.4)	1.7 (0.5)
	2	4.8 (0.2)	1.7 (0.3)
1.15 x 10^{11}	1	3.7 (0.0)[a]	0.6 (0.0)[a]
	2	N/A[b]	N/A[b]
2.30 x 10^{11}	1	N/A[b]	N/A[b]
	2	N/A[b]	N/A[b]

[a]Variability was not measured because only one fish survived to test termination
[b]No survivors for length/weight measurements.

E. REPORTED RESULTS AND STATISTICS:

Logistic regression was used to determine the LC50 for B. subtilis D747 in rainbow trout. Treatments of 1.15 x 10^{11} cfu/L and above gave significantly reduced survival compared to the controls. Therefore, based on these data the following LC_{50}, LOEC, and NOEC values were obtained:

LC_{50} (30-day): 8.1 x 10^{10} cfu/L
LOEC: 1.15 x 10^{11} cfu/L
NOEC: 5.75 x 10^{10} cfu/L

A general linear model was used to determine whether mean fish length or weight were significantly different from the controls. Fish surviving to Day 30 showed significant reduction in body length and weight at test concentrations of 2.88 x 10^{10} cfu/L and above. Based on these data, the following LOEC and NOEC values were obtained:

LOEC: 2.88 x 10^{10} cfu/L
NOEC: 1.44 x 10^{10} cfu/L

On 23 out of the 28 feeding occasions from Day 2 onwards, all test groups showed a delayed feeding response compared to the controls. This may have been due to reduced visibility of the feed, as all exposure concentrations were markedly opaque.

Upon *post mortem* examination, no sporadic mortalities or surviving fish at termination exhibited any pathological changes compared to the controls that were considered to have been a result of exposure to the test material.

III. CONCLUSION:

A. **REVIEWER'S CONCLUSIONS:** The reviewer agrees with the results of the study. Based on the calculated LC50, NOEC, and LOEC, *Bacillus subtilis* D747 is expected to cause adverse effects in fish at the concentrations identified as these endpoints.

Because all test concentrations were reported to be opaque due to the presence of the test substance, an attenuated control should have been included to account for the possible physical interference of the test material with the health of the fish. Because this was not included, it is not possible to determine if the effects were due to the toxicity/pathogenicity or other factors.

This study is **acceptable** and satisfies the data requirement for a Tier I freshwater fish toxicity/pathogenicity study.

B. **STUDY DEFICIENCIES:**

Aeration does not appear to be justified based on the dissolved oxygen content reported; however, it does not appear that this necessarily provided an advantage. An attenuated or sterile filtrate control should have also been included, since the test material caused the water to be opaque.

Conversation about B. amyloliquefaciens
Joel Gagliardi to: cdively 07/27/2011 03:44 PM
Cc: Susanne Cerrelli
This message is digitally signed.

Chris,
Thanks for your quick response.

I think based on the MIDI data alone you would be most correct calling D747 *Bacillus amyloliquefaciens*, a member of the *Bacillus subtilis* group. A quick glance at phenotypic characteristics shows D747 fits snugly into this species. Let us know what you think.

Attached is the Bergey's Manual 2nd edition entry, and pasted below is what is listed on the NIH-NCBI server.

Bergeys_Bacillus_amyloliquefaciens.pdf

Also, here is our newest guidance for microbial CSF preparation. I suggest trying to separate out the water component from the fermentation milieu especially in cases where a product is a liquid. Otherwise it is largely a semantic issue for a fermentation product;
http://www.epa.gov/pesticides/biopesticides/regtools/biopest_csf.pdf
Please see page 16. Let Susanne know if you will change the CSF of either product.

Thanks again and let us know if you would like to have another teleconference.
Joel

http://www.ncbi.nlm.nih.gov/Taxonomy/Browser/wwwtax.cgi
Bacillus subtilis group
- Bacillus amyloliquefaciens
  - Bacillus amyloliquefaciens LL3
  - Bacillus amyloliquefaciens PGK1
  - Bacillus amyloliquefaciens subsp. amyloliquefaciens
  - Bacillus amyloliquefaciens DSM 7
  - Bacillus amyloliquefaciens subsp. plantarum
  - Bacillus amyloliquefaciens FZB42
  - Bacillus amyloliquefaciens TA208
  - Bacillus amyloliquefaciens XH7
- Bacillus atrophaeus
  - Bacillus atrophaeus 1013-1
  - Bacillus atrophaeus 1013-2
  - Bacillus atrophaeus 1942
  - Bacillus atrophaeus ATCC 49822
  - Bacillus atrophaeus ATCC 49822-1
  - Bacillus atrophaeus ATCC 49822-2
  - Bacillus atrophaeus ATCC 9372
  - Bacillus atrophaeus ATCC 9372-1
  - Bacillus atrophaeus ATCC 9372-2
  - Bacillus atrophaeus BACI051-E

Bacillus sp. M101(2010)
Bacillus sp. M103(2010)
Bacillus sp. M110(2010)
Bacillus sp. M112(2010)
Bacillus sp. M14(2010)
Bacillus sp. M2(2010)
Bacillus sp. M21(2010)
Bacillus sp. M22(2010)
Bacillus sp. M25(2010)
Bacillus sp. M29(2010)
Bacillus sp. M30(2010)
Bacillus sp. M35(2010)
Bacillus sp. M38(2010)
Bacillus sp. M4(2010b)
Bacillus sp. M40(2010)
Bacillus sp. M5(2010)
Bacillus sp. M63(2010)
Bacillus sp. M64(2010)
Bacillus sp. M67(2010)
Bacillus sp. M68(2010)
Bacillus sp. M88(2010)
Bacillus sp. M90(2010)
Bacillus sp. M94(2010)
Bacillus sp. M95(2010)
Bacillus sp. M98(2010)
Bacillus sp. TT106(2010)
Bacillus sp. TT45(2010)
Bacillus sp. TT46(2010)
Bacillus sp. TT53(2010)
Bacillus sp. TT80(2010)

****

Joel V. Gagliardi, Ph.D.
U.S. Environmental Protection Agency, Mailcode 7511-P
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1200 Pennsylvania Avenue, NW
Washington, DC 20460

703-308-0116 - phone / 703-305-0118 or 703-308-7026 - fax
http://www.epa.gov/pesticides/biopesticides
****

U. S. Environmental Protectic .gency
Office of Prevention, Pesticides, and Toxic Substances (OPPTS)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

DOCKET VERIFICATION AND CERTIFICATION FORM
For Internal OPPTS Use Only

Title of Action: (1) **Notice of RECEIPT:** New Active Ingredients and their Products (FIFRA)
(2) **and Notice of Filing of Pesticide Petitions for Residues of Pesticide Chemicals in or on Various Commodities for** *Bacillus subtilis* var. *amyloliquefaciens* strain D747

RIN #:	**Docket ID #:** EPA-HQ-OPP-20 t0-0944	**FRL#:**

Docket Title: *Bacillus subtilis* var. *amyloliquefaciens* strain D747

Contact Information:	**Name:** Susanne Cerrelli	**Phone #:** 703-308-8077

Legacy Information: ; **FDMS Docket # EPA-HQ-OPP0346;**

Program Lead's Verification: I have reviewed the docket and verified the following:
- ☑ All of the documents identified in the attached Docket Index have been submitted to the appropriate Docket Manager for inclusion in the docket identified above.
- ☑ Documents containing copyrighted, CBI, or otherwise protected information have been identified to allow for "special" processing by the appropriate Docket Staff.
- ☑ The material has been assembled in a useable form to support the document being published in the FEDERAL REGISTER (FR).
- ☑ **COMMENTS** Susanne Cerrelli **is the primary Docket Contact Person. Estimated FR publication date is** mid Dec 2010

Date: 11/17/10	Initials: SC	Phone #: 703-308- 8077

Docket Manager's Verification and Sign-off: I hereby confirm the following:
- ☒ The Docket ID # identified above matches our records.
- ☒ The documents identified in the attached Docket Index have been received by the OPP Docket Staff.
- ☒ The documents have been properly processed for inclusion in EPA FDMS Dockets, as appropriate.
- ☒ The documents either already are in the docket or are being processed for inclusion in the docket.
- ☐ COMMENTS:

Date: 11/17/2010	Signature: Kathy O. Wunderlin	Phone #: 703- 305-5805

Program Lead's Certification: I hereby certify that:
- ☑ I have completed the verification above.
- ☑ I have submitted to the Docket Manager all of the documents that I identified needed to be updated or added to the docket.
- ☑ I have obtained the Docket Manager's sign-off.
- ☑ The docket is complete and ready for public release.
- ☐ COMMENTS:

Date 11/17/10	Signature: Susanne Cerrelli Susanne Cerrelli	Phone #: 703-7308-8077

→ this is being batched
Notices expected in mid Dec 2010

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EPA-HQ-OPP-2010-0944-DRAFT-0003	CX-9032 Draft Label	07/26/2010	

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CX-9030

Water Dispersible Granular Biofungicide

For Organic Production

Active Ingredient:

Bacillus subtilis var. *amyloliquefaciens* strain D747* 25.0%

Other Ingredients 75.0%

Total 100.0%

*Contains a minimum of 5×10^{10} colony-forming units (cfu) per gram

EPA Reg. No. 70051-

EPA Est. No. 70051-CA-001

Manufactured by: Certis USA, L.L.C.
9145 Guilford Rd., Suite. 175
Columbia, MD 21046

NET WEIGHT: 5 LBS Lot No.

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF ON SKIN: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for further treatment advice.

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for further treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product label with you when calling a poison control center or doctor.
Hot Line No.:1-800-255-3924

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS
CAUTION

Harmful if absorbed through skin. Harmful if inhaled. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
- NIOSH approved respirator with any N, P, R or HE filter

Follow manufacturer's instructions for cleaning and maintaining PPE. In no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. AS soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply when weather conditions favor drift or runoff from treated areas.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: cover-alls, waterproof gloves, shoes plus socks.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a dry area inaccessible to children. Store in original containers only. Keep container closed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

Container Disposal: Non-refillable Container. Do not reuse or refill this container

Completely empty bag into application equipment. Clean container promptly after emptying. Then dispose of empty bag in a sanitary landfill or by incinerating, or if allowed by local authorities, by burning. If disposal is by burning, stay out of smoke.

GENERAL INFORMATION

CX-9030 is a broad-spectrum preventative biofungicide for control or suppression of fungal and bacterial plant diseases. The active ingredient of CX-9030 is a naturally occurring strain (D747) of the beneficial rhizobacterium *Bacillus subtilis* var. *amyloliquefaciens*, which colonizes roots, leaves, and other plant surfaces, killing pathogenic organisms by means of antibiotic compounds (iturins) which disrupt pathogen cell wall production. D747 rapidly colonizes plant root hairs, leaves, and other surfaces, preventing establishment of disease-causing fungi and bacteria.

CX-9030 can be applied alone or in combination and/or rotation with chemical fungicides as a tool for integrated disease management in agricultural crops, ornamental and nursery plants, and turfgrass. CX-9030 offers a valuable tool for management of resistance to chemical fungicides through its multiple and unique modes of action.

CX-9030 is exempt from the requirement for residue tolerance and therefore can be applied up to and including the day of harvest.

CX-9030 complies with the USDA National Organic Program (NOP) and is listed by the Organic Materials Review Institute (OMRI) for use in organic production.

MIXING AND HANDLING INSTRUCTIONS

Mix the required amount of CX-9030 in cool water with sufficient agitation to maintain a uniform suspension in the spray or mixing tank. Tank should be cleaned prior to use. Do not use highly alkaline or highly acidic water to mix sprays. Use a buffering agent if necessary to maintain neutrality (pH 6 to 8) of water in the tank. Maintain agitation during application. Apply immediately after mixing; do not allow spray mix to stand overnight.

APPLICATION METHODS

Ground: CX-9030 can be applied in most commonly-used ground application equipment, such as tractor-mounted boom, airblast, high clearance, hose-end, backpack, and other pressurized sprayers; hose-end or hand-held sprayers; foggers or mist blowers; water wheel and other drench applicators; and shank or other soil injection method.

Aerial: CX-9030 can be applied by fixed or rotary winged aircraft in a minimum of 3 gallons of water per acre. Standard precautions should be taken to minimize spray drift.

Chemigation: CX-9030 can be applied through drip (trickle) and sprinkler type irrigation equipment. Refer to the section entitled "Chemigation Instructions" for detailed instructions.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the Agency responsible for pesticide regulation.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Agricultural crops

CROPS	DISEASES/PATHOGENS (See footnotes for additional information)
Vegetables and melons, including but not limited to:	
Brassica vegetables such as broccoli, cabbage, cauliflower, Brussels sprouts, kohlrabi, and other cole crops.	Pin rot complex (*Alternaria/Xanthomonas*)* Leaf spots (*Alternaria* spp., *Xanthomonas* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe polygoni*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Bulb vegetables such as onions, garlic, shallots, and others.	*Botrytis* spp. (neck rot, leaf blight) Purple blotch (*Alternaria* spp.) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Rust (*Puccinia pori*)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Cucurbits such as cucumbers, squash (all types), cantaloupes, muskmelons, watermelons, and other melons.	Powdery mildew (*Erisyphe* and *Sphaerotheca* spp.) Downy mildew (*Pseudoperonospora* spp.) Gummy stem blight (*Didymella bryoniae* and *Phoma cucurbitacearum*) See instructions below for "Soil application" against the following diseases: Vine decline (*Monosporascus cannonballus*) Charcoal rot (*Macrophomina phaseoli*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp.
Fruiting vegetables such as tomatoes, peppers, eggplant, tomatillo, okra, and others.	Bacterial spot (*Xanthomonas* spp.)*[1] Bacterial speck (*Pseudomonas syringae* pv. *tomato*)*[1] Gray mold (*Botrytis cinerea*) Powdery mildew* (*Leveillula, Oidiopsis, Erisyphe*, and *Sphaerotheca* spp.) Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. Southern blight (*Sclerotium rolfsii*)*
Leafy vegetables such as head and leaf lettuce, celery, spinach, radicchio, arugula, watercress, and others (including leafy *Brassica* vegetables such as mustard and collard greens, kale, bok choi, and related crops).	Downy mildew (*Bremia lactucae*, *Peronospora* spp.)* Powdery mildew (*Golovinomyces (Erisyphe) cichoracearum*)* Bacterial blights Head and leaf drop (*Sclerotinia* spp.)[2] Pink rot (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* spp.) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. Bottom rot (*Rhizoctonia solani*)

Legume vegetables succulent and dried beans and peas such as green, snap, shell, and Lima beans, garbanzo beans, chickpeas, soybeans, dry beans, peas, split peas, lentils, and other legumes.	White mold (*Sclerotinia sclerotiorum*)[2] Gray mold (*Botrytis cinerea)* Powdery mildew (*Microsphaera diffusa*) Rusts*, including *Uromyces appendiculatus*, *Puccinia* spp., and Asian soybean rust (*Phayospora pachyrhizi*) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Root, tuber, and corm vegetables such as potato, sweet potato, carrot, cassava, beets, ginger, radish, horseradish[22], ginseng, turnip, and other root, tuber and corm crops.	Black root/crown rot (*Alternaria* spp.) Bacterial leaf blight (*Xanthomonas campestris*) Downy mildew (*Peronospora* spp.) Powdery mildew (*Erisyphe* spp.) Gray mold (*Botrytis* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Black leg /bacterial soft rot (*Erwinia carotovora*) Early blight (*Alternaria solani*)* Late blight (*Phytophthora infestans*)* See instructions below for "Soil application" against the following diseases: Black scurf (*Rhizoctonia solani*) Cavity spot (*Pythium* spp.) "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytophthora*, or *Verticillium** spp.
Other vegetables such as sweet corn, popcorn, asparagus, peanut, and watercress	*Botrytis* spp. Rusts (*Puccinia* spp.) White mold (*Sclerotinia sclerotiorum*)[2] Leaf spots (*Cercospora* and *Cercosporidium* spp.)* "Damping off," seedling blights, and root or crown diseases caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Phytaphthora*, or *Verticillium** spp. (see instructions below for "Soil application").
Tree fruits and nuts, including but not limited to:	
Citrus such as orange, lemon, lime, grapefruit, tangerine (mandarin), tangelo, pummelo, and other citrus	*Alternaria* leaf spot (*Alternaria alternata*) Postbloom fruit drop (*Colletotrichum acutatum*)* Greasy spot (*Mycosphaerella citri*)*[3] Citrus canker (*Xanthomonas campestris* pv. *citri*)[1] Scab (*Elsinoe fawcetti*)*[4] Melanose (*Diaporthe citri*)*
Pome fruits such as apple, pear, crabapple, quince, and others	Powdery mildew (*Podosphaera leucotricha*)[5] Scab (*Venturia* spp.)* Flyspeck (*Zygophiala jamaicensis*)[6] Sooty blotch disease complex[6] Brooks spot (*Mycosphaerella pomi*)[6] Bot rot/white rot (*Botryosphaeria dothidea*)[6] Bitter rot (*Colletotrichum* spp.)[6] Cedar apple rust (*Gymnosporangium juniperi-virginianae*)[6] Fire blight (*Erwinia amylovora*)*[7]
Stone fruits such as apricot, cherry, nectarine, peach, plum, prune, pluot, and others	Powdery mildew (*Sphaerotheca* and *Podosphaera* spp.)*[8] Bacterial canker (*Pseudomonas* spp.) Brown rot blossom blight (*Monilinia laxa*)[9] Brown rot (*Monilinia fructicola*)*[10] Gray mold (*Botrytis cinerea*)[10] Peach leaf curl (*Taphrina deformans*) Bacterial leaf spot (*Xanthomonas arbicola* pv. *pruni*)[1] Rusty spot (*Podosphoera leucotricha*)[1]
Tree nuts such as almond, pistachio, pecan, walnut, filbert, hazelnut, chestnut, macadamia, and other tree nuts.	Walnut blight (*Xanthomonas campestris*)[11] Anthracnose (*Colletotrichum acutatum*)* Bacterial canker (*Pseudomonas syringae*) Shot hole (*Wilsonomyces carpophilus*)* Brown rot (*Monilinia* spp.)* Pecan scab (*Cladosprium caryigenum*)*[1]

Pomegranates	Leaf and fruit spots (*Cercospora, Gloeosporium* and *Pestalotia* spp.)[1] Fruit rots (*Alternaria, Botrytis*, and other spp.)[10] Powdery mildew (*Sphaerotheca pannosa*)
Other fruits, including but not limited to:	
Strawberry	Powdery mildew (*Sphaerotheca macularis, Erisyphe* spp.)*[12] Gray mold (*Botrytis cinerea*)*[11] Anthracnose (*Colletotrichum acutatum*) Angular leaf spot (*Xanthomonas fragariae*)[1] For the following diseases, see instructions below for "Soil application" (and also root dip instructions[22]): "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. Charcoal rot (*Macrophomina phaseolina*)
Berries, including blueberry, blackberry, raspberry, loganberry, huckleberry, gooseberry, elderberry, cranberry (non-flooded fields), current, and other berries	Mummy berry (*Monilinia voccinii-corymbosi*)* Botrytis blight (*Botrytis cinerea*) Bacterial canker (*Pseudomonas* spp.)[13] Anthracnose fruit rot (*Colletotrichum acutatum*)[10]
Grapes including wine grapes, table grapes, and raisins	Powdery mildew (*Erisyphe* (formerly *Uncinula*) *necotor*)[14] Gray mold (*Botrytis cinerea*)[15] Sour rot complex[15] Downy mildew (*Plasmopara viticola*)* Phomopsis (*Phomapsis viticola*)[16] Eutypa (*Eutypa lata*)[17]
Tropical fruits such as avocado[18], mango[18], papaya[19], pineapple[19], banana, plantain, and others.	Anthracnose (*Colletotrichum* spp.) Scab (*Sphacelomo perseoe*) Bacterial canker (*Xanthomonas campestris*) Sigatoka (*Mycosphaerella fijiensis*)[20]
Other Crops	
Herbs and spices such as basil, thyme, coriander, dill, cilantro, parsley, mint, and others.	Powdery mildews (*Oidium* spp. and others) Downy mildews (*Peronospora* spp. and others)* Damping off diseases (*Rhizoctonia, Pythium, Alternoria*, and *Fusarium* spp.) Leaf spots (*Alternaria, Septoria, Colletotrichum*, and *Cercospora* spp.)* Bacterial diseases (*Erwinia, Xanthomonas*, and *Pseudomonas* spp.) Rusts (*Puccinia* spp. and others) "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Coffee	Coffee berry disease (*Colletotrichum caffeanum*)[1] Coffee rust (*Hemileia vastatrix*)[1] Anthracnose (*Colletotrichum* spp.) *Botrytis* flower blight *Cercospora* leaf spot and berry blotch "Damping off" and root or crown diseases caused by *Rhizoctonia, Fusarium, Pythium, Phytophthora*, and/or *Verticillium** spp. (see instructions below for "Soil application").
Tobacco	Angular leaf spot (*Pseudomonas* spp.) Anthracnose (*Colletotrichum* and *Glomerella* spp.) Blue mold or downy mildew (*Peronospora* spp.)* Brown spot (*Alternaria*) Barn spot/ frogeye leaf spot (*Cercospora nicotianae*)[10] Collar rot (*Sclerotinia sicerotiorum*)[2] Gray mold (*Botrytis cinerea*) Powdery mildew (*Erysiphe cichoracearum*) Target spot (*Rhizoctonia solani*) See instructions below for "Soil application" against the following diseases: "Damping off," seedling blights, and root or crown diseases caused by *Pythium, Rhizoctonia, Fusarium, Olpidium, Phytophthora*, or *Verticillium** spp.

	Charcoal rot (*Macrophomina phaseolina*) Black root rot (*Thielaviopsis basicola*) Black shank (*Phytophthora* spp.)* Southern blight/southern stem rot (*Sclerotium rolfsii*)*
Mint	Rust (*Puccinia* spp.)
Hops	Powdery mildew (*Sphaerotheca macularis*)[21]

Footnotes:

*Suppression only; for improved control mix or rotate with chemical fungicide approved for such use.

[1] Tank mix or rotate with copper-based fungicides at label rates for improved control.

[2] Apply at or immediately following planting (but before plant emergence) as a banded seedline treatment 4 to 6 inches wide. Make second application at thinning or cultivation in sufficient water and multiple nozzles to ensure thorough coverage of lower leaves and surrounding soil surface. Incorporation with light irrigation after application may improve disease control. Repeat at 10-14 day intervals if conditions promoting disease persist.

[3] For greasy spot suppression, apply at first new foliar flush and repeat with each new flush. Tank mix with spray oil or copper based fungicide at labeled rates.

[4] For suppression of citrus scab, start applications at first new foliage flush and repeat at petal fall and when fruit are ½ inch in diameter.

[5] Make first application at or before tight cluster if conditions favor disease development. Repeat at 7-10 day intervals through the second cover spray or longer on susceptible varieties or if environmental conditions favor rapid disease development.

[6] Begin applications before bloom when environmental conditions favor disease development, repeating at 7 to 14 day intervals or as needed. Control may be enhanced by addition of a surfactant to improve spray coverage. Use only surfactants known to be safe for use on the crop and for which such use is allowed.

[7] Rotate with antibiotics registered for fire blight control for improved performance. Begin applications at 1-5% open blossoms and repeat every 3-7 days as necessary until petal fall, when intervals can be increased to 7 days. CX-9032 can also be used in summer "cover spray" applications to control the shoot blight phase of fire blight and summer diseases. Can be mixed with copper fungicides to improve control.

[8] Make first application at popcorn stage and repeat every 7 days.

[9] Start applying at early bloom stage and repeat every 7 days through petal fall.

[10] Pre-harvest applications in sufficient water to cover fruit or other harvested plant parts may improve control of postharvest infections.

[11] Begin applications at or before pistillate bloom, repeating every 7-10 days. Apply before rainfall if possible, and tank mix or rotate with a copper-based bactericide registered for such use for improved control.

[12] Start applications at or just before flowering and repeat every 7-10 days as needed through harvest.

[13] Apply before fall rains and again during dormancy before spring growth.

[14] Start applications when new shoots are ½ to 1½ inches long. Repeat at 3-5 inches, 8-10 inches, and then at 7-10 day intervals until disease conditions no longer exist.

[15] Apply at bloom, before bunch closure, at veraison, and before harvest.

[16] Apply when shoots are ½ to 1 inch long and again when 6-8 inches long.

[17] Mix 2 fluid ounces CX-9032 per gallon of water and apply to pruning wounds.

[18] Apply at budbreak and repeat on 14-21 day interval as needed through harvest.

[19] Apply at flowering and repeat on 14-21 day interval as needed through harvest

[20] Apply at first appearance of leaves and repeat at 7-21 day intervals as needed, in sufficient water to obtain thorough coverage of foliage. Tank mix with spray oil or other registered fungicides for improved control.

[21] Mix 6 to 10 fluid ounces CX-9032 per 100 gallons of water and apply in minimum of 20 gallons per acre form emergence to training, 50 gallons per acre from training to wire, and 100 gallons per acre from wire touch through harvest.

[22] For treatment of horseradish or strawberry roots immediately before transplanting: immerse bare roots (individually or in bunches) for 10 seconds in a suspension of 1 to 2 pints CX-9032 per gallon of water.

Foliar application: For control of diseases on foliage, flowers, fruit, or other above-ground parts of plants: Mix CX-9030 in water and apply as a spray at a rate of **0.25 to 3 pounds per acre** in sufficient water to achieve thorough coverage of the crop canopy with minimal runoff. Begin applications at crop emergence, transplanting, or when conditions are conducive to development of disease. Repeat application every 7 to 10 days, or as needed, for as long as conditions favor disease development. Lower rates (0.25 to 1 pound per acre) may be applied under light disease pressure, to smaller (e.g. newly-emerged) plants, or when CX-9030 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (1 to 3 pounds per acre), apply more frequently (every 3 to 7 days), and mix or rotate CX-9030 with other fungicides for improved performance.

Soil application: For control of soilborne diseases infecting seeds, seedlings, roots, crown, stems, or other plant parts below ground or in contact with soil: Apply CX-9030 at **0.125 to 1 pound per acre**. Mix the required amount in sufficient water to apply by one of the following methods:

- Soil drench applied to transplants in flats or pots in the greenhouse or nursery any time prior to transplanting (see additional drench instructions under "Nurseries, greenhouses, shade houses, and ornamental plants" below).
- Soil drench at transplanting, using a "water wheel" injector, spray nozzles/hoses, or other method to drench each root ball and/or planting hole.
- Soil or seedline drench, or banded spray (in-furrow) at planting. See the section on "Banded (in-furrow) application" below for additional instructions.

Follow-up (post-planting) preventative applications can be made every 2-4 weeks by one or more of the following methods, if needed:

- Drip (trickle) or any type of sprinkler irrigation, any time after planting or transplanting. See Chemigation Instructions for additional information.
- Spray directly onto the soil surface and/or lower plant parts. If targeting root disease, follow immediately with sufficient overhead sprinkler irrigation to move CX-9030 to the root zone.
- Injection directly into the rooting zone using shanks or similar equipment.

Lower rates (0.125 to 0.5 pounds per acre) may be applied under light disease pressure, to smaller plants, or when CX-9030 is used in a tank mix with other fungicides whose labels allow such use. Under moderate to severe disease pressure, or when environmental conditions and plant stage are conducive to rapid disease development, use higher label rates (0.5 to 1 pound per acre), apply more frequently (every 2 weeks), and mix or rotate CX-9030 with other fungicides for improved performance.

Banded (in-furrow) application: Use the table below to determine the correct application rate of CX-9030 per 1,000 row feet, based on row spacing and desired rate per acre. Mix the required amount of CX-9030 in water and apply as banded spray (4" to 6" wide) or seedline drench centered over the planting furrow. Apply directly over seeds in the furrow just before they are covered with soil. The volume of water required per acre or per 1,000 row feet will depend on the application equipment used. Consult your local cooperative extension service if you need assistance calibrating band spraying equipment.

Rates for banded (in-furrow) application: Find desired application rate in the left column. Read across that line to the correct row spacing indicated at the top to find the number of ounces (dry) per 1,000 row feet that will provide the desired application rate per acre. To convert to **level teaspoons**, multiply the number of ounces by 8.2. For **level tablespoons**, multiply the number of ounces by 2.75.

Rate/acre	Space between rows (inches)														
(pounds)	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
0.25	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3
0.5	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6
0.75	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9
1.0	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.2	1.2
1.25	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.4	1.5	1.5
1.5	0.6	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.7	1.8
1.75	0.6	0.7	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1
2.0	0.7	0.9	1.0	1.1	1.2	1.3	1.5	1.6	1.7	1.8	2.0	2.1	2.2	2.3	2.4
2.25	0.8	1.0	1.1	1.2	1.4	1.5	1.7	1.8	1.9	2.1	2.2	2.3	2.5	2.6	2.8
2.5	0.9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1
2.75	1.0	1.2	1.3	1.5	1.7	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.0	3.2	3.4
3.0	1.1	1.3	1.5	1.7	1.8	2.0	2.2	2.4	2.6	2.8	2.9	3.1	3.3	3.5	3.7

Nurseries, greenhouses, shadehouses, and ornamental plants

Spray application: Mix **0.25 to 3 pounds of CX-9030 per 100 gallons of water** and apply as a foliar spray of sufficient volume to wet the entire plant with minimal runoff. Begin preventative applications at plant emergence and repeat every 3-28 days as needed (every 3-7 days if disease pressure is high or environmental conditions are highly favorable to disease outbreak, 10-28 days under low pressure or less conducive conditions).

Drench application: Mix **0.125 to 2 pounds of CX-9030 per 100 gallons of water** and apply as a drench or coarse spray to soil or other growing media in pots, flats, plugs, trays, or planting beds, for control or suppression of soilborne diseases of seedlings, cuttings, bedding plants, and transplants (including vegetables and other transplanted food crops). Make first application at or immediately before seeding, sticking, germination, or transplanting. Repeat applications every 14-28 days as needed. Transplants can be treated immediately before transplanting into field soils to protect against damping-off and other diseases that reduce plant establishment.

Cutting or root dip: Dip basal end of cuttings or bare roots (individually or in bunches) in a suspension of **1 to 2 pounds of CX-9030 per gallon of water.** Immerse for 5-10 seconds immediately before planting.

Chemigation: Mix **0.125 to 2 pounds of CX-9030 per 100 gallons of water** and apply via drip, handheld, or sprinkler irrigation systems. Refer to "Chemigation Instructions" for more details.

CROPS/USE SITES	DISEASES/PATHOGENS
Indoor, outdoor, and shade- or other cover-grown ornamental trees and shrubs, flowering plants, foliage plants, tropical plants, potted plants, potted or cut flowers, bedding plants, forestry seedlings, conifer production for reforestation, fruit trees, vegetables and other crops grown in greenhouses or nurseries.	Powdery mildews caused by *Erisyphe, Podosphaera, Sphaerotheca, Oidium,* and *Golovinomyces* spp.) Anthracnose (*Colletotrichum* spp.) Bacterial leaf spots caused by *Erwinia, Pseudomonas,* and *Xanthomonas* spp. Damping-off disease (*Rhizoctonia, Pythium, Fusarium* spp.) Late blight, blackeye, and root rots caused by *Phytophthora* spp. Gray mold and blight caused by *Botrytis cinerea* Black root rot (*Aspergillus* spp.) Black spot of roses (*Diplocarpon rosae*) Downy mildew (*Peronospora* spp.) Leaf spots caused by *Alternaria, Septoria, Cercospora, Entomosporium, Helminthosporium,* and *Myrothecium* spp.) Rust (*Puccinia* spp.) Scab (*Venturia* spp.) Root rot, bottom rot, or stem rot caused by *Rhizoctonia solani* *Sclerotinia* blight *Fusarium* wilts

Turfgrass application

For control of foliar diseases, apply CX-9030 at **0.5 to 1 ounce per 1,000 square feet** as a ground-directed spray in sufficient water to provide thorough coverage. To control root and crown diseases in or on the soil, immediately follow the spray with sufficient overhead sprinkler irrigation to move the product into the root zone.

USE SITES/CROPS	DISEASES/PATHOGENS
Turf, sod, lawns, golf course (fairways, roughs, greens, tees), grass seed production Including but not limited to: Bluegrass, Bentgrass,	Anthracnose (*Colletotrichum graminicola*) Brown patch (*Rhizoctonia solani*) Dollar spot (*Lanzia* and *Moellerodiscus* spp., formerly *Sclerotinia homeocarpa*) Powdery mildew (*Erisyphe graminis*) Rust (*Puccinia* spp.)

Bermudagrass (common & hybrid), Dichondra, Fescue, Orchardgrass, *Poa annua*, St. Augustine grass, Ryegrass, *Zoysia*, mixtures, and other grasses or ornamental turf	Gray leaf spot (*Pyricularia grisea*) "Damping off" or seedling blights caused by *Pythium*

CHEMIGATION INSTRUCTIONS

General information:

Apply this product through pressurized irrigation systems such as drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (including impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

Drip (trickle) and micro-irrigation chemigation

1. The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.

Sprinkler chemigation:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
8. Do not apply when wind speed favors drift beyond the area intended for treatment.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purpose referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the disease problem, condition of the crop, incompatibility with other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

The following claims may be presented on the product's labeling:

OMRI Listed
OMRI seal

10/13/10

Note to file

Points to explain to Dively for

EPA File Symbol 70051-RNI + -RNT

for CX-9030 (70051-RNI)

→ The [redacted] listed differs from MSDS provided?

→ Can you confirm which [redacted] it is?

→ Dively will get back to me

- I need to make sure cleared for food use +

for organic → list 4?

Let her know not sure considered organic...

for Cx-9032 (70051-RNT)

[redacted]

are NOT Organic ingredients

- delete cas # for mix on CSF

- Do they want to withdraw formula or move forward for ~~the~~ pesticide w/out organic claim?

→ She will get back to me @ [redacted] considering options to deal w/ data comp

Have to buy [redacted] from another source as [redacted] is not willing to pay data comp.

If in fact inert ingredient replaced [redacted] with another similar product how will this effect assessment?

[redacted] is not being supported.

Bayer + Syngenta paid for the data but not the manufacturer

Certis can not afford $50,000 for inert, more likely to find substitute ingredient that is being supported

Can replace or remove the [redacted]

Not sure @ decision.

Union was not informed @ data comp cost

Inert ingredient information may be entitled to confidential treatment

Clarification about remaining issues EPa reg no. 70051-rnt and 70051-RNI
Susanne Cerrelli to: Dively, Chris 10/01/2010 04:40 PM

Our guidance for preparing microbial CSFs is on our website. In general, fermentation products that include the ai are listed on line one along with a measure for viability. In most instances the viability measure is the enforceable limit and should be a guaranteed minimum.

[redacted]

We do not expect a dry or wet weight of a microbial ai to be put on the CSF unless there is a specific reason to do so, and a method to reliably separate only the ai from other fermentation products. Since most microbial a.i.'s are inseparable from fermentation products they are most often considered and tested in this manner.

In rare instances such as if a toxic product is present after fermentation, there may be a requirement to list this on a separate line of the CSF: see 40CFR158.350(a)(3)

Our guidance for preparing biopesticide CSF is on our webpage with a sample CSF on page 16 of the guidance document: http://www.epa.gov/pesticides/biopesticides/regtools/biopest-csf.pdf

Another issue is the inert ingredients. In order to meet the organic certification sought on the label they must be on the old EPA I4a or 4b inerts list or EPA 25b list and generally be from a natural source, or qualify separately based on internal guidance. This guidance should be sent to the registrant early in the process where organic certification is sought.

http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067226

7 CFR.pdf completelist_inerts CAS.pdf

I can not email CBI but need to explain to talk to you about 2 inerts as they all need to be on list 4 to be organic.

Susanne Cerrelli

Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

CX-9032 (70051-RNT)
Tracy Jackson to: cdively 08/04/2010 10:05 AM
Cc: InertsBranch, rock.sandra, Sree Nair

From: Tracy Jackson/DC/USEPA/US
To: cdively@certisusa.com
Cc: InertsBranch@EPA, rock.sandra@epamail.gov, Sree Nair/DC/USEPA/US@EPA

Dear Ms. Dively,

I am contacting you regarding your submission of **CX-9032 (70051-RNT)**. There is a deficiency on both the Basic and Alternate Confidential Statement of Formula.

Based on the compositional information in the Agency's proprietary inert mixture database, there are one or more inert ingredients in a (**surfac**tant) for which data protection rights have been asserted and for which the Agency must ensure such rights are protected in the pesticide registration process. In order for the Agency to make a determination as to the acceptability of this proprietary mixture for use as an inert ingredient in food use pesticide formulations, further documentation is required from the manufacturer. The product manufacturer can get specific information on the chemicals in question and the documentation required to determine acceptability for data compensation by contacting the Inert Ingredient Assessment Branch at InertsBranch@epamail.epa.gov

Please open document below:

Inert Status form.doc

Thank you

Tracy Jackson
Macfadden/EPA Contractor
2777 S. Crystal Drive
Arlington, VA 22202
703-308-7227
jackson.tracy@epa.gov

Data Screen for Nontarget Organism Data Requirements for *Bacillus subtilis* var. *amyloliquefaciens* strain D747
Shannon Borges, 9/16/2010

The data package for *Bacillus subtilis* var. *amyloliquefaciens* strain D747 provides studies that address the following Tier 1 Nontarget Organism data requirements:

- Avian oral toxicity/pathogenicity
- Freshwater fish toxicity/pathogenicity
- Freshwater invertebrate toxicity/pathogenicity
- Nontarget plant testing
- Nontarget insect testing
- Honey bee testing

No studies or data waiver rationale were submitted to specifically address the wild mammal toxicity/pathogenicity; however, according to the data matrix, an acute oral toxicity/pathogenicity with laboratory mammals has been submitted. This study should be sufficient for use in wild mammal risk assessment, and no additional studies are required at this time to address that data requirement.

A study or waiver rationale for avian inhalation toxicity/pathogenicity has not been submitted. The results of the avian oral toxicity/pathogenicity test indicate that *B. subtilis* var. *amyloliquefaciens* strain D747 is not toxic or pathogenic to birds, and *B. subtilis* var. *amyloliquefaciens* is not known to be an inhalation risk to birds. Therefore, a study or data waiver rationale to address the avian inhalation toxicity/pathogenicity data requirement is not needed at this time.

A study or waiver rational for marine/estuarine fish and invertebrate testing has also not been submitted. The studies submitted for freshwater fish toxicity/pathogenicity and freshwater invertebrate toxicity/pathogenicity indicate, upon brief examination, that adverse effects occur at the concentrations tested. However, it has not been determined yet whether exposure in marine/estuarine environments will be significant and whether exposure will be high enough to result in adverse effects in aquatic environments. This will be determined in the risk assessment, and if adverse effects to marine/estuarine fish and invertebrates is suspected, then additional testing may be required after this determination is made. Studies or data waiver rationale are not required for the marine/estuarine fish and invertebrate testing data requirement at this time.

Based on this preliminary screen, the data package submitted to address the nontarget organism data requirements is complete and can be placed in review.

21-Day Screen Completed by Contractor

21-Day Expires on 8-16-10

Jacket # 70051-RNI
MRID# 481657

Content Screen: Recommended to Pass/Fail

86-5 Review: Passed/Failed/NA

Transfer This Jacket to:

SHERYL REILLY

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 7-26-10

Experts In-Processing Signature: B.R. Date 7-29-10 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes _____ Date _____

EPA Reg. Number: 70051-RNI	EPA Receipt Date: 7-26-10

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
		yes	no			
	a) Selective Method (Fee category experts use)	X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

Passed 86-5 Review. MRID 481657
Inerts approved for pre & post harvest food use
-JD

481657

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly **encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: Christine Dively
Phone #: 301-483-3806
Email: cdively@certisusa.com

First Call/Initials:	**Second Call/Initials:**
Date: 7/30	**Date:**
Time: 9:45	**Time:**

This is_____**, EPA contractor.**

I'm calling regarding your submission in support of
70051-RNT, RNI.

We have found the following deficiencies regarding:
PR Notice 86.5: Yes or No
Volume/Study Title:

Volume/Study Title:

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: Yes or No
Both - Certification - "selective method" should be selected
RNT - insert on CSF has wrong CAS #

These deficiencies have been approved by EPA.
The corrections can be faxed to 703-305-5060/Attn: _____.

Second Call/Email:
If we do not receive the corrections by _____**, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.**

Registration Applications 70051-RNT and RNI

Jennifer Drobish to: cdively 07/30/2010 09:44 AM
Cc: Sree Nair

Ms Dively,

This is Jennifer Drobish, EPA contractor. I'm writing in regards to your submissions in support of the subject registrations. We have found the following deficiencies regarding the application packages:

-for both RNT and RNI, on the Certifications with Respect to Citation of Data the "selective method" should be selected.
-for RNT, the CSF has a CAS # that is not in our database. This could be a typo as I have found the ingredient with a different CAS #. Please see the attached form regarding this inert ingredient.

These corrections can either be faxed to me at 703-305-5060/Attn: Jennifer Drobish or emailed to me at drobish.jennifer@epa.gov

Thank you,
Jennifer Drobish
EPA Contractor
703-305-1671

FW: You Have Received a New Scan
Dively, Chris to: Jennifer Drobish 08/02/2010 05:31 PM
Cc: "Dively, Chris"

Jennifer,
Per your request, please find attached the revised
CSF for 70051-RNT and the revised
Certification with Respect to Citation of Data Form for both 70051-RNT and
RNI.

Regards,
Chris

-----Original Message-----
From: AdminScanner@certisusa.com [mailto:AdminScanner@certisusa.com]
Sent: Monday, August 02, 2010 5:16 PM
Cc: Dively, Chris
Subject: You Have Received a New Scan

KM-2560
[00:c0:ee:1d:8d:0d]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 28, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-437753
EPA File Symbol or Registration Number: 70051-RNI
Product Name: CX-9030
EPA Receipt Date: 26-Jul-2010
EPA Company Number: 70051
Company Name: CERTIS USA, LLC

CHRISTINE A. DIVELY
CERTIS USA, LLC
9145 GUILFORD ROAD, SUITE 175
COLUMBIA, MD 21046

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B590

NEW AI;FOOD USE;MICROBIAL/BIOCHEMICAL WITH EXEMPTION;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-7973.

Sincerely, Teresa Dowos
Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{8791712~

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ○ AD
- ◉ BPPD
- ○ RD

Risk Mgr. 92

Receipt No.	S- 879171
EPA File Symbol/Reg. No.	70051-RNI
Pin-Punch Date:	7/26/2010

☐ This item is NOT subject to FFS action.

Action Code:

Requested:	B590
Granted:	B590
Amount Due:	$ (pd) 27,563

Parent/Child Decisions:

Secondary = 70051-RNT

Pet. = OF 7760

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: S Reid Date: 7/28/10

Remarks:

Receipt for Section 3

S: 879171 Resubmission: Yes No

Print Letter

Enter More Information

Tracking

Regulatory Type: Product Registration - Section 3 Fee For Service: Yes No

Application Type: New Registration Billable: Yes No

Company: 70051 CERTIS USA, LLC V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92

Product #: 70051-RNI Product Name: CX-9030

Overdue:

Me Too Section3: Me Too Product Name:

Application Date: 12-Jul-2010 OPP Rec'vd Date: 26-Jul-2010

Front End Date: 27-Jul-2010 Risk Manager Send Date:

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Receipt Content	
Study	
CSF	

View/Edit

Fast Track: New Ingredient:

Receipt Description:

New product registration application containing new active ingredient (Primary)

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date: Form B: Signature Date:

FEE FOR SERVICE

Online Payment

Step 3: Confirm Payment 1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 2516483K
Agency Tracking ID: 74128171126
Transaction Date and Time: 07/22/2010 17:13 EDT

Payment Summary

Address Information

Account Holder Name: Certis USA LLC
Billing Address: 9145 Guilford Road, Suite 175
Billing Address 2:
City: Columbia
State / Province: MD
Zip / Postal Code: 21046
Country: USA

Account Information

Card Type: American Express
Card Number: **********1018
Decision Number:
Registration Number:
Company Name: Certis U.S.A., L.L.C.
Company Number: 70051
Action Code: B590

Payment Information

Payment Amount: $27,563.00
Transaction Date and Time: 07/22/2010 17:13 EDT

Please read instructions on reverse before completing form. Form Approved. O.M.B. No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number
70051- RNI

2. EPA Product Manager
Alan Reynolds

3. Proposed Classification
[X] None [ ] Restricted

4. Company/Product (Name)
CX-9030

PM#
Microbial Pest Control

5. Name and Address of Applicant *(Include ZIP Code)*
Certis U.S.A., L.L.C.
9145 Guilford Road, Suite 175
Columbia, Maryland 21046
[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

New active ingredient application (Primary) ; secondary application new active ingredient - same a.i. different form)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistent Packaging
[ ] Yes*
[X] No
** Certification must be submitted*

Unit Packaging
[ ] Yes
[X] No
If "Yes" Unit Packaging wgt. No. per container

Water Soluble Packaging
[ ] Yes
[X] No
If "Yes" Package wgt No. per container

2. Type of Container
[ ] Metal
[ ] Plastic
[ ] Glass
[X] Paper
[ ] Other (Specify) _____

3. Location of Net Contents Information
[X] Label [ ] Container

4. Size(s) Retail Container
5 lb. bag

5. Location of Label Directions
[X] On Label
[ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
[ ] Lithograph
[X] Paper glued
[ ] Stenciled
[X] Other may be film

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Christine A. Dively	Director of Reg. Affairs	01-483-3806

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature
Christine A. Dively

3. Title
Director of Reg. Affairs

4. Typed Name
Christine A. Dively

5. Date
July 09, 2010

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046

(301) 604-7340

FAX: 301-604-7015
www.certisusa.com

481655-00

July 14, 2010

Dr. Sheryl Reilly, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7504P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: Certis U.S.A., L.L.C. / EPA Company Number: 70051
Transmittal Document
New Product Registration Application Containing New Active Ingredient
(Secondary Registration Application)
PRIA Category B590

Dear Dr. Reilly:

On behalf of Certis U.S.A., L.L.C. (9145 Guilford Road, Suite 175, Columbia, MD 21046), I am respectfully submitting documents to support the registration of a new end-use product containing the new active ingredient *Bacillus subtilis* var. *amyloliquefaciens* strain D747. The registration application contains two products with the same new active ingredient, a primary and secondary end-use product. Data submitted under this cover supports the secondary end-use formulation.

Included with this submission are the following administrative and data volumes:

Volume 1 – Administrative Materials

- Application for Pesticide Product; EPA Form 8570-1
- Confidential Statements of Formula; EPA Form 8570-4
- Data Matrix – non-confidential; EPA Form 8570-35
- Data Matrix –confidential; EPA Form 8570-35
- Certification with Respect to Citation of Data; EPA Form 8570-34
- Five Copies of Draft Labeling

48165501 Volume II – Product Chemistry

- OPPTS 885.1100 Product Identity
- OPPTS 885.1200 Manufacturing Process
- OPPTS 885.1300 Discussion of formation of unintentional ingredients
- OPPTS 885.1400 Analysis of samples
- OPPTS 885.1500 Certification of Limits

48165502 Volume III – Product Properties

- OPPTS 830.6302 Color
- 830.6303 Physical State
- 830.6304 Odor
- OPPTS 830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions
- OPPTS 830.6317 Storage Stability of the Liquid Concentrate
- OPPTS 830.6319 Miscibility
- OPPTS 830.6320 Corrosion Characteristics
- OPPTS 830.7000 pH
- OPPTS 830.7100 Viscosity
- OPPTS 830.7300 Bulk Density

48165503 Volume IV – Product Properties

- 830.6317 Storage Stability of the End-use Product

48165504 Volume V – Toxicology Data

- OPPTS 870.1100 Acute Oral Toxicity Request for No Further Testing
- OPPTS 870.1200 Acute Dermal Toxicity Request for No Further Testing
- OPPTS 870.1300 Acute Inhalation Toxicity Request for No Further Testing
- OPPTS 885.3400 Hypersentivity Request for No Further Testing

48165505 Volume VI – OPPTS 870.2400 Acute Eye Irritation Study in Rabbits

48165506 Volume VII – OPPTS 870.2500 Acute Dermal Irritation Study in Rabbits

As stated previously in this transmittal letter, this registration application is for the secondary formulation of a new end-use product containing the new active ingredient *Bacillus subtilis* var. *amyloliquefaciens* strain D747

Please do not hesitate to contact me if you have any questions about this submission. I can be contacted by telephone at 301-483-3806 or by email at cdively@certisusa.com.

Respectfully,

Christine A. Dively

Christine A. Dively
Director of Regulatory Affairs

Certis USA, L.L.C.
9145 Guilford Road
Suite 175
Columbia, MD 21046
(301) 604-7340
FAX (301) 604-7015
www.certisusa.com

July 12, 2010

Dr. Sheryl Reilly, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7504P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: **Certis U.S.A., L.L.C./EPA Company Number: 70051**
Transmittal Document
New Product Registration Application Containing New Active Ingredient (Primary and Secondary Registration Applications)
Tolerance Exemption Petition for *Bacillus subtilis* var. *amyloliquefaciens* strain D747
PRIA Category B590

Dear Dr. Reilly:

On behalf of Certis U.S.A., L.L.C., (9145 Guilford Road, Suite 175, Columbia, Maryland 21046), I am respectfully submitting documents to support the registration of a new end use product containing the new active ingredient, *Bacillus subtilis* var. *amyloliquefaciens* strain D747. The registration application contains two products with the same new active ingredient, a primary and secondary endues product. Product information for the secondary endues formulation is submitted under separate cover and accompanies this submission.

Included in this submission with administrative and data volumes is the Notice of Filing for Pesticide Petitions Published in the Federal Register and a Petition Proposing an Exemption from the Requirement of a Tolerance for the Use of the Microbial Pest Control Agent Bacillus subtilis var. amyloliquefaciens strain D747.

Volume I - Administrative Materials

- Application for Pesticide Product; EPA Form 8570-1
- Confidential Statement of Formula; EPA Form 8570-4
- Data Matrix –non-confidential; EPA Form 8570-35
- Data Matrix – confidential; EPA Form 8570-35
- Certification With Respect To Citation Of Data; EPA Form8570-34
- Copies (3) of the proposed label
- PRIA Fee payment receipt

Volume II – Product Chemistry

- Product Identity – OPPTS: 885.1100
- Manufacturing Process – OPPTS: 885.1200
- Discussion of Formation of Unintentional Ingredients- OPPTS: 885.1300
- Analysis of Samples – OPPTS: 885.1400
- Certification of Limits – OPPTS: 885.1500

Volume III – Product Properties

- OPPTS:830.6302 color
- OPPTS: 830.6303 Physical State
- OPPTS: 830.6304 Odor
- OPPTS: 830.6313 Stability to Normal and Elevated Temp., Metals, Metal Ions
- OPPTS: 830.6317 Storage Stability (TGAI)
- OPPTS 830.6319 Miscibility
- OPPTS: OPPTS: 830.6320 Corrosion Characteristics
- OPPTS: 830.7000 pH
- OPPTS 830.7100 Viscosity
- OPPTS: 830.7300 Bulk Density

Volume IV – Product Properties

- OPPTS: 830.6317 Storage Stability –enduse product

Volume V a- OPPTS: 885.3050 Acute Oral Toxicity/Pathogenicity

Volume V b – OPPTS: 885.3200 Acute injection (intravenous) toxicity/pathogenicity

Volume VI – OPPTS: 885.3150 Acute Pulmonary Toxicity/Pathogenicity

Volume VII – OPPTS: 870.1100 Acute Oral Toxicity

Volume VIII – OPPTS: 870.1200 Acute Dermal Toxicity

Volume IX – OPPTS: 870.1300 Acute Inhalation Toxicity

Volume X – OPPTS: 870.2400 Acute Eye Irritation

Volume XI – OPPTS: 870.2500 Primary Dermal Irritation

Volume XII – OPPTS: 885.4050 (850.2100) Acute Oral Toxicity with Northern Bobwhite

Volume XIII – OPPTS: 885.4200 Freshwater Fish Toxicity/Pathogenicity

Volume XIV – OPPTS: 885.4280 Freshwater Invertebrate Toxicity/Pathogenicity

Volume XV – OPPTS: 885.4300N ontarget Plant Testing

Volume XVI – OPPTS: 885.4340 Nontarget Insect Testing

Volume XVII – OPPTS: 885.4380 Honey Bee Testing

As stated previously in this transmittal letter, the registration application for the secondary formulation, as defined by PRIA, is being submitted under separate cover letter, with the required administrative forms and data.

Please do not hesitate to contact me if there are any questions about the contents of this submission. I can be reached by telephone at 301-483-3806 or by email at cdively@certisusa.com.

Sincerely,

Christine A. Dively
Director of Regulatory Affairs
Certis USA

enclosure

Form Approved OMB Nos 2070-0060; 2070-0057; 2070-0107, 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 1.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, Collection Strategies Division (2822T), U S Environmental Protection Agency, 1200 Pennsylvania Avenue, N W , Washington, DC 20460 Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Certis U.S.A., L.L.C. 9145 Guilford Road, Suite 175, Columbia, Maryland 21046	EPA Registration Number/File Symbol 70051-RNt
Active Ingredient(s) and/or representative test compound(s) Bacillus subtilis var.amyloliquefaciens strain O-747	Date July 9, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Agricultural, Ornamental and Residential Applications	Product Name CX-9030

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Christina A. Dively	7/09/10	Christine A. Dively

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Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 7/12/2010	EPA Reg No./File Symbol	Page 1 of 2
Applicant's/Registrant's Name & Address Certis U.S.A., L.L.C., 9145 Guilford Road, Suite 175, Columbuia, MD 21064	Product CX-9030	

Ingredient Bacillus subtilis var. amyloliquefaciens

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Product Identity		Certis USA	Own	
885.1200	Manufacturing process		Certis USA	Own	
885.1300	Discussion of formation of unintentional ingredients		Certis USA	Own	
885.1400	Analysis of samples		Certis USA	Own	
885.1500	Certification of limits		Certis USA	Own	
830.6302	Color		Certis USA	Own	
830.6303	Physical state		Certis USA	Own	
830.6304	Odor		Certis USA	Own	
830.6313	Stability to normal and elevated temperatures, metals		Certis USA	Own	
830.6317	Storage stability		Certis USA	Own	
830.6319	Miscibility		Certis USA	Own	
830.6320	Corrosion Characteristics		Certis USA	Own	
830.7000	pH		Certis USA	Own	
830.7100	Viscosity		Certis USA	Own	
830.7300	Density/relative density/bulk density (specific gravity)		Certis USA	Own	

Signature	Name and Title	Date
Christine A. Dively	Christina A. Dively/Director Regulatory Affairs	July 09, 2010

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DATA MATRIX

Date 7/12/2010	EPA Reg No./File Symbol 70051-	Page 2 of 2
Applicant's/Registrant's Name & Address Certis U.S>A., L.L.C. 9145 Guilford Road, Suite 175, Columbia, Maryland 21046	Product CX-9030	

Ingredient Bacillus subtilis var. amyloliquefaciens strain D747

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS: 885.3050	Acute oral toxicity/pathogenicity		Certis USA	own	
OPPTS.8853150	Acute pulmonary toxicity/pathogenicity		Certis USA	own	
OPPTS: 885.3200	Acute injection(intravenous) toxicity/pathogenicity		Certis USA	own	
OPPTS: 885.3400	Hypersensitivity Incidents		Certis USA	own	refer to CX-9032
OPPTS: 870.1100	Acute oral toxicity		Certis USA	own	
OPPTS: 870.1200	Acute dermal toxicity		Certis USA	own	
OPPTS: 870.1300	Acute inhalation toxicity		Certis USA	own	
OPPTS: 870.2400	Acute eye irritation		Certis USA	own	
OPPTS: 870.2500	Primary dermal irritation		Certis USA	own	
OPPTS: 885.4050 (850.2100)	Acute avian oral toxicity		Certis USA	own	
OPPTS: 885.4200	Freshwater Fish toxicity/pathogenicity		Certis USA	own	
OPPTS: 885.4240	Freshwater invertebrate toxicity/pathogenicity		Certis USA	own	
OPPTS: 885.4300	Nontarget plant testing		Certis USA	own	
OPPTS: 885.4340	Nontarget insect testing		Certis USA	own	
OPPTS: 885.4380	Honey bee testing		Certis USA	own	

Signature	Name and Title	Date
Christine A. Direly	Christine A. Direly	July 09, 2010

Pages 445-452*Confidential Statement of Formula may be entitled to confidential treatment*

Certis USA, L.L.C.
9145 Guilford Road
Suite 175
Columbia, MD 21046
(301) 604-7340
FAX (301) 604-7015
www.certisusa.com

November 21, 2011

Ms. Susanne Cerrelli
Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
US Environmental Protection Agency

Re: Certis USA/EPA File Symbol: 70051-RNI/CX-9030
Alternate Confidential Statement of Formula

Dear Ms. Cerrelli:

As discussed in our teleconference, attached is an alternate Confidential Statement of Formula (CSF) that Certis would like to include in the pesticide application referenced. This alternate CSF is substantially similar to the primary formulation, with the exception of the direct substitution of one inert ingredient. This inert ingredient is on EPA List 4, and has been reviewed and accepted by the Agency in other products that are manufactured by Certis (*Bt* formulations, specifically Agree WG). The percent active ingredient in the formulation has not been changed, nor has any other inert ingredient identity.

Please do not hesitate to contact me if you have any questions about this request. I can be reached by telephone at 301-483-3806 or by email at cdively@certisusa.com.

Sincerely,

Christine A. Dively

Christine A. Dively
Director of Regulatory Affairs
Certis USA

enclosure