EPA Reg # 264-1132

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: 12/21/10		EPA Reg. Number: 264-RRGE		
	Check List Item	Yes	No	N/A
1	Has the **PRIA Fee been Paid**; is a copy of the check or Pay.gov receipt included in the Submission Package?	✓		
2	Is an **Application Form** (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	✓		
3	Is a **Confidential Statement of Formula** (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	✓		
4	Is a **Formulator's Exemption Statement** (EPA Form 8570-27) Included in the Submission Package?	✓		
5	Is a **Certification with Respect to Citation of Data** (EPA Form 8570-34) Included in the Submission Package?	✓		
6	Is a **Data Matrix** (EPA Form 8570-35) Included in the Submission Package?	✓		
7	Is a **Label** Included in the Submission Package?	✓		
8	Are **Data** Included in the Submission Package?		✓	
9	**Is the Submission an Amendment?**		✓	

Material Sent for Data Extraction

Reg. # _____264-1132_____

Description: _Agency ltr 8/2/12, pc review 7/30/12, 8570-1 9/13/11, registrant letter 8/22/11

- ☐ Material(s) Sent to Data Extraction Contractors:
  - ☐ New Stamped Label Dated _____
  - ☐ Notification Dated _____
  - ☐ New CSF(s) Dated _____
  - ☐ Other: _____
- ☐ Decision #: _____
- ☐ 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: ___Marianne Lewis_____

Phone: _308-8043_____ Division: ___IRB/RD_____

Date: _____8/10/12_____

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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

AUG 2 2012

Jamin Huang
Senior Regulatory Manager
Bayer CropScience
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Subject: Submission of storage stability and corrosion characteristics data
Poncho/GB126
EPA Registration No. 264-1132
Your submission dated September 13, 2011

The conditional data referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable. A copy of the review is enclosed. If you have any questions, please contact me at (703) 308-8043 or lewis.marianne@epa.gov.

Regards,

Marianne Lewis
Biologist
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

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
264-1109 and 264-1132	Venus Eagle	[ ] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Poncho/VOTIVO and Poncho/GB126	1	

5. Name and Address of Applicant *(Include ZIP Code)*

Bayer CropScience
P.O. Box 12014; 2 T.W. Alexander Drive
Research Triangle Park, NC 27709

[ ] *Check if this is a new address*

6. Expedited Reveiw. 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 repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

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

Conditional Requirements for storage stability (830-6317) and corrosion characteristics (830-6320) per approval letter for Poncho/Votivo (264-1109) dated 03/16/2010.
Also satisfies same requirements for Poncho/GB126 (264-1132) dated 04/29/2011.
CONTACT: Robyn Kneen; Tel: (919) 549-2412; Cell: (919-599-1310); email: robyn.kneen@bayer.com

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
[ ] No	[ ] No	[ ] No	[ ] Plastic
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	[ ] Glass
			[ ] Paper
			[ ] Other (Specify) _____

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ]

6. Manner in Which Label is Affixed to Product [ ] 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)
Robyn Kneen	Registration Manager	919-549-2412

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 knowlingly 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
Robyn Kneen	Registration Product Manager
4. Typed Name	**5. Date**
Robyn Kneen M-413861-01-1	September 13, 2011

Bayer CropScience

August 22, 2011

Document Processing Desk
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: Venus Eagle (PM 01, RD, Insecticide-Rodenticide Branch)

Re: Submission of One-Year Storage Stability and Corrosive Characteristic Report for

Poncho Votivo (EPA Reg. No.: 264-1109)
Poncho/GB126 (EPA Reg. No.: 264-1132)

Bayer CropScience
2 T.W. Alexander Drive
P. O. Box 12014
Research Triangle Park
NC 27709
Tel. 919-549-2000

Dear Ms. Eagle,

Bayer CropScience is herein submitting 3 copies of the enclosed study report to comply with the requirement # 3 in the March 16, 2010 Notice of Registration for Poncho Vovito (EPA Reg No. 264-1109) and the requirement # 1 in the April 29, 2011 Notice of Registration for Poncho GB126 (EPA Reg No. 264-1132). Both products have the identical formulation.

MRID # **48577801**

"The Storage Stability and Corrosion Characteristics of L1902 end-use product"

Please contact me at jamin.huang@bayer.com or at 919-549-2634 if you have any questions regarding this submission.

Sincerely,

Jamin Huang, Ph.D.
Senior Regulatory Manager

M-412860-01-1

Material to be added to an e-Jacket/Jacket

Reg. No. 264-RRGE (-1132)

Description: Reg Notice 4/29/11, accept label 4/29/11, email 4/27/11, new csf (basic & alternate 4/26/11) emails: 4/19/11 (2x), 4/18/11(2x), 2/2/11, 1/28/11, DATA MATRIX FOR 264-1113 8/5/10

1. ☒ Placement within the e-Jacket/jacket:
   - ☐ Default: (chronological, top = newest)
   - ☐ File Location: (PDF page number, i.e., "before page 45")

default = top is newest

2. ☒ Send to Data Extraction contractors this material:
   - ☒ Newly stamped accepted label
   - ☐ Notification
   - ☒ New CSF
   - ☒ Other: 226 NOTICE 4/29/11 (FORM 8570-6)

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Marianne Lewis

Phone: 703-308-8043 Division: RD/IRB

Date: 4/29/11

This form was created on 4/29/2011

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
264-1132	4/29/11

Term of Issuance: Conditional

Name of Pesticide Product: PONCHO/GB126

Name and Address of Registrant (include ZIP Code):

Bayer CropScience LP
2 T.W. Alexander Drive
P.O. Box 12014
Research Triangle Park, NC 27709

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration 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 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 product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
2. For future submissions, make the following changes to your Confidential Statement of Formulation (EPA Form 8570-4):
   a. Box 4: Revise the EPA Reg. No. so it reads, "EPA Reg. No. 264-1132."

Signature of Approving Official: Venus Eagle

Venus Eagle, Product Manager 01
Insecticide-Rodenticide Branch, Registration Division (7505P)

Date: 4/29/11

EPA Form 8570-6

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. If you have any questions, please contact Marianne Lewis at 703-308-8043 or lewis.marianne@epa.gov.

Venus Eagle
Product Manager
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

PONCHO®/GB126

PONCHO®/GB126 is a systemic insecticide and biological seed treatment for use on cereals and sugarbeets for the protection from listed insect pests and listed soil plant pathogenic nematodes

ACTIVE INGREDIENTS:

Clothianidin	40.3%
Bacillus firmus I-1582	8.1%
OTHER INGREDIENTS:	51.6%
TOTAL:	**100.0%**

Contains 4.17 pounds clothianidin per U.S. gallon
Contains 0.84 pounds Bacillus firmus per U.S. gallon (contains a minimum of 2 $X10^9$ cfu/ml)

E.P.A. Reg. No. 264-1132 **E.P.A. Est. No. 7501-IA-01, 7501-ID-01**

KEEP OUT OF REACH OF CHILDREN
CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF SWALLOWED:	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	• Hold eye 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. • Call a poison control center or doctor for treatment advice.
In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577. Have a product container or label with you when calling a poison control center or doctor, or going for treatment.	

NOTE TO PHYSICIAN: No specific antidote is available. Treat the patient symptomatically.

ACCEPTED
4/29/11
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide Registered under EPA Reg. No. 264-1132

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing.

This product contains a microbial pesticide that may have the potential to be a respiratory sensitizer.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are **barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton**. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Workers involved with treating the seed (e.g. connecting and disconnecting hoses and transfer pumps, mixing, equipment calibration, etc.) and others exposed to the concentrate, and cleaners/repairers of seed treatment equipment must wear a long-sleeve shirt and long pants, shoes plus socks, chemical-resistant gloves, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95.

Baggers and bag sewers must wear a long-sleeve shirt and long pants, shoes plus socks, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95.

Respiratory protection is required for handlers and other workers who have repeated exposure to the product.

ENGINEERING CONTROL STATEMENT:

When engineering controls that meet the OSHA requirements as defined in 29 CFR Part 1910.1000 are used the respirator requirement may be waived or modified as specified in 29 CFR Part 1910.1000.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should 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

This product is toxic to aquatic invertebrates. 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 cleaning equipment or disposing of equipment washwaters. Do not apply where runoff is likely to occur. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Apply this product only as specified on the label.

This chemical has properties and characteristics associated with chemicals detected in ground water. **This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow**. Therefore contain any product spills or equipment leaks and dispose of wastes according to the disposal instructions on this label.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read entire label before using this product.

For use only in commercial seed treatment equipment. Not for use in hopper box, planter box, slurry box, or other on-farm seed treatment applications.

Read the entire label and observe all label directions and precautions before use. Do not use this product except as directed on this label or on other Bayer CropScience supplemental labeling for this product.

USE INFORMATION

Poncho/GB126 is a combination insecticide and biological seed treatment that, when applied to seed, protects the seed and seedling against certain early season insects and provides early season protection from **listed** plant pathogenic nematodes that attack the root system. As a result of the dual protection, there is an improvement in plant vigor, which often results in more uniform plants and greater yields. In areas of high nematode infestation additional control measures may be warranted.

COMPATIBILITY

It is essential that before using Poncho/GB126 seed treatment in any tank mixture the compatibility of the mixture be established. Add Poncho/GB126 at the labeled rate to a clean quart jar containing approximately one-half the amount of water intended for a final slurry application rate. Next, follow with all other tank mix components that will be used in the total slurry application. Add last the remaining balance of water. The total amount of volume is determined by the seed size and how much is necessary to ensure complete and uniform coverage and distribution on the seed, as well as the type of commercial seed treating application equipment that will be used.

DO NOT USE MIXTURES THAT CURDLE, PRECIPITATE, OR GEL. USE TANK MIXTURES IMMEDIATELY AFTER MIXING WITH ADEQUATE AGITATION.

DIRECTIONS FOR SEED TREATMENT

All seed treated with this product must be colored with an EPA-approved dye or colorant that imparts an unnatural color to the seed to help prevent the inadvertent use of treated seed for food, feed or oil purposes.

FOR USE AS A SEED TREATMENT

Apply Poncho/GB126 as a commercial water-based slurry either alone or with other registered seed treatment insecticides and fungicides through standard slurry or mist commercial seed treatment equipment. Follow the most restrictive of the labeling limitations and precautions of all products used in mixtures. Treated seed must be labeled in accordance with the requirements of the Federal Seed Act.

MIXING INSTRUCTIONS

When applied with seed treatment application equipment designed to treat seed utilizing a treatment slurry mixture, add approximately ½ to ⅔ of the required water to the treatment slurry tank followed by the accompanying seed treatment products and Poncho/GB126. The order of product addition is dependant on the accompanying seed treatment products and application equipment used. Allow each slurry component to disperse completely prior to the next addition until a uniform suspension is obtained. After all slurry components have been added and dispersed completely add the remaining ½ to ⅓ of required water for proper slurry volume and mix until uniform. Do not store mixed slurries for greater than 72 hours. Maintain adequate agitation until treatment slurry is applied. For additional instructions for use, slurry component mixing order, and other application suggestions contact your Bayer CropScience representative.

APPLICATION RATES

May be used in combination with other registered Bayer CropScience seed treatment fungicides and insecticides. Pre-test for compatibility with other seed treatment products.

CROP	INSECT PESTS	NEMATODE PESTS	RATE PONCHO/GB126
Sugarbeet[1]	Black bean aphids Cutworms (Black) Flea beetles Leafminers Subterranean springtails Sugarbeet leafhoppers Sugarbeet root maggot Wireworms	Early season soil plant parasitic nematodes including: False Root-Knot nematode Root Knot nematodes Stubby Root nematodes SugarBeet Cyst nematode	4.1 fl oz/unit* of seed * a unit = 100,000 seed
Crops of crop group 15, except field corn, popcorn, sweet corn, sorghum & rice	Aphids (including Bird Cherry Oat, English Grain, Greenbug, Russian Wheat) Hessian fly Wireworms	Early season soil plant parasitic nematodes including: Cereal Cyst nematode Root Lesion nematodes Root Knot nematodes	0.71 – 2.14 fl oz / cwt** Use the higher rate to provide increased length of protection and from heavy insect pressure and from wireworms, and to reduce potential spread of Barley yellow dwarf virus due to aphid vectors. For wireworms only; 0.13 – 0.23 fl oz / cwt **cwt = 100 pounds of seed

[1] Apply Poncho/GB126 to seed with a coating system that gives a minimum build-up of approximately 30% weight gain

Restrictions:

Regardless of type of application (seed treatment or foliar), do not apply more than 0.14 lb clothianidin/A/**season for sugarbeets and do not apply more than 0.2 lbs clothianidin/A/season for cereal grains (except corn, rice, sorghum).**

Resistance Management

The components in Poncho/GB126 belong to multiple chemistry classes. Because resistance development cannot be predicted, the use of this product should conform to resistance management strategies established for the crop and use area. Such strategies may include rotating and/or tank mixing with products having different modes of action; or limiting the total number of applications per season. Use labeled rates. Contact your local extension specialist, certified crop advisor, and/or manufacturer for fungicide/insecticide resistance management and/or integrated pest management recommendations for specific crops and pest populations. Bayer CropScience encourages responsible product stewardship to ensure effective long-term control of pests on this label.

LABELING OF TREATED SEED

The Federal Seed Act requires that the container of seed treated with PONCHO®/GB126 must be labeled with the following statements:

- **This seed has been treated with Poncho/GB126, which contains 40.3% clothianidin and 8.1% Bacillus firmus.**
- Do not use treated seed for food, feed or oil processing **or ethanol production**.
- Use planting equipment that will plant treated seed into the soil to a minimum depth of 0.5 inch.

In addition, the US Environmental Protection Agency requires the following statements on the container of seed treated with PONCHO®/GB126:

- Store away from feeds and foodstuffs.
- Rapeseed greens and seed grown or harvested from PONCHO®/GB126 -treated seed must not be used for feed or human consumption. Rapeseed grown and harvested from PONCHO®/GB126 -treated seed is only for industrial uses and can not be used for edible oil or any other human/feed consumption.
- Wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements.
- This compound is toxic to birds and mammals. Treated seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect treated seeds spilled during loading.
- For Cereals **(except corn, rice, sorghum)**: Immediate plant back: cotton, corn (field, sweet and pop), rapeseed, sorghum, sugarbeet, potato, cereal grains (Crop Group 15 except rice), canola, soybeans and the following vegetable crops: root vegetables (Crop Group 1), bulb vegetables (Crop Group 3), leafy green vegetables (Crop Group 4A), Brassica (cole) leafy vegetables (Crop Group 5), fruiting vegetables (Crop Group 8), cucurbit vegetables (Crop Group 9). These areas may also be replanted after 30 days with dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.
- For Sugarbeet: Immediate plant back: cotton, corn (field, sweet and pop), rapeseed, sorghum, sugarbeet, canola and soybeans. These areas may also be replanted after 30 days with cereal grains (Crop Group 15 except rice), dried beans, and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.
- Regardless of type of application (seed treatment or foliar), do not apply more than 0.2 lbs of the active ingredient clothianidin per acre per season.
- This compound may be highly toxic to bees exposed directly (contact). Ensure **that** planting equipment is functioning properly in accordance with manufacturing recommendations to minimize seed coat abrasion during planting to reduce dust which can drift to blooming crops or weeds.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store in cool, dry conditions.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Containers with capacities equal to or less than 5 gallons

Non-refillable container. Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Offer for recycling, if available, or puncture and dispose of in a sanitary landfill, or by incineration.

Containers that are too large to shake (i.e., with capacities greater than 5 gallons)

Non-refillable containers - Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square **Stackable)**

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inch on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g.– Snyder 120 Next Gen, Bonar B120, Drums, and Kegs).

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience no claims are made to guarantee germination of carry-over seed.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS: 2.5, 15, 30 GALLONS

Bayer CropScience

Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)
http://www.bayercropscienceus.com

PONCHO®/GB126 (Pending) 12/17/2010, RESUBMITTED 01/28/2011, RESUBMITTED 02/02/2011, RESUBMITTED 02/03/2011, RESUBMITTED 04/18/2011, RESUBMITTED 04/27/2011

4/27/11

Dear Ms. Kneen:

In order to move forward with the label amendment for your product, EPA Reg. No. 264-RRGE, please make the following revisions to your label:

1. On page 1 of the label, under "Hazards to Human and Domestic Animals" add the following: "This product contains a microbial pesticide that may have the potential to be a respiratory sensitizer." (and add an 's' to subheader "Human")

2. On page 2 of the label, to be consistent with EPA Reg. No. 264-1109 under the "Environmental Hazards" revise the sentence "The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination." to read "**This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow**." (changes indicated in **bold**)

3. On page 2 of the label, under "Use Information" revise "… early season protection from plant pathogenic nematodes…" to read "… early season protection from **listed** plant pathogenic nematodes…" (change indicated in **bold**)

4. On page 3 of the label, in the application table under "Crop" it states "crops of crop group 15 except … rice" and then stating "Barley, buckwheat, …wheat." The only crop from group 15 that is not listed is below is "Milo." For clarity and consistency please either pick the statement "crops of crop group 15 except…rice" or simply put the list of crops down or rewrite it so it is less confusing.

5. On page 3 of the label, directly after the "Application Table" under "Restrictions" revise "… do not apply more than 0.14 lb clothianidin/A (sugarbeet) and 0.2 lb clothianidin/A (cereal grains) of active ingredient clothianidin per acre per season." to read "… do not apply more than 0.14 lb clothianidin/A/**season for sugarbeets and do not apply more than 0.2 lbs clothianidin/A/season for cereal grains (except corn, rice, sorghum)**. (changes indicated in bold) This change makes the restrictions very explicit.

6. On page 4 of the label, under "Labeling of Treated Seed" transform the bullet "In addition, the US Environmental Protection Agency … with Poncho/GB126" into a subheader so that it looks as follows:

   "Labeling of Treated Seed
   - This seed has been treated … firmus.
   - Do not use treated … ethanol production.
   - Use planting equipment … of 0.5 inch.

   In addition, the US Environmental Protection Agency requires the following statements on the container of seed treated with Poncho/GB126
   - Store away from feed and foodstuffs.
   - Rapeseed greens …."

   (now the label looks like the 264-1109 which it is substantially similar too)

7. On page 4 of the label, under "Labeling of Treated Seed" revise the bullet "For Cereals: Immediate plant back…" to read "For Cereals **(except corn, rice, sorghum)**: Immediate plant back…" (change indicated in **bold**)

8. On page 4 of the label, for consistency and clarity under "Labeling of Treated Seed – For Sugarbeet" revise "…with cereal grains (CG15 except rice), dried beans, …" to read "…with cereal grains (Crop Group 15 except rice), dried beans,…" (change indicated in bold) The "CG" hasn't been defined anywhere in the label and can't be used here. If you wish to use CG define it the first time you mention 'crop group.'

9. On page 4 of the label, under "Labeling of Treated Seed" in the last bullet revise "Ensure than planting equipment…" to read "Ensure **that** planting equipment…" (change indicated in **bold**) Oops – my spelling mistake in the last email.

10. On page 5 of the label, for clarity and consistency under "Storage and Disposal – Container Disposal" close the parentheses around "Bottom Discharge IBC (e. – Schuetz Caged IBC or Snyder Square **Stackable)** (change indicated in **bold** – parentheses closed)

Please submit these label changes back to me via email (lewis.marianne@epa.gov) as soon as possible so that I can proceed with this action and stamp off on a clean label.

If you have any questions please call or email.

Thanks,

Marianne Lewis
Biologist
IRB/RD
703 308-8043

Revised CSF's for Poncho/GB126
Robyn Kneen
to:
Marianne Lewis
04/19/2011 03:17 PM
Cc:
Jamin Huang
Show Details

Dear Marianne
Please find attached the CSF's with the CAS number corrected for the [redacted]
As mentioned before, the "cfu/mL for poncho/GB126" in the first line is actually correct. It is the "cfu/g for Poncho/Votivo" on the CSF for 264-1109 Poncho/Votivo which is actually a typographical error.
I will revise the Poncho/Votivo CSF with this correction and to update it to EPA new format regulations, upon my return from vacation (May 2nd)
In the meantime, if you have any other questions - please contact Jamin Huang
Thanks!!!!

Robyn Kneen
Regulatory Affairs
Bayer CropScience
RTP, USA
Tel:+1 919 549 2412
Cell: +1 919 599 1310

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Inert ingredient information may be entitled to confidential treatment

Dear Ms. Kneen:

In order to move forward with the label amendment for your product, EPA Reg. No. 264-RRGE, please make the following revisions to your label:

1. On page 1 of the label, under "Personal Protective Equipment (PPE)" directly after the sentence "Baggers and bag sewers … R-95 or P-95" insert "Respiratory protection is required for handlers and other workers who have repeated exposure to the product."

2. On page 2 of the label, under "Engineering Control Statement" replace the sentence "When handlers use closed systems … as specified in the WPS" with the following:

   "When engineering controls that meet the OSHA requirements as defined in 29 CFR Part 1910.1000 are used the respirator requirement may be waived or modified as specified in 29 CFR Part 1910.1000."

3. On page 2 of the label, replace the existing "Environmental Hazards" statements with the following:

   "This product is toxic to aquatic invertebrates. 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 cleaning equipment or disposing of equipment washwaters. Do not apply where runoff is likely to occur. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Apply this product only as specified on the label.

   This chemical has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination. Therefore contain any product spills or equipment leaks and dispose of wastes according to the disposal instructions on this label."

4. On page 3 of the label, directly above the subheader "Resistance Management" insert the following:

   "Restrictions: Regardless of type of application (seed treatment or foliar), do not apply more than xx lbs (Sugarbeet) and xx lbs (barley, buckwheat …wheat) of active ingredient clothianidin per acre per season."

   (please fill in the amount ai for these two crop sites)

5. On page 4 of the label, under "Labeling of Treated Seed" revise "Do not use treated seed for food, feed or oil processing" to read "Do not use treated seed for food, feed or oil processing **or ethanol production**." (change indicated in **bold**)

6. On page 4 of the label, under "Labeling of Treated Seed" directly after "Do not use treated seed for food, feed, or oil processing." add the following bullet:

   - "Use planting equipment that will plant treated seed into the soil to a minimum depth of 0.5 inch."

7. On page 4 of the label, for consistency and clarity under "Labeling of Treated Seed" insert the following bullet: -"Regardless of type of application (seed treatment or foliar), do not apply more than 0.2 lbs of the active ingredient clothianidin per acre per season."

8. On page 4 of the label, for consistency and clarity under "Labeling of Treated Seed" insert the following bullet:

   -"This compound may be highly toxic to bees exposed directly (contact). Ensure than planting equipment is functioning properly in accordance with manufacturing recommendations to minimize seed coat abrasion during planting to reduce dust which can drift to blooming crops or weeds."

9. On page 5 of the label, for clarity and consistency in the "Storage and Disposal" box revise "Bottom Discharge IBC (e. – Schuetz Caged IBC or Snyder Square Stackable" to read "Bottom Discharge IBC (e. – Schuetz Caged IBC or Snyder Square **Stackable)** (change indicated in **bold** – parentheses closed)

Please submit these label changes back to me via email (lewis.marianne@epa.gov) as soon as possible so that I can proceed with this action and stamp off on a clean label.

If you have any questions please call or email.

Thanks,

Marianne Lewis
Biologist
IRB/RD
703 308-8043

Fw: Poncho GB126
Robyn Kneen to: Marianne Lewis 04/19/2011 11:34 AM

Hi Marianne
Here's the other label. Hope its ok?
I'm having the chemist check the CAS numbers on the CSFs. However the units (ml
instead of g) are actually wrong on the Poncho/Votivo CSF. Its a typo that we caught and corrected for the Poncho/GB126.
What I actually will need to do at some point is send you a corrected one for the Poncho/Votivo instead.
Robyn

Robyn Kneen
Registrations Manager

Sent from my Blackberry Wireless Handheld

----- Original Message -----
From: Natalie Mauchmar
Sent: 04/19/2011 10:29 AM EDT
To: Robyn Kneen
Subject: Poncho GB126
(See attached file: P PONCHO_GB126 12-17-10, 01-28-11,02-02-11, 02-03-11, 04-18-11.pdf)

*** Please note new email address***
Natalie Mauchmar
Label Specialist

Bayer CropScience LP
2 T.W. Alexander Drive
Research Triangle Park, NC 27709
Phone: 919-549-2550
Mobile: 919-621-9686
Fax: 919-549-2945
E-mail: natalie.mauchmar@bayer.com

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Revised CSF for 264-RRGE Poncho/GB126
Robyn Kneen
to:
Marianne Lewis
04/18/2011 06:16 PM
Cc:
Venus Eagle
Show Details

Dear Marianne
As discussed by phone today, please replace the 100% Repack CSF originally submitted for this product with the attached CSF's instead.
There is one basic CSF and one alternate CSF. These CSF's are exactly the same as the approved basic CSF for Poncho/Votivo 264-1109.
In this case the CSF has just been split out into one basic and one alternate to comply with the Agencys new CSF policy.
The revised label will follow in the morning. Let me know if you need anything further
Thanks
Robyn

Robyn Kneen
Regulatory Affairs
Bayer CropScience
RTP, USA
Tel:+1 919 549 2412
Cell: +1 919 599 1310

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Re: EPA Reg. No. 264-RRGE clothianidin label

Marianne Lewis to: Robyn Kneen 02/02/2011 02:34 PM

Robyn,

After conferring with the PM, need three more changes to be made:

1) On page 2 of the label, under the subheader "For Use as a Seed Treatment" revise "Apply Poncho/GB126 as a water-based slurry..." to read "Apply Poncho/GB126 as a **commercial** water-based slurry..." (change indicated in **bold**) This is to emphasize that this is only to be applied to the seed in a commercial setting.

2) On page 2 of the label, under the subheader "For Use as a Seed Treatment" revise "Observe the most restrictive of the labeling..." to read "**Follow** the most restrictive of the labeling..." (change indicated in **bold**) The word 'observe' can be taken as more of a suggestion rather than a direction - 'follow' is more definitive.

3) On page 4 of the label, under "Labeling of Treated Seed" revise the first bullet "This seed has been treated with Poncho/GB126, which contains clothianidin and Bacillus firmus." to read "This seed has been treated with Poncho/GB126, which contains **40.3%** clothianidin and **8.1%** Bacillus firmus." (change indicated in **bold**)

This should be it.

Thanks,

Marianne

Robyn Kneen Hi Marianne, Hopefully these have everything. 02/02/2011 01:54:57 PM

From: Robyn Kneen <robyn.kneen@bayer.com>
To: Marianne Lewis/DC/USEPA/US@EPA
Date: 02/02/2011 01:54 PM
Subject: Re: EPA Reg. No. 264-RRGE clothianidin label

Hi Marianne,
Hopefully these have everything.
Let me know if you need anything else
Thanks
Robyn

Robyn Kneen
Regulatory Affairs
Bayer CropScience
RTP, USA
Tel:+1 919 549 2412
Cell: +1 919 599 1310

Lewis.Marianne@epamail.epa.gov

To Robyn Kneen <robyn.kneen@bayer.com>

02/02/2011 10:05 AM

cc

Subject Re: EPA Reg. No. 264-RRGE clothianidin label

Robyn,

Thanks for the response. I missed one minor thing in the Storage and Disposal box:

Under "Container Disposal - less than 5 gallons" please delete "or if allowed by state and local authorities, by burning. If burned stay out of smoke."

Thanks,

Marianne

From: Robyn Kneen <robyn.kneen@bayer.com>
To: Marianne Lewis/DC/USEPA/US@EPA
Date: 02/02/2011 09:46 AM
Subject: Re: EPA Reg. No. 264-RRGE clothianidin label

Dear Marianne,
Many thanks for your message last week and the required revisions to the Poncho/GB126 label
Sorry for the delay in responding to you, however I have now made those changes and attached the labels (one copy with changes highlighted)

Please let me know if you need anything further
Regards,
RObyn

Robyn Kneen
Regulatory Affairs
Bayer CropScience
RTP, USA
Tel:+1 919 549 2412
Cell: +1 919 599 1310

Lewis.Marianne@epamail.epa.gov

01/28/2011 11:19 AM

To robyn.kneen@bayer.com

cc

Subject
EPA Reg. No. 264-RRGE
clothianidin label

Ms. Kneen,

In order to move forward with the new me-too product registration please make the following revisions to your EPA Reg. No. 264-RRGE label:

(See attached file: 000264-RRGE clothianidin label comments 28jan11.doc)

Please submit these label changes back to me via email (lewis.marianne@epa.gov) as soon as possible so that I can proceed with this action and stamp off on a clean label.

If you have any questions please call or email.

Thanks,

Marianne Lewis
Biologist
IRB/RD
703 308-8043

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[attachment "000264-RRGE clothianidin label comments 28jan11.doc" deleted by Marianne Lewis/DC/USEPA/US] [attachment "P PONCHO_GB126 12-17-10, 01-28-11_shaded.pdf" deleted by Marianne Lewis/DC/USEPA/US] [attachment "P PONCHO_GB126 12-17-10, 01-28-11.pdf" deleted by Marianne Lewis/DC/USEPA/US]

[attachment "P PONCHO_GB126 12-17-10, 01-28-11,02-02-11_shaded.pdf" deleted by Marianne Lewis/DC/USEPA/US] [attachment "P PONCHO_GB126 12-17-10, 01-28-11,02-02-11.pdf" deleted by Marianne Lewis/DC/USEPA/US]

Dear Ms. Kneen:

In order to move forward with the new me-too product, EPA Reg. No. 264-RRGE, please make the following revisions to your label:

1. On page 1 of the label, for clarity and consistency under "First Aid – If Swallowed" revise "... vomiting unless told to do so by a poison control center..." to read "...vomiting unless told to by a poison control center ..." ("do so" was **deleted**)

2. On page 1 of the label, for clarity and consistency under "Hazards to Humans and Domestic Animals" delete "Wash thoroughly with soap and water .... clothing and wash before reuse." These sentences do not belong in this section.

3. On page 1 of the label, for clarity and consistency under "Personal Protective Equipment (PPE)" revise "...chemical resistant to this product are listed below." to read "... chemical resistant to this product are **barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton**." (changes indicated in **bold**)

4. On page 1 of the label, for clarity and consistency under "Personal Protective Equipment (PPE)" revise "...shoes plus socks, chemical resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or viton), and a dust/mist ..." to read "...shoes plus socks, chemical resistant gloves, and a dust/mist ..." (The types of gloves to be used were **deleted)** These are now indicated above (see #3). This new placement of the types of gloves helps this information stand out more – doesn't get lost in the second paragraph.

5. On page 2 of the label, for clarity and consistency directly under the "Engineering Control Statement" and above the "User Safety Recommendations" box insert the following:

   "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."

6. On page 4 of the label, for consistency and clarity under "Labeling of Treated Seed" revise "This seed has been treated with Poncho/GB126, which contains clothianidin." to read "This seed has been treated with Poncho/GB126, which contains clothianidin **and *Bacillus firmus***." (changes indicated in **bold**) Both ai's need to be indicated on the container.

7. On page 5 of the label, for consistency and clarity in the "Storage and Disposal" box revise "Do not contaminate water, food, or feed by storage or disposal" to read "Do not contaminate water, food, or feed by storage **and** disposal." (change in **bold**)

Please submit these label changes back to me via email (lewis.marianne@epa.gov) as soon as possible so that I can proceed with this action and stamp off on a clean label.

If you have any questions please call or email.

Thanks,

Marianne Lewis
Biologist
IRB/RD
703 308-8043

Commercial/financial information may be entitled to confidential treatment

THIS DOCUMENT MUST HAVE A COLORED B ROUND ULTRAVIOLET FIBERS AND A WATERMARK O E BACK - VERIFY FOR AUTHENTICITY.

BNY MELLON, N.A.
PITTSBURGH 15262

Bayer
Pittsburgh, PA 15205

Contact for Questions
1-866-283-6752

CHECK NO.3200045341
60-160
433

PAY:
***ONE THOUSAND ONE HUNDRED
FIFTY-NINE AND 00/100 DOLLARS***

VOID 180 DAYS AFTER DATE OF CHECK

DATE:12-16-10 $********1,159.00

TO THE ORDER OF
ENVIRONMENTAL PROTECTION AGENCY
USEPA WASHINGTON FINANCE CENTER
PESTICIDE REGISTRATION SERVICE
PO BOX 979074
ST. LOUIS MO 63197-9000

Authorized Signatures

⑈3200045341⑈ [redacted]

Bayer
Pittsburgh, PA 15205

Contact for Questions
1-866-283-6752

PBC/528 BEPBB

VENDOR NO.	VENDOR NAME	DATE	CHECK NO.	CHECK AMOUNT
6768799	Environmental Protection Agency	12-16-10	3200045341	1,159.00

REFERENCE NO.	DATE	DOCUMENT NO	GROSS AMOUNT	DISCOUNT	NET AMOUNT
IP15121010390612	12-15-10	2400508548	1,159.00	0.00	1,159.00
Return to Claudia Bradley Co. # 264					

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709 (919-549-2718)	EPA Registration Number/File Symbol 264-XXXX
Active Ingredient(s) and/or representative test compound(s) Bacillus firmus (Strain I-1582) and clothianidin	Date December 15, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Seed Treatment, Terrestrial Food Crops, Terrestrial Feed Crops	Product Name PONCHO/GB126

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
Robyn Kneen	Dec 15, 2010	Robyn Kneen, Registration Manager

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-01634

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DATA MATRIX

Date: August 5, 2010	EPA Reg. No.: 264-1113	Page 1 of 11
Applicant's/Registrant's Name & Address Bayer CropScience LP 2 T.W. Alexander Drive, P.O. Box 12014 Research Triangle Park, NC 27709	Product: PONCHO®/VOTiVO™	
Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
§158.2120 Microbial pesticides products analysis data requirements					
885.1100	Product identity - TGAI	46933001 47963601 47973701 48110301 48110401 48159501	Bayer CropScience LP	OWN	
885.1100	Product identity - EP	47835907 47985401	Bayer CropScience LP	OWN	
885.1200	Manufacturing process - TGAI	46933002 47963601 47973701 48049301 48050201 48110301 48110401 48159501	Bayer CropScience LP	OWN	
885.1200	Manufacturing process – EP	47835907 47985401	Bayer CropScience LP	OWN	

Signature	Name and Title: Danielle A. Larocheile Registration Product Manager	Date: August 5, 2010

EPA Form 8750-35 (12-2003) Electronic Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-01634

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DATA MATRIX

Date: August 5, 2010	EPA Reg. No.: 264-1113	Page 2 of 11
Applicant's/Registrant's Name & Address Bayer CropScience LP 2 T.W. Alexander Drive, P.O. Box 12014 Research Triangle Park, NC 27709	Product: PONCHO®/VOTiVO™	

Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Deposition of a sample in a nationally recognized culture collection - TGAI				1
885.1300	Discussion of formation of unintentional ingredients - TGAI	46933003 47024801 47187202 47963601 47973701 48110301 48110401 48159501	Bayer CropScience LP	OWN	
885.1300	Discussion of formation of unintentional ingredients - EP	47835907	Bayer CropScience LP	OWN	
885.1400	Analysis of samples – TGAI	47024803 47963601 47973701 48049301 48050201 48110301 48110401 48159501	Bayer CropScience LP	OWN	

Signature	Name and Title: Danielle A. Larocheile Registration Product Manager	Date: August 5, 2010

Form Approved OMB No. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-01634

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
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DATA MATRIX

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Applicant's/Registrant's Name & Address Bayer CropScience LP 2 T.W. Alexander Drive, P.O. Box 12014 Research Triangle Park, NC 27709	Product: PONCHO®/VOTiVO™	

Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1400	Analysis of samples - EP	47835907 47835908	Bayer CropScience LP	OWN	
885.1500	Certification of limits - TGAI	47469601 47963601 47973701 48110301 48110401 48159501	Bayer CropScience LP	OWN	
885.1500	Certification of limits - EP	47835907 47985401	Bayer CropScience LP	OWN	
151-25	Analytical methods – TGAI	46933005	Bayer CropScience LP	OWN	
151-26	Physical and chemical properties - TGAI	47024805	Bayer CropScience LP	OWN	
830.6302	Color - TGAI	47024805 47963601 47973701 48110301 48110401	Bayer CropScience LP	OWN	
830.6302	Color - EP	47835907	Bayer CropScience LP	OWN	

Signature	Name and Title: Danielle A. Larochelle Registration Product Manager	Date: August 5, 2010

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6303	Physical state - TGAI	47024805 47963601 47973701 48110301 48110401	Bayer CropScience LP	OWN	
830.6303	Physical state - EP	47835907	Bayer CropScience LP	OWN	
830.6304	Odor - TGAI	47024805 47963601 47973701 48110301 48110401	Bayer CropScience LP	OWN	
830.6304	Odor - EP	47835907	Bayer CropScience LP	OWN	
830.6313	Stability to normal and elevated temperatures, metals and metal ions – TGAI	47526404 47963601 47973701 48049301 48050201 48110301 48110401	Bayer CropScience LP	OWN	
830.6314	Oxidation/reduction – EP	47835907	Bayer CropScience LP	OWN	

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6315	Flammability – EP	47835907	Bayer CropScience LP	OWN	
830.6316	Explodability – EP	47835907	Bayer CropScience LP	OWN	
830.6317	Storage stability – TGAI	47469602	Bayer CropScience LP	OWN	
830.6317	Storage stability – EP		Bayer CropScience LP	OWN	Study is ongoing
830.6319	Miscibility - TGAI	47963601 47973701 48110301 48110401	Bayer CropScience LP	OWN	
830.6319	Miscibility - EP	47835907	Bayer CropScience LP	OWN	
830.6320	Corrosion characteristics - TGAI	47469602	Bayer CropScience LP	OWN	
830.6320	Corrosion characteristics - EP		Bayer CropScience LP	OWN	Study is ongoing
830.7000	pH - TGAI	47024805 47963601 47973701 48110301 48110401	Bayer CropScience LP	OWN	
830.7000	pH - EP	47835907	Bayer CropScience LP	OWN	

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7100	Viscosity - TGAI	47963601 47973701 48110301 48110401	Bayer CropScience LP	OWN	
830.7100	Viscosity - EP	47835907	Bayer CropScience LP	OWN	
830.7300	Density/relative density/bulk density (specific gravity) - TGAI	47024805 47963601 47973701 48110301 48110401	Bayer CropScience LP	OWN	
830.7300	Density/relative density/bulk density (specific gravity) - EP	47835907	Bayer CropScience LP	OWN	
§ 158.2130 Microbial pesticides residue data requirements					
885.2100	Chemical identity				2
885.2200	Nature of t he residue in plants - EP				3
885.2250	Nature of the residue in animals - EP				3
885.2300	Analytical methods – plants - TGAI				3
885.2350	Analytical methods – animals - TGAI				3

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.2400	Storage stability – EP				3
885.2500	Magnitude of residue in plants - EP				3
885.2550	Magnitude of residues in meat, milk, poultry, eggs - EP				3
885.2600	Magnitude of residues in potable water, fish, and irrigated crops - EP				3
§ 158.2140 Microbial pesticides toxicology data requirements					
885.3050	Acute oral toxicity/pathogenicity – TGAI	46933007	Bayer CropScience LP	OWN	
885.3100	Acute dermal toxicity/pathogenicity – TGAI	46933008	Bayer CropScience LP	OWN	
885.3150	Acute pulmonary toxicity/pathogenicity – TGAI	46933009	Bayer CropScience LP	OWN	
885.3200	Acute injection toxicity/pathogenicity (intravenous) – TGAI	46933010	Bayer CropScience LP	OWN	
885.3400	Hypersensitivity incidents - TGAI				4
885.3400	Hypersensitivity incidents - EP				4
885.3500	Cell culture - TGAI				5
870.1100	Acute Oral Toxicity - MP	46933007	Bayer CropScience LP	OWN	
870.1100	Acute Oral Toxicity - EP	47835901	Bayer CropScience LP	OWN	

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1200	Acute Dermal Toxicity - MP	46933008	Bayer CropScience LP	OWN	
870.1200	Acute Dermal Toxicity - EP	47835902	Bayer CropScience LP	OWN	
870.1300	Acute Inhalation Toxicity - MP	46933009	Bayer CropScience LP	OWN	
870.1300	Acute Inhalation Toxicity - EP	47835903	Bayer CropScience LP	OWN	
870.2400	Acute Eye Irritation - MP	47469603	Bayer CropScience LP	OWN	
870.2400	Acute Eye Irritation - EP	47835904	Bayer CropScience LP	OWN	
870.2500	Primary Dermal Irritation - MP	47469604	Bayer CropScience LP	OWN	
870.2500	Primary Dermal Irritation - EP	47835905	Bayer CropScience LP	OWN	
870.2600	Dermal Sensitization - EP	47835906	Bayer CropScience LP	OWN	
152-36	Hypersensitivity - TGAI	47024807	Bayer CropScience LP	OWN	
885.3550	Acute toxicology – TGAI	46933011	Bayer CropScience LP	OWN	
885.3600	Subchronic toxicity/pathogenicity – TGAI	46933011	Bayer CropScience LP	OWN	
885.3650	Reproductive fertility effects – TGAI	46933011	Bayer CropScience LP	OWN	
870.4200	Carcinogenicity – TGAI				6
870.7800	Immunotoxicity - TGAI				6

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3000	Infectivity/pathogenicity analysis				6
152-38	Immune response, Tier I – TGAI	47024806	Bayer CropScience LP	OWN	
152-46	Immune response, Tier II - TGAI	47024806	Bayer CropScience LP	OWN	
152-48	Reproductive/fertility effects (virulence enhancement) - TGAI	47024806	Bayer CropScience LP	OWN	
152-49	Reproductive/fertility effects (mammalian mutagenicity) - TGAI	47024806	Bayer CropScience LP	OWN	
§ 158.2150 Microbial pesticides nontarget organisms and environmental fate data requirements					
885.4050	Avian oral toxicity - TGAI	46933012	Bayer CropScience LP	OWN	
885.4100	Avian inhalation toxicity/pathogenicity - TGAI	46933013	Bayer CropScience LP	OWN	
885.4150	Wild mammal toxicity/pathogenicity - TGAI	46933013	Bayer CropScience LP	OWN	
885.4200	Freshwater fish toxicity/pathogenicity – TGAI and TEP	46933013	Bayer CropScience LP	OWN	
885.4240	Freshwater invertebrate toxicity/pathogenicity – TGAI and TEP	46933014	Bayer CropScience LP	OWN	
885.4280	Estuarine and marine invertebrate testing - TGAI	46933015	Bayer CropScience LP	OWN	
885.4300	Nontarget plant testing - TGAI and TEP	46933015	Bayer CropScience LP	OWN	

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Nontarget insect testing - TGAI	46933015	Bayer CropScience LP	OWN	
885.4380	Honey bee testing - TGAI	46933016	Bayer CropScience LP	OWN	
885.4380	Honey bee testing - TGAI	47850201	Bayer CropScience LP	OWN	
885.5200	Terrestrial environmental expression tests – TGAI or TEP	46933017	Bayer CropScience LP	OWN	
885.5300	Freshwater environmental expression tests – TGAI or TEP	46933017	Bayer CropScience LP	OWN	
885.5400	Marine or estuarine environmental expression tests – TGAI or TEP	46933017	Bayer CropScience LP	OWN	
155-25	Terrestrial wildlife and aquatic organisms – TGAI or TEP				6
885.4600	Avian chronic pathogenicity and reproduction test - TGAI				6
885.4650	Aquatic invertebrate range testing - TGAI				6
885.4700	Fish life cycle studies - TGAI				6
885.4750	Aquatic ecosystem test - TGAI				6
885.2500 850.1950	Field testing for terrestrial wildlife and Field testing for aquatic organisms – TGAI or TEP				8

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.2500	Simulated or actual field tests (birds, mammals) - TEP				8
885.1950	Simulated or actual field test (aquatic organisms) - TEP				8
885.2500	Simulated or actual field tests (insect predators, parasites) - TEP				8
885.3040	Simulated or actual field tests (insect pollinators) - TEP				8
885.4300	Simulated or actual field tests (plants) - TEP				8

NOTES KEY

1 = Deposited with the CNCM 5/29/95 (See page 20 of MRID No. 46933001)	5 = N/A – *Bacillus firmus* is a nonpathogenic bacterium
2 = Refer to Group A Data	6 = Tier III testing not warranted based on Tier I data/information
3 = N/A – Tolerance exemption at 40 CFR 180.1282	7 = N/A – Not warranted based on Tier I data/information
4 = No hypersensitivity incidents have occurred	8 = Tier IV testing not warranted based on Tier I data/information

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
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			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	

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			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
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			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
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Applicant's/Registrant's Name & Address Bayer CropScience LP 2 T.W. Alexander Drive, P.O. Box 12014 Research Triangle Park, NC 27709	Product: PONCHO®/VOTiVO™	

Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	

Signature	Name and Title: Danielle A. Larochelle Registration Product Manager	Date: August 5, 2010

EPA Form 8750-35 (12-2003) Electronic Paper versions available. Submit only Paper version.

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Form Approved OMB No. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-01634

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date: August 5, 2010	EPA Reg. No.: 264-1113	Page 6 of 11
Applicant's/Registrant's Name & Address Bayer CropScience LP 2 T.W. Alexander Drive, P.O. Box 12014 Research Triangle Park, NC 27709	Product: PONCHO®/VOTiVO™	

Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	

Signature	Name and Title: Danielle A. Larochelle Registration Product Manager	Date: August 5, 2010

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DATA MATRIX

Date: August 5, 2010	EPA Reg. No.: 264-1113	Page 7 of 11
Applicant's/Registrant's Name & Address Bayer CropScience LP 2 T.W. Alexander Drive, P.O. Box 12014 Research Triangle Park, NC 27709	Product: PONCHO®/VOTiVO™	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	

Signature	Name and Title: Danielle A. Larochelle Registration Product Manager	Date: August 5, 2010

EPA Form 8750-35 (12-2003) Electronic Paper versions available. Submit only Paper version.

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

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 264-~~XXXX~~ RRGE	2. EPA Product Manager Venus Eagle	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) Poncho/GB126	PM# 1	
5. Name and Address of Applicant *(Include ZIP Code)* Bayer CropScience P.O. Box 12014; 2 T.W. Alexander Drive Research Triangle Park, NC 27709 [ ] *Check if this is a new address*	6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 264-1109 Product Name Poncho/Votivo	

Section - II

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

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

REGFEE: R300 $1,434 (check submitted for $1,159; Bayer has an unused fund credit with the Agency, please debit the remaining $275 from this). New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end use or manufacturing-use product that requires no data submission nor data matrix
CONTACT: Robyn Kneen; Tel: (919) 549-2412; Cell: (919-599-1310); email: robyn.kneen@bayer.com

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	2.5 Gal, 15 Gal, 30 Gal	[ ]

6. Manner in Which Label is Affixed to Product [ ] 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)
Robyn Kneen	Registration Manager	919-549-2412

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 knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature Robyn Kneen	3. Title Registration Product Manager
4. Typed Name Robyn Kneen	5. Date December 15, 2010

Bayer CropScience

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

17 December 2010

Bayer CropScience
Research Triangle Park
P. O. Box 12014
NC 27709
919 549-2412

Attention: Ms Venus Eagle; Registration Division
Subject: PONCHO®/GB126; New me-too product

With this submission, Bayer CropScience proposes registration of **PONCHO®/GB126**. This product is a 100% Repack of PONCHO®/VOTiVO™ (EPA Reg# 264-1109) and is for use as a seed treatment on Cereals (CG15, except rice) and Sugarbeets.

Both active ingredients (clothianidin and *Bacillus firmus* I-1582) contained in this product are also contained in other products already registered for this use at an equivalent rate, as illustrated in the table below

Crop	Max Rate on New Product Poncho/GB126	Max Rate on Poncho Beta (EPA Reg# 264-106)	Max Rate on Sepresto 75 WS (EPA Reg# 264-1081)	Max Rate on Votivo FS (EPA Reg# 264-1108)
Rate of Clothianidin on Sugarbeet	4.1 fl oz / unit of seed (4.1 x 40.3% = 1.67 oz / unit of seed)	5.07 fl oz / unit of seed (5.07 x 30.43% = 1.74 oz / unit of seed)		
Rate of Clothianidin on Cereals	2.14 fl oz / cwt seed (2.14 x 40.3% = 0.86 oz / cwt)		2.0 oz / cwt seed (2.0 x 56.25% = 1.13 oz cwt)	
Rate of *B. firmus* I-1582 on Sugarbeet	4.1 fl oz / unit of seed = 0.41 fl oz / 1000 seed (0.041 x 8.1% = 0.003 oz / 1000 seed)			0.014 fl oz / 1000 seed (0.014 x 21.5% = 0.003 oz / 1000 seed)
Rate of *B. firmus* I-1582 on Cereals	2.14 fl oz / cwt seed (equivalent to 2.14 x 8.1% = 0.173 oz / cwt)			0.014 fl oz / 1000 seed (0.014 x 21.5% = 0.003 oz). Equivalent to 0.6-5.4 oz / cwt*

* Based upon 1450 seeds / lb for corn to 18080 seeds / lb for rye

Appropriate tolerances which cover the proposed uses are already established for clothianidin. A tolerance exemption was established for *B. firmus* I-1582 on

all food/feed commodities when applied/used as soil applications and seed treatments (Federal Register, May 7, 2008).

To satisfy the requirements for registration, the following materials are included with this application:

1. Application for new me-too product (EPA Form 8570-1)

2. A copy of the check in the amount of $1,159 has been paid (Please note that Bayer has an unused fund credit with the Agency, please debit the remaining $275 from this). RegFee R300 $1,434

3. Confidential Statement of Formula, CSF dated 12/15/2010

4. Formulator's Exemption Statement (EPA Form 8570-27) for [redacted]

5. Certification with Respect to Citation of Data (EPA Form 8570-34) for *Bacillus firmus* I-1582, EPA Reg. No. 264-1113.

6. Data matrix, EPA and Public versions, for *Bacillus firmus* I-1582, EPA Reg. No. 264-1113, and PONCHO/VOTiVO, EPA Reg. No. 264-1109.

7. Five (5) copies of the proposed labeling.

Please contact me at (919) 549-2412 or at robyn.kneen@bayer.com if you have any questions regarding this submission.

Sincerely,

Robyn Kneen

Robyn Kneen
Registration Manager
Bayer CropScience

Product ingredient source information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
Bayer CropScience P.O. Box 12014 2 T.W. Alexander Drive Research Triangle Park, NC 27709	264-XXXX
	Product Name PONCHO/GB126
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 12/15/2010

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Clothianidin

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☑ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
[redacted]		

Signature	Name and Title	Date
Robyn Kneen	Robyn Kneen, Registration Manager	12/15/2010

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

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

January 5, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-443491
EPA File Symbol or Registration Number: 264-RRGE
Product Name: PONCHO/GB126
EPA Receipt Date: 20-Dec-2010
EPA Company Number: 264
Company Name: BAYER CROPSCIENCE LP

Robyn Kneen
BAYER CROPSCIENCE LP
2 T.W. ALEXANDER DRIVE, PO Box 12014
RESEARCH TRIANGLE PARK, NC 27709

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee -**Correction**

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. 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: R300

NEW PRODUCT;ME-TOO PRODUCT FAST TRACK;

The fee associated with this action is $ 1,434. Payment in the amount of $ 1,159 has been recevied. Please remit additional payment in the amount of $ 275 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074
St. Louis, MO 63197-9000

By Courier:
U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how th request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room S4900 Potomac Yard 1
2777 S. Crystal Dr.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 30 days, the Agency will presume that you no longer want to pursue this action. The Agency will then reject your application and issue an invoice for any applicable outstanding fees.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

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

December 23, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-443491
EPA File Symbol or Registration Number: 264-RRGE
Product Name: PONCHO/GB126
EPA Receipt Date: 20-Dec-2010
EPA Company Number: 264
Company Name: BAYER CROPSCIENCE LP

MARGARET CHERNY
BAYER CROPSCIENCE LP
2 T.W. ALEXANDER DRIVE, PO Box 12014
RESEARCH TRIANGLE PARK, NC 27709

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: R300

NEW PRODUCT;ME-TOO PRODUCT FAST TRACK;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,
Front End Processing Staff
Information Technology & Resources Management Division

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

December 23, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-443491
EPA File Symbol or Registration Number: 264-RRGE
Product Name: PONCHO/GB126
EPA Receipt Date: 20-Dec-2010
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Sincerely,
Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{887640-~

This package includes the following

- (•) New Registration
- ( ) Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ( ) AD
- ( ) BPPD
- (•) RD

Risk Mgr. 1

Receipt No. S-	887640
EPA File Symbol/Reg. No.	264-RRGE
Pin-Punch Date:	12/20/2010

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R300

Granted: R300

Amount Due: $ 1434

Inerts approved. S. Rock 1/13/11

Parent/Child Decisions:

☒ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Hope Johnson Date: 12/23/10

Remarks: Resubmit for coding if R301. They included a data matrix?

R 300 and 301

100% identical (repack): YES or NO (circle one)
{If **yes**, it's a 100% repack - then product chemistry, acute toxicity and efficacy data are not required}

Data on Group and A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition		
830.1600	Description of materials used to produce the product		
830.1650	Description of formulation process		
830.1670	Discussion on the formation of impurities		
830.1700	Preliminary analysis		
830.1750	Certified limits (158.345)		
830.1800	Enforcement analytical method		

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.6302	Color		
830.6303	Physical State		
830.6304	Odor		
830.6314	Oxidation/Reduction (Chemical incompatibility)		
830.6315	Flammability		
830.6316	Explodability		
830.6317	Storage stability		
830.6319	Miscibility		
830.6320	Corrosion Characteristics		
830.6321	Dielectric Breakdown voltage		
830.7000	pH		
830.7100	Viscosity		
830.7300	Density		

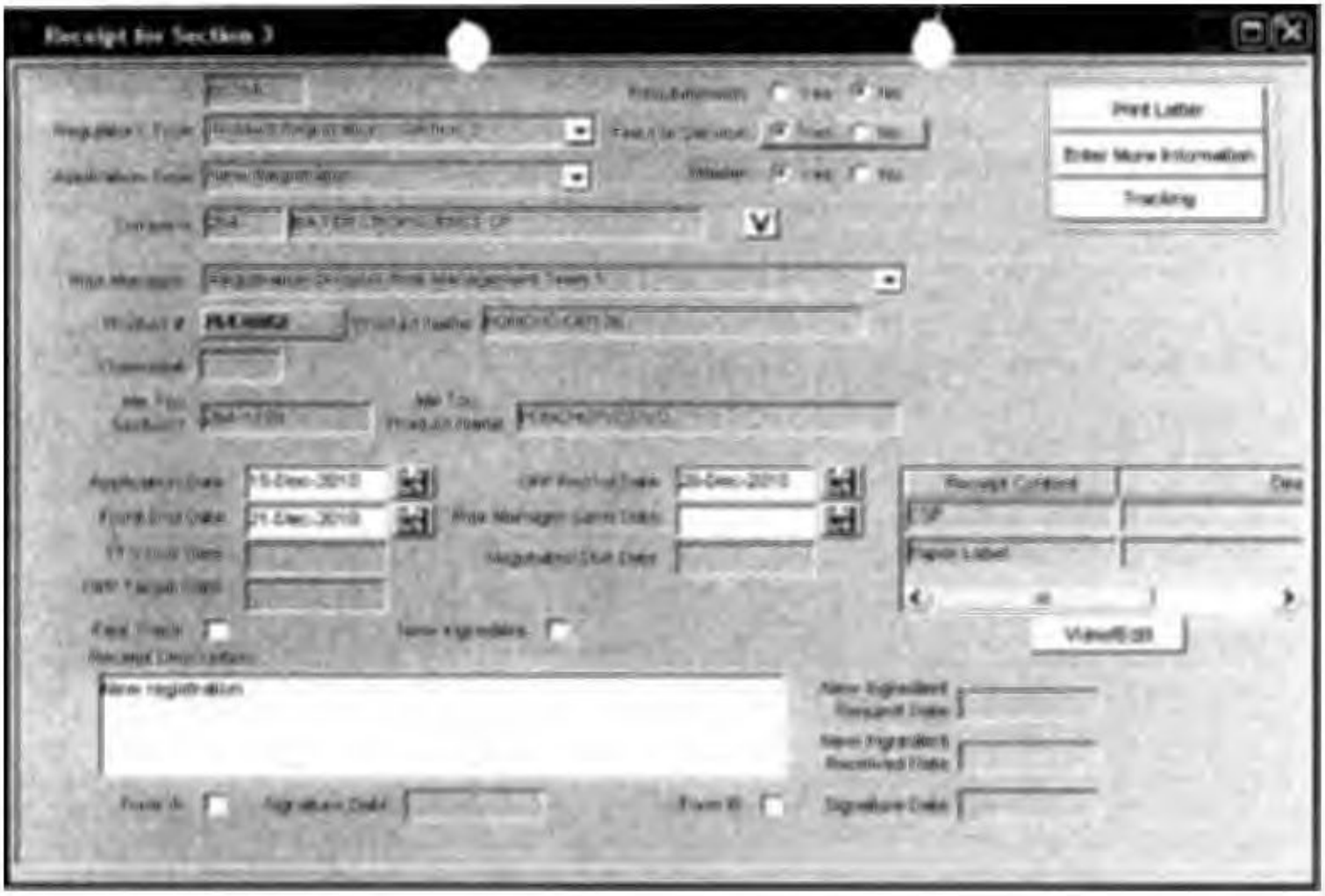
R 300 and 301

New products must provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cited	
		Yes	No
870.1100	Acute Oral (LD50)		
870.1200	Acute Dermal (LD50)		
870.1300	Acute Inhalation (LC50)		
870.2400	Acute Eye Irritation		
870.2500	Acute Dermal Irritation		
870.2600	Dermal Sensitization		

Efficacy – which guideline depends on the proposed label use and they must cite the data to be used for the bridging rationale.

Guideline No.	Efficacy Study Titles	Cited		Comments
		Yes	No	
810.3100	Soil Treatments for Imported Fire Ants			
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments			
810.3300	Treatments to Control Pests of Humans and Pets			
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments			
810.3500	Premises Treatments			
810.3600	Structural Treatments			
810.3800	Methods for Efficacy Testing of Termite Baits			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Print Letter
Enter More Information
Tracking
Receipt Content
Paper Label
View/Edit
New registration

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WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DATE OUT: July 30, 2012

SUBJECT: Storage Stability and Corrosion Study - Product Chemistry Review

FROM: Hari Mukhoty / Shyam Mathur
Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

TO: Tawanda Maignan / Tony Kish
Dianne Morgan / Kathryn Montague
Emily Hartman / Kable Davis
Marianne Lewis / Venus Eagle
Registration Division (7505P)

Company Name / Number: BAYER CROPSCIENCE LP / 264

INTRODUCTION:

In support of previous applications, the company / applicant has submitted the one year Storage Stability and Corrosion Characteristics studies for the following products:

PM	Reg. No.	DP Barcode	Decision No.	MRID No.	PC Code
20	264-1090	402348	465138	482487-01	129112; 080302
20	264-1091	402346	465137	482485-01	128997; 080302
22	264-1080	383999	441923	482712-01	113961; 129112
22	264-1093	384001	441925	482712-01	129112; 113961
23	264-1099	393271	452618	485419-01	122009; 122019
25	264-1103	402511	465330	488280-01	122009; 122021
01	264-1109	394386	455056	485778-01	029072; 044309
01	264-1132	394340	455055	485778-01	029072; 044309

SUMMARY OF FINDINGS:

The Technical Review Branch has performed a fast track review of the associated products and concludes all of the studies are "acceptable". No products exhibited degradation of the active ingredient(s) in the products or corrosion of the packing material were observed during the period of testing.

FEE FOR SERVICE

Form Approved OMB No. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-01634

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Bayer CropScience LP	OWN	
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			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	

Signature	Name and Title: Danielle A. Larochelle Registration Product Manager	Date: August 5, 2010

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			Bayer CropScience LP	OWN	
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Signature	Name and Title: Danielle A. Larochelle Registration Product Manager	Date: August 5, 2010

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DATA MATRIX

Date: August 5, 2010	EPA Reg. No.: 264-1113	Page 10 of 11
Applicant's/Registrant's Name & Address Bayer CropScience LP 2 T.W. Alexander Drive, P.O. Box 12014 Research Triangle Park, NC 27709	Product: PONCHO®/VOTiVO™	

Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	

Signature	Name and Title: Danielle A. Larochelle Registration Product Manager	Date: August 5, 2010

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

NOTES KEY

Signature		Name and Title: Danielle A. Larochelle Registration Product Manager	Date: August 5, 2010

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PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 1-5-11 Release Date

Experts In-Processing Signature: MF Harrington Date 1-5-11 Fee Paid: Yes ✓

Division management contacted on issues No_____Yes _____Date _____

EPA Reg. Number: 264-RRGE	EPA Receipt Date: 1-5-11

	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:

C/D

- No studies associated w/ jacket
- Product is a 100% Re-pack thus no inerts to review.

Jacket Approval Status: Pass

* 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.

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	

Signature Robyn Kneen	Name and Title: Robyn Kneen Registration Manager	Date: December 15, 2010

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			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	
			Bayer CropScience LP	OWN	

Signature Robyn Kneen	Name and Title: Robyn Kneen Registration Manager	Date: December 15, 2010

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Applicant's/Registrant's Name & Address Bayer CropScience LP 2 T.W. Alexander Drive, P.O. Box 12014 Research Triangle Park, NC 27709	Product: PONCHO®/GB126	

Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

NOTES KEY

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
§158.2120 Microbial pesticides products analysis data requirements					
885.1100	Product identity - TGAI	46933001 47963601 47973701 48110301 48110401 48159501	Bayer CropScience LP	OWN	
885.1100	Product identity - EP	47835907 47985401	Bayer CropScience LP	OWN	
885.1200	Manufacturing process - TGAI	46933002 47963601 47973701 48049301 48050201 48110301 48110401 48159501	Bayer CropScience LP	OWN	
885.1200	Manufacturing process – EP	47835907 47985401	Bayer CropScience LP	OWN	

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Deposition of a sample in a nationally recognized culture collection - TGAI				1
885.1300	Discussion of formation of unintentional ingredients - TGAI	46933003 47024801 47187202 47963601 47973701 48110301 48110401 48159501	Bayer CropScience LP	OWN	
885.1300	Discussion of formation of unintentional ingredients - EP	47835907	Bayer CropScience LP	OWN	
885.1400	Analysis of samples – TGAI	47024803 47963601 47973701 48049301 48050201 48110301 48110401 48159501	Bayer CropScience LP	OWN	

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1400	Analysis of samples - EP	47835907 47835908	Bayer CropScience LP	OWN	
885.1500	Certification of limits - TGAI	47469601 47963601 47973701 48110301 48110401 48159501	Bayer CropScience LP	OWN	
885.1500	Certification of limits - EP	47835907 47985401	Bayer CropScience LP	OWN	
151-25	Analytical methods – TGAI	46933005	Bayer CropScience LP	OWN	
151-26	Physical and chemical properties - TGAI	47024805	Bayer CropScience LP	OWN	
830.6302	Color - TGAI	47024805 47963601 47973701 48110301 48110401	Bayer CropScience LP	OWN	
830.6302	Color - EP	47835907	Bayer CropScience LP	OWN	

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6303	Physical state - TGAI	47024805 47963601 47973701 48110301 48110401	Bayer CropScience LP	OWN	
830.6303	Physical state - EP	47835907	Bayer CropScience LP	OWN	
830.6304	Odor - TGAI	47024805 47963601 47973701 48110301 48110401	Bayer CropScience LP	OWN	
830.6304	Odor - EP	47835907	Bayer CropScience LP	OWN	
830.6313	Stability to normal and elevated temperatures, metals and metal ions – TGAI	47526404 47963601 47973701 48049301 48050201 48110301 48110401	Bayer CropScience LP	OWN	
830.6314	Oxidation/reduction – EP	47835907	Bayer CropScience LP	OWN	

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6315	Flammability – EP	47835907	Bayer CropScience LP	OWN	
830.6316	Explodability – EP	47835907	Bayer CropScience LP	OWN	
830.6317	Storage stability – TGAI	47469602	Bayer CropScience LP	OWN	
830.6317	Storage stability – EP		Bayer CropScience LP	OWN	Study is ongoing
830.6319	Miscibility - TGAI	47963601 47973701 48110301 48110401	Bayer CropScience LP	OWN	
830.6319	Miscibility - EP	47835907	Bayer CropScience LP	OWN	
830.6320	Corrosion characteristics - TGAI	47469602	Bayer CropScience LP	OWN	
830.6320	Corrosion characteristics - EP		Bayer CropScience LP	OWN	Study is ongoing
830.7000	pH - TGAI	47024805 47963601 47973701 48110301 48110401	Bayer CropScience LP	OWN	
830.7000	pH - EP	47835907	Bayer CropScience LP	OWN	

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7100	Viscosity - TGAI	47963601 47973701 48110301 48110401	Bayer CropScience LP	OWN	
830.7100	Viscosity - EP	47835907	Bayer CropScience LP	OWN	
830.7300	Density/relative density/bulk density (specific gravity) - TGAI	47024805 47963601 47973701 48110301 48110401	Bayer CropScience LP	OWN	
830.7300	Density/relative density/bulk density (specific gravity) - EP	47835907	Bayer CropScience LP	OWN	
§ 158.2130 Microbial pesticides residue data requirements					
885.2100	Chemical identity				2
885.2200	Nature of t he residue in plants - EP				3
885.2250	Nature of the residue in animals - EP				3
885.2300	Analytical methods – plants - TGAI				3
885.2350	Analytical methods – animals - TGAI				3

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.2400	Storage stability – EP				3
885.2500	Magnitude of residue in plants - EP				3
885.2550	Magnitude of residues in meat, milk, poultry, eggs - EP				3
885.2600	Magnitude of residues in potable water, fish, and irrigated crops - EP				3
§ 158.2140 Microbial pesticides toxicology data requirements					
885.3050	Acute oral toxicity/pathogenicity – TGAI	46933007	Bayer CropScience LP	OWN	
885.3100	Acute dermal toxicity/pathogenicity – TGAI	46933008	Bayer CropScience LP	OWN	
885.3150	Acute pulmonary toxicity/pathogenicity – TGAI	46933009	Bayer CropScience LP	OWN	
885.3200	Acute injection toxicity/pathogenicity (intravenous) – TGAI	46933010	Bayer CropScience LP	OWN	
885.3400	Hypersensitivity incidents - TGAI				4
885.3400	Hypersensitivity incidents - EP				4
885.3500	Cell culture - TGAI				5
870.1100	Acute Oral Toxicity - MP	46933007	Bayer CropScience LP	OWN	
870.1100	Acute Oral Toxicity - EP	47835901	Bayer CropScience LP	OWN	

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1200	Acute Dermal Toxicity - MP	46933008	Bayer CropScience LP	OWN	
870.1200	Acute Dermal Toxicity - EP	47835902	Bayer CropScience LP	OWN	
870.1300	Acute Inhalation Toxicity - MP	46933009	Bayer CropScience LP	OWN	
870.1300	Acute Inhalation Toxicity - EP	47835903	Bayer CropScience LP	OWN	
870.2400	Acute Eye Irritation - MP	47469603	Bayer CropScience LP	OWN	
870.2400	Acute Eye Irritation - EP	47835904	Bayer CropScience LP	OWN	
870.2500	Primary Dermal Irritation - MP	47469604	Bayer CropScience LP	OWN	
870.2500	Primary Dermal Irritation - EP	47835905	Bayer CropScience LP	OWN	
870.2600	Dermal Sensitization - EP	47835906	Bayer CropScience LP	OWN	
152-36	Hypersensitivity - TGAI	47024807	Bayer CropScience LP	OWN	
885.3550	Acute toxicology – TGAI	46933011	Bayer CropScience LP	OWN	
885.3600	Subchronic toxicity/pathogenicity – TGAI	46933011	Bayer CropScience LP	OWN	
885.3650	Reproductive fertility effects – TGAI	46933011	Bayer CropScience LP	OWN	
870.4200	Carcinogenicity – TGAI				6
870.7800	Immunotoxicity - TGAI				6

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3000	Infectivity/pathogenicity analysis				6
152-38	Immune response, Tier I – TGAI	47024806	Bayer CropScience LP	OWN	
152-46	Immune response, Tier II - TGAI	47024806	Bayer CropScience LP	OWN	
152-48	Reproductive/fertility effects (virulence enhancement) - TGAI	47024806	Bayer CropScience LP	OWN	
152-49	Reproductive/fertility effects (mammalian mutagenicity) - TGAI	47024806	Bayer CropScience LP	OWN	
§ 158.2150 Microbial pesticides nontarget organisms and environmental fate data requirements					
885.4050	Avian oral toxicity - TGAI	46933012	Bayer CropScience LP	OWN	
885.4100	Avian inhalation toxicity/pathogenicity - TGAI	46933013	Bayer CropScience LP	OWN	
885.4150	Wild mammal toxicity/pathogenicity - TGAI	46933013	Bayer CropScience LP	OWN	
885.4200	Freshwater fish toxicity/pathogenicity – TGAI and TEP	46933013	Bayer CropScience LP	OWN	
885.4240	Freshwater invertebrate toxicity/pathogenicity – TGAI and TEP	46933014	Bayer CropScience LP	OWN	
885.4280	Estuarine and marine invertebrate testing - TGAI	46933015	Bayer CropScience LP	OWN	
885.4300	Nontarget plant testing - TGAI and TEP	46933015	Bayer CropScience LP	OWN	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Nontarget insect testing - TGAI	46933015	Bayer CropScience LP	OWN	
885.4380	Honey bee testing - TGAI	46933016	Bayer CropScience LP	OWN	
885.4380	Honey bee testing - TGAI	47850201	Bayer CropScience LP	OWN	
885.5200	Terrestrial environmental expression tests – TGAI or TEP	46933017	Bayer CropScience LP	OWN	
885.5300	Freshwater environmental expression tests – TGAI or TEP	46933017	Bayer CropScience LP	OWN	
885.5400	Marine or estuarine environmental expression tests – TGAI or TEP	46933017	Bayer CropScience LP	OWN	
155-25	Terrestrial wildlife and aquatic organisms – TGAI or TEP				6
885.4600	Avian chronic pathogenicity and reproduction test - TGAI				6
885.4650	Aquatic invertebrate range testing - TGAI				6
885.4700	Fish life cycle studies - TGAI				6
885.4750	Aquatic ecosystem test - TGAI				6
885.2500 850.1950	Field testing for terrestrial wildlife and Field testing for aquatic organisms – TGAI or TEP				8

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Ingredients: 1) *Bacillus firmus* (Strain I-1582); 2) Clothianidin, CAS No. 210880-92-5

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.2500	Simulated or actual field tests (birds, mammals) - TEP				8
885.1950	Simulated or actual field test (aquatic organisms) - TEP				8
885.2500	Simulated or actual field tests (insect predators, parasites) - TEP				8
885.3040	Simulated or actual field tests (insect pollinators) - TEP				8
885.4300	Simulated or actual field tests (plants) - TEP				8

NOTES KEY

1 = Deposited with the CNCM 5/29/95 (See page 20 of MRID No. 46933001)	5 = N/A – *Bacillus firmus* is a nonpathogenic bacterium
2 = Refer to Group A Data	6 = Tier III testing not warranted based on Tier I data/information
3 = N/A – Tolerance exemption at 40 CFR 180.1282	7 = N/A – Not warranted based on Tier I data/information
4 = No hypersensitivity incidents have occurred	8 = Tier IV testing not warranted based on Tier I data/information

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