EPA Registration Number 264-789 Vol. 2
Part 1

DP #: (312449) Decision #: 351931

DATA PACKAGE BEAN SHEET

Date: 26-Jan-2005

SCANNED 10.4.04

* * * Registration Information * * *

Registration: 264-789 - PONCHO 600

Company: 264 - BAYER CROPSCIENCE LP

Risk Manager: RM 01 - Daniel Kenny - (703) 305-7546 Room# CM-2 229

Risk Manager Reviewer: Carmen Rodia CRODIA

Sent Date: Calculated Due Date: Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R35) NON-FAST TRACK (CHANGES TO REI;PPE;PHI;RATE AND NUMBER OF APPLICATI

Ingredients: 044309, Clothianidin(48%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 26-Jan-2005 Due Back:

DP Ingredient: 044309, Clothianidin

DP Title: Revised (Shortened) PBIs for Potato & Sugarcane

CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #:

	Assigned To	Date In	Date Out		
Organization:	HED / RAB2			Administrative Due Date:	21-May-2006
Team Name:				Negotiated Due Date:	
Reviewer Name:				Projected Completion Date:	
Contractor Name:					

* * * Studies Sent for Review * * *

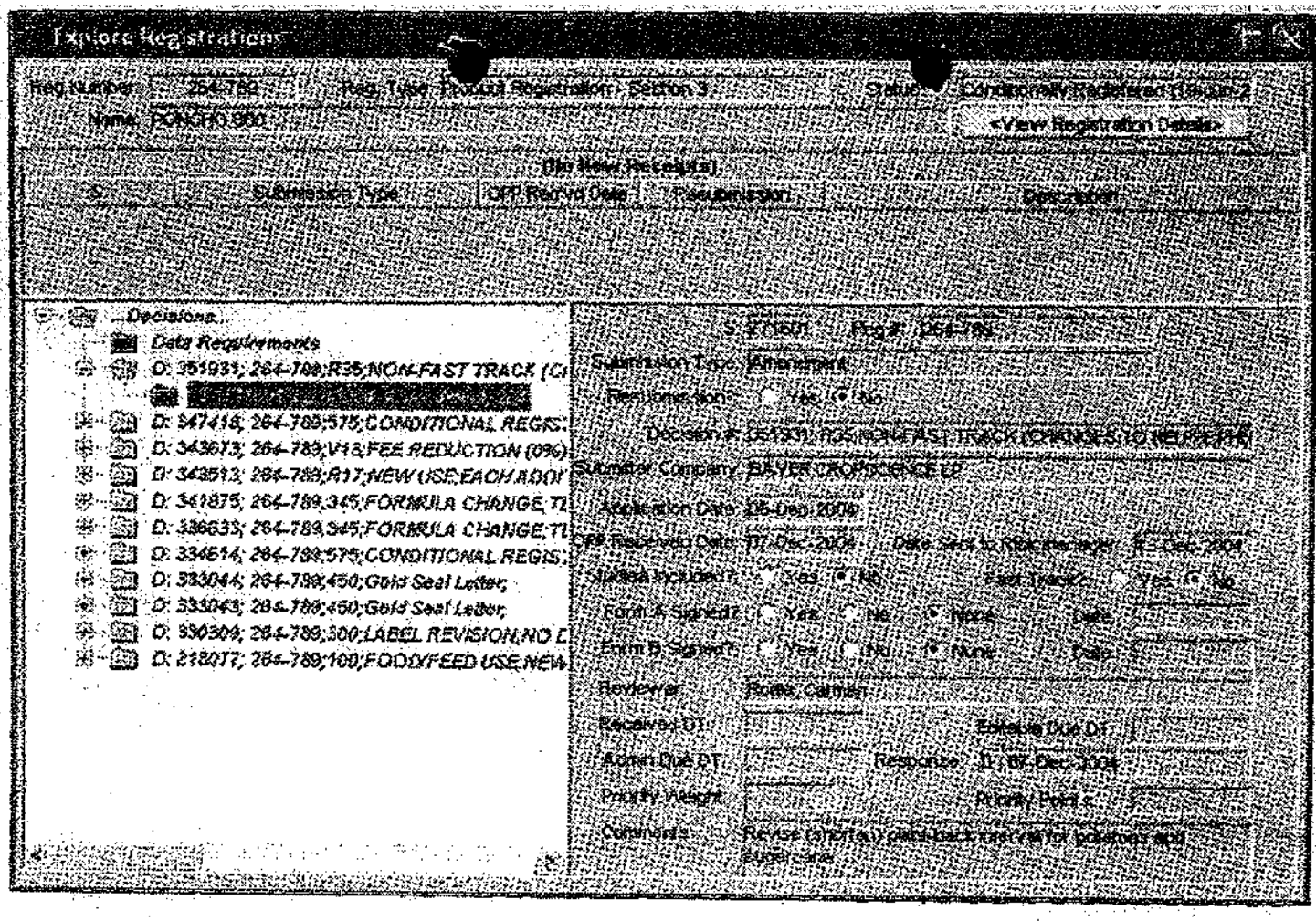
No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

On December 6, 2004, Bayer CropScience submitted a label amendment to request a 30-day plant back interval (PBI) for potatoes planted after corn or canola treated with clothianidin. In addition, Bayer also requested an 8 month PBI for sugarcane planted after corn treated with clothianidin. On the current label, the PBIs for potatoes and sugarcane (that is, all other crops) is 1 year. I am forwarding along hard copies of the following: (1) Bayer's request for the PBIs for potatoes and sugarcane; (2) a copy of Bayer's justification for these amended PBIs; and (3) a revised copy of the Poncho 600 label with all the changes highlighted in yellow. Please review the referenced information and let us know your decision regarding the amended PBIs. If you have any questions, please call Carmen Rodia at 305-0327.


Explore Registrations
Reg Number 264-789
Reg. Type Product Registration - Section 3
Status Conditionally Registered
Name PONCHO 800
<View Registration Details>
(No New Receipts)
Submission Type
OPP Rec'vd Date
Resubmission
Description
...Decisions...
Data Requirements
D: 351931; 264-789;R35;NON-FAST TRACK (C
D: 347418; 264-789;575;CONDITIONAL REGIS
D: 343673; 264-789;V18;FEE REDUCTION (0%)
D: 343513; 264-789;R17;NEW USE;EACH ADDI
D: 341875; 264-789;345;FORMULA CHANGE;TI
D: 336633; 264-789;345;FORMULA CHANGE;TI
D: 334614; 264-789;575;CONDITIONAL REGIS
D: 333044; 264-789;450;Gold Seal Letter;
D: 333043; 264-789;450;Gold Seal Letter;
D: 330309; 264-789;300;LABEL REVISION;NO D
D: 218077; 264-789;100;FOOD/FEED USE;NEW
Submission Type Amendment
Resubmission Yes No
Decision # 351931; R35;NON-FAST TRACK (CHANGES TO HELPFE PHI
Submitter Company BAYER CROPSCIENCE LP
Application Date 05-Dec-2004
OPP Received Date 07-Dec-2004
Date Sent to Risk Manager 13-Dec-2004
Studies Included? Yes No
Fast Track? Yes No
Form A Signed? Yes No None Date
Form B Signed? Yes No None Date
Reviewer Rotte, Carmen
Received DT
Editable Due DT
Admin Due DT
Response 11 / 07-Dec-2004
Priority Weight
Priority Points
Comments Revise (shorten) plant-back interval for potatoes and sugarcane

PM7

FEE FOR SERVICE

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

December 13, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-351931
EPA File Symbol or Registration Number: 264-789
Product Name: PONCHO 600
EPA Receipt Date: 07-Dec-2004
EPA Company Number: 264
Company Name: BAYER CROPSCIENCE LP

Jamin Huang, Ph.D.
BAYER CROPSCIENCE LP
2 T.W. ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, NC 27709

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. 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: R35

NON-FAST TRACK (CHANGES TO REI;PPE;PHI;RATE AND NUMBER OF APPLICATIONS;ADD AERIAL APPLICATION;MODIFY GW/SW ADVISORY STATEMENT;

Please remit payment in the amount of: $ 10,000 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

By Courier:
U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
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.

You may be eligible for a full or 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 soley 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.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 305-6249.

Sincerely,

Front-End Processing Staff
Information Resources and Services Division

Fee for Service

This package includes the following	for Division
New Registration	X RD
X Amendment	AD
Waiver Request	BPPD
Voluntary Payment Request	

Receipt Nos. S- 171601

Product/Risk Manager: 7

EPA File Symbol/Reg. No. 264-789

Pin-Punch Date: 12/1/2004

Action Code:

Requested: R-34

Granted: R-35 Amount due: $ 10K

VolPay Reduction:

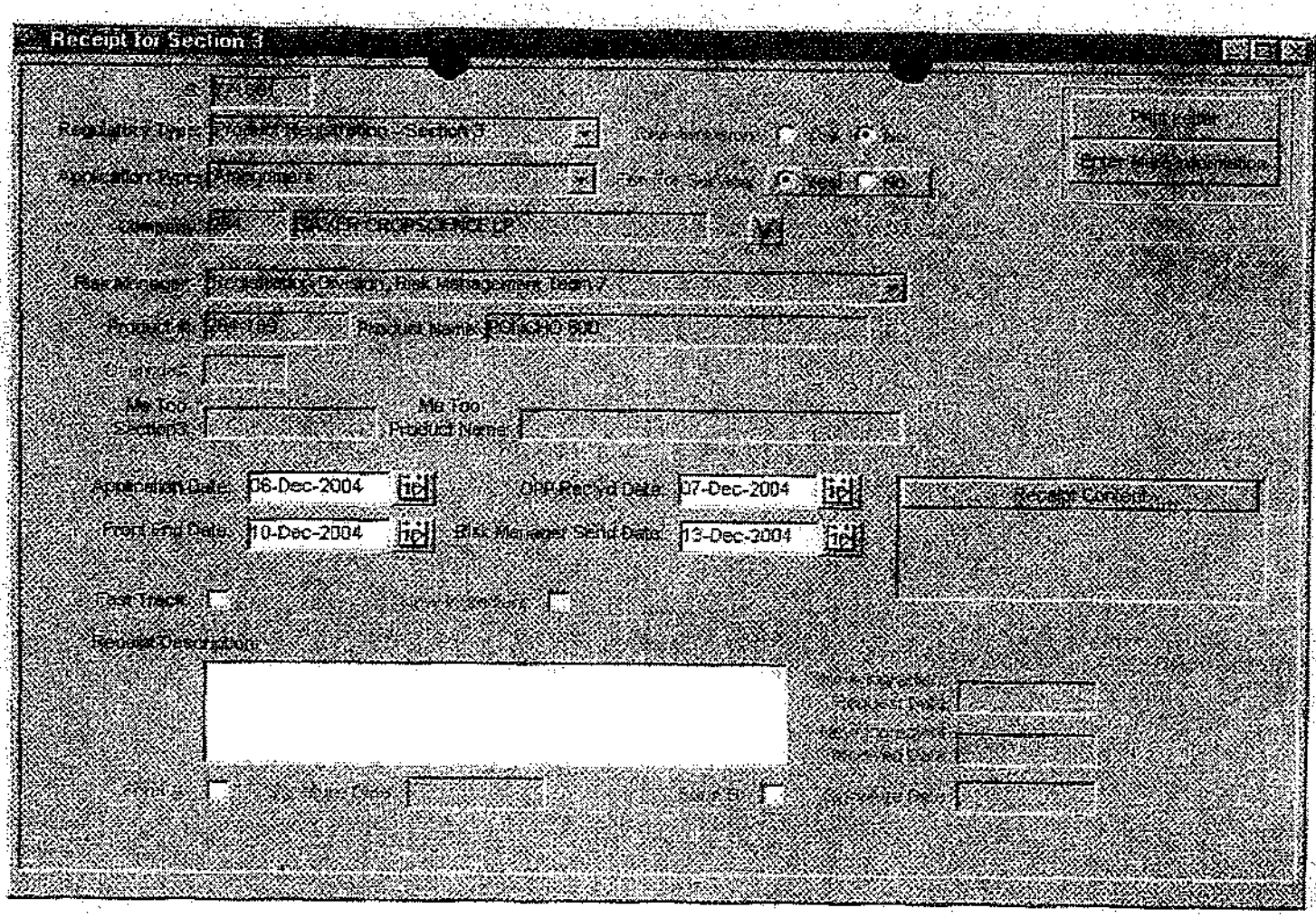
____% Original Decision #: D-

Parent/Child Decisions:

Reviewer: [illegible] Date: 12/13/2004

Remarks: [illegible]

FFS cover sheet revision 4A


Receipt for Section 3
Regulatory Type:
Application Type:
Company:
Risk Manager:
Product #:
Product Name:
Me Too Section3:
Me Too Product Name:
Application Date:
06-Dec-2004
OPP Recvd Date:
07-Dec-2004
Front End Date:
10-Dec-2004
Risk Manager Send Date:
13-Dec-2004
Receipt Content
Fast Track:
Receipt Description:

4 copies of revised
label dated
11/17/04

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95

EPA United States Environmental Protection Agency Washington, DC 20460

[ ] Registration
[✓] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 264-789	2. EPA Product Manager: Daniel C. Kenny	3. Proposed Classification: [ ] None [ ] Restricted
4. Company/Product (Name): Poncho 600	PM#: Team 01	
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 Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. ____ Product Name ____	

Section - II

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

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

REGFEE: EPA No. R34, Non-Fast Track. Shorten planiback interval (PBI) for corn and sugarcane based on data already reviewed by the Agency. Fee amount due $ 3,000. We consulted with Dr. Rick Loranger of EPA about our justification prior to this submission and he agreed that our justification can support this request. See the cover letter and attached justification document.

CONTACT: Jamin Huang, e-mail address: jamin.huang@bayercropscience.com

Section - III

1. Material This Product Will Be Packaged In:

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

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] 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)
Jamin Huang, Ph.D.	Product Registration Manager, Insecticides	(919) 549-2634

Certification

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

6. Date Application Received (Stamped)

2. Signature: Jamin Huang	3. Title: Product Registration Manager, Insecticides
4. Typed Name: Jamin Huang, Ph. D.	5. Date: December 6, 2004

Bayer CropScience

December 6, 2004

Ms. Stephanie Nguyen
Document Processing Desk
Registration Division
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

Re: Label Amendment to Shorten Plantback Interval (PBI) for Potatoes and Sugarcane based on data reviewed by EPA

Poncho 600 (EPA Reg. No.: 264-789)

Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709
Phone: 919 549-2000

Dear Ms. Nguyen,

Bayer CropScience is herein submitting a label amendment to request a 30 day plantback interval (PBI) for potatoes planted after corn or canola treated with clothianidin, and a 8 month plantback interval (PBI) for sugarcane planted after corn. We are also providing our justifications to support this amendment. This revision is based on data already reviewed by the Agency, so it does not need to be reviewed again by any other Branches of EPA. In addition, we have consulted with Dr. Rick Loranger of EPA about our proposed justifications and he agreed that our current data could support the proposed revisions of the plantback interval for potatoes and sugarcane. A copy of our e-mail communications with Dr. Loranger is included as an attachment to the justification for these amendments.

In support of this amendment, we are submitting the following:

1. Application for Pesticide Amendment (EPA Form 8570-1) dated December 6, 2004.

2. Five copies of the revised Poncho 600 labeling dated November 17, 2004.

3. One copy of the above labeling with all of the changes highlighted in yellow.

4. Three (3) copies of our justification for these amended plantback intervals

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

Sincerely,

Jamin Huang, Ph.D.
Product Registration Manager

Attachments

CC: Dr. Rick Loranger (USEPA) – a PDF copy of this submission via e-mail

Poncho™ 600

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insect pests.
All seed treated with this product must be conspicuously coloured at the time of treatment.

ACTIVE INGREDIENT:
Clothianidin 48.0%
INERT INGREDIENTS: 52.0%
Contains 5 lbs. active ingredient per gallon. TOTAL 100.0%

E.P.A. Reg. No. 264-789 **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:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • 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.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.
Have the 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.

PRECAUTIONARY STATEMENTS

CAUTION
HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables, 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. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment 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. Contain any product spills or equipment leaks and dispose of wastes according to disposal instructions on this label. Do not contaminate water when disposing of equipment washwaters.

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 by commercial treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting. This product is to be used in commercial liquid or slurry treaters. Mix thoroughly before use or use entire container at one time.

All seed treated with this product must be conspicuously coloured at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by *40 CFR 153.155* must be strictly adhered to when using this product.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SEED QUALITY AND STORAGE OF TREATED SEED

Treatment of highly mechanically damaged seed, or seed of known low vigor or 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.

LABELING OF TREATED SEED

Seed commercially treated with Poncho™ 600 must be labelled in compliance with the *Federal Seed Act*.

All bags containing treated seed must be labelled or tagged as follows:

- This seed has been treated with Poncho™ 600 seed protectant, which contains clothianidin.
- Do not use treated seed for feed, food or oil processing.
- Rapeseed greens and seed grown or harvested from Poncho™ 600-treated seed must not be used for feed or human consumption. Rapeseed grown and harvested from Poncho™ 600-treated seed is only for industrial uses and can not be used for edible oil or any other human/feed consumption.
- Store away from feeds and other foodstuffs.
- Wear long-sleeved shirt, long pants and waterproof gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be doublesown 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.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, dried beans and potatoes. These areas may also be replanted after 8 months with sugarcane. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

GENERAL INFORMATION

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insects.

For use in commercially available equipment designed for seed treatment only. Not for use in hopper-box, slurry-box, or similar seed treatment applications used at planting. This product is to be used in liquid or slurry treaters. Mix thoroughly before use or use entire

container at one time. All tank mixes should be pre-tested to determine physical compatibility between formulations. Observe all cautions and limitations on labeling of all products used in mixtures.

For Early Season Protection Against Certain Insects:

Poncho™ 600 will aid in the protection of seeds and seedlings against injury by certain early season insects.

RECOMMENDED APPLICATIONS

CROP	INSECT PESTS	RATE PONCHO™ 600	
		mg a.i./Kernel	80,000 Unit of Seed
Corn (including field, sweet and pop)	Corn rootworm (including Northern, Western, Southern and Mexican) Southern corn billbug[1]	1.25	5.64 fl. oz. or 166.7 mL
	Chinch bug Corn flea beetle Corn leaf aphid Cutworm, black Grape colaspis Seedcorn maggot Southern corn leaf beetle Southern corn rootworm Southern green stinkbug Storage pests[2] (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) Sugarcane beetle White grub (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Thrips Wireworm	0.25	1.13 fl. oz or 33.3 mL
	Corn flea beetle (through first true seed leaf) Seedcorn maggot[3] Storage pests[2] (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) White grub[3] (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Wireworm[3]	0.125	0.57 fl. oz or 16.7 mL

CROP	INSECT PESTS	RATE PONCHO™ 600	REMARKS
Canola Rapeseed	Flea beetle Wireworm	3.84 fl. oz per 100 lbs. seed or 250 mL per 100 kg seed	Use this rate under low to moderate flea beetle pressure.
		5.12 fl. oz per 100 lbs. seed or 333 mL per 100 kg seed	Use this rate under moderate flea beetle pressure.
		10.23 fl. oz per 100 lbs. seed or 666 mL per 100 kg seed	Use this rate under high to extreme flea beetle pressure where extended control is required.

[1] Follow-up foliar sprays of a locally registered insecticide may be needed under heavy pest pressure. Consult your local Extension office for recommendations.

[2] It is recommended that seed with existing populations of storage pests be fumigated prior to treating and bagging seed.

[3] For seed protection only.

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.

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 should 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: 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. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: 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 CROPSCIENCES ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS: 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™ 600 (PENDING) Submitted 11/17/04.

Poncho™ 600

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insect pests.
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ACTIVE INGREDIENT:
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INERT INGREDIENTS: 52.0%
Contains 5 lbs. active ingredient per gallon. TOTAL 100.0%

E.P.A. Reg. No. 264-789 **E.P.A. Est. No. 7501-IA-01, 7501-ID-01**

KEEP OUT OF REACH OF CHILDREN

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For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF SWALLOWED:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • 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.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.
Have the 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.

PRECAUTIONARY STATEMENTS

CAUTION
HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables, 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. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment 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. Contain any product spills or equipment leaks and dispose of wastes according to disposal instructions on this label. Do not contaminate water when disposing of equipment washwaters.

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 by commercial treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting. This product is to be used in commercial liquid or slurry treaters. Mix thoroughly before use or use entire container at one time.

All seed treated with this product must be conspicuously coloured at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by *40 CFR 153.155* must be strictly adhered to when using this product.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SEED QUALITY AND STORAGE OF TREATED SEED

Treatment of highly mechanically damaged seed, or seed of known low vigor or 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.

LABELING OF TREATED SEED

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All bags containing treated seed must be labelled or tagged as follows:

- This seed has been treated with Poncho™ 600 seed protectant, which contains clothianidin.
- Do not use treated seed for feed, food or oil processing.
- Rapeseed greens and seed grown or harvested from Poncho™ 600-treated seed must not be used for feed or human consumption. Rapeseed grown and harvested from Poncho™ 600-treated seed is only for industrial uses and can not be used for edible oil or any other human/feed consumption.
- Store away from feeds and other foodstuffs.
- Wear long-sleeved shirt, long pants and waterproof gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be doublesown 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.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, dried beans and potatoes. These areas may also be replanted after 8 months with sugarcane. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

GENERAL INFORMATION

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insects.

For use in commercially available equipment designed for seed treatment only. Not for use in hopper-box, slurry-box, or similar seed treatment applications used at planting. This product is to be used in liquid or slurry treaters. Mix thoroughly before use or use entire

container at one time. All tank mixes should be pre-tested to determine physical compatibility between formulations. Observe all cautions and limitations on labeling of all products used in mixtures.

For Early Season Protection Against Certain Insects:

Poncho™ 600 will aid in the protection of seeds and seedlings against injury by certain early season insects.

RECOMMENDED APPLICATIONS

CROP	INSECT PESTS	RATE PONCHO™ 600	
		mg a.i./Kernel	80,000 Unit of Seed
Corn (including field, sweet and pop)	Corn rootworm (including Northern, Western, Southern and Mexican) Southern corn billbug[1]	1.25	5.64 fl. oz. or 166.7 mL
	Chinch bug Corn flea beetle Corn leaf aphid Cutworm, black Grape colaspis Seedcorn maggot Southern corn leaf beetle Southern corn rootworm Southern green stinkbug Storage pests[2] (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) Sugarcane beetle White grub (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Thrips Wireworm	0.25	1.13 fl. oz or 33.3 mL
	Corn flea beetle (through first true seed leaf) Seedcorn maggot[3] Storage pests[2] (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) White grub[3] (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Wireworm[3]	0.125	0.57 fl. oz or 16.7 mL

CROP	INSECT PESTS	RATE PONCHO™ 600	REMARKS
Canola Rapeseed	Flea beetle Wireworm	3.84 fl. oz per 100 lbs. seed or 250 mL per 100 kg seed	Use this rate under low to moderate flea beetle pressure.
		5.12 fl. oz per 100 lbs. seed or 333 mL per 100 kg seed	Use this rate under moderate flea beetle pressure.
		10.23 fl. oz per 100 lbs. seed or 666 mL per 100 kg seed	Use this rate under high to extreme flea beetle pressure where extended control is required.

[1] Follow-up foliar sprays of a locally registered insecticide may be needed under heavy pest pressure. Consult your local Extension office for recommendations.

[2] It is recommended that seed with existing populations of storage pests be fumigated prior to treating and bagging seed.

[3] For seed protection only.

IMPORTANT: READ BEFORE USE

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DISCLAIMER OF WARRANTIES: 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. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: 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: 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™ 600 (PENDING) Submitted 11/17/04.

Poncho™ 600

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insect pests.
All seed treated with this product must be conspicuously coloured at the time of treatment.

ACTIVE INGREDIENT:
Clothianidin 48.0%
INERT INGREDIENTS: 52.0%
Contains 5 lbs. active ingredient per gallon. **TOTAL** 100.0%

E.P.A. Reg. No. 264-789 **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:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • 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.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.
Have the 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.

PRECAUTIONARY STATEMENTS

CAUTION
HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables, 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. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment 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. Contain any product spills or equipment leaks and dispose of wastes according to disposal instructions on this label. Do not contaminate water when disposing of equipment washwaters.

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 by commercial treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting. This product is to be used in commercial liquid or slurry treaters. Mix thoroughly before use or use entire container at one time.

All seed treated with this product must be conspicuously coloured at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by *40 CFR 153.155* must be strictly adhered to when using this product.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SEED QUALITY AND STORAGE OF TREATED SEED

Treatment of highly mechanically damaged seed, or seed of known low vigor or 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.

LABELING OF TREATED SEED

Seed commercially treated with Poncho™ 600 must be labelled in compliance with the *Federal Seed Act*.

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- Dispose of seed packaging in accordance with local requirements.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, dried beans and potatoes. These areas may also be replanted after 8 months with sugarcane. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

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RECOMMENDED APPLICATIONS

CROP	INSECT PESTS	RATE PONCHO™ 600	
		mg a.i./Kernel	80,000 Unit of Seed
Corn (including field, sweet and pop)	Corn rootworm (including Northern, Western, Southern and Mexican) Southern corn billbug[1]	1.25	5.64 fl. oz. or 166.7 mL
	Chinch bug Corn flea beetle Corn leaf aphid Cutworm, black Grape colaspis Seedcorn maggot Southern corn leaf beetle Southern corn rootworm Southern green stinkbug Storage pests[2] (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) Sugarcane beetle White grub (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Thrips Wireworm	0.25	1.13 fl. oz or 33.3 mL
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[1] Follow-up foliar sprays of a locally registered insecticide may be needed under heavy pest pressure. Consult your local Extension office for recommendations.

[2] It is recommended that seed with existing populations of storage pests be fumigated prior to treating and bagging seed.

[3] For seed protection only.

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NET CONTENTS: 30 GALLONS

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Poncho™ 600 (PENDING) Submitted 11/17/04.

Poncho™ 600

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ACTIVE INGREDIENT:
Clothianidin 48.0%
INERT INGREDIENTS: 52.0%
Contains 5 lbs. active ingredient per gallon. **TOTAL** 100.0%

E.P.A. Reg. No. 264-789 **E.P.A. Est. No. 7501-IA-01, 7501-ID-01**

KEEP OUT OF REACH OF CHILDREN

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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

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

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.
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NOTE TO PHYSICIAN: No specific antidote is available. Treat the patient symptomatically.

PRECAUTIONARY STATEMENTS

CAUTION
HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

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ENVIRONMENTAL HAZARDS

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DIRECTIONS FOR USE

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STORAGE AND DISPOSAL

STORAGE

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PESTICIDE DISPOSAL

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Bayer CropScience

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http://www.bayercropscienceus.com

Poncho™ 600 (PENDING) Submitted 11/17/04.

1 copy of the revised
label (dated 11/17/04)
with all changes
highlighted in
yellow

Poncho™ 600

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ACTIVE INGREDIENT:
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Harmful if swallowed or absorbed through the skin. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables, 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. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment 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. Contain any product spills or equipment leaks and dispose of wastes according to disposal instructions on this label. Do not contaminate water when disposing of equipment washwaters.

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 by commercial treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting. This product is to be used in commercial liquid or slurry treaters. Mix thoroughly before use or use entire container at one time.

All seed treated with this product must be conspicuously coloured at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by *40 CFR 153.155* must be strictly adhered to when using this product.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SEED QUALITY AND STORAGE OF TREATED SEED

Treatment of highly mechanically damaged seed, or seed of known low vigor or 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.

LABELING OF TREATED SEED

Seed commercially treated with Poncho™ 600 must be labelled in compliance with the *Federal Seed Act*.

All bags containing treated seed must be labelled or tagged as follows:

- This seed has been treated with Poncho™ 600 seed protectant, which contains clothianidin.
- Do not use treated seed for feed, food or oil processing.
- Rapeseed greens and seed grown or harvested from Poncho™ 600-treated seed must not be used for feed or human consumption. Rapeseed grown and harvested from Poncho™ 600-treated seed is only for industrial uses and can not be used for edible oil or any other human/feed consumption.
- Store away from feeds and other foodstuffs.
- Wear long-sleeved shirt, long pants and waterproof gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be doublesown 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.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, dried beans and potatoes. These areas may also be replanted after 8 months with sugarcane. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

GENERAL INFORMATION

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insects.

For use in commercially available equipment designed for seed treatment only. Not for use in hopper-box, slurry-box, or similar seed treatment applications used at planting. This product is to be used in liquid or slurry treaters. Mix thoroughly before use or use entire

container at one time. All tank mixes should be pre-tested to determine physical compatibility between formulations. Observe all cautions and limitations on labeling of all products used in mixtures.

For Early Season Protection Against Certain Insects:

Poncho™ 600 will aid in the protection of seeds and seedlings against injury by certain early season insects.

RECOMMENDED APPLICATIONS

CROP	INSECT PESTS	RATE PONCHO™ 600	
		mg a.i./Kernel	80,000 Unit of Seed
Corn (including field, sweet and pop)	Corn rootworm (including Northern, Western, Southern and Mexican) Southern corn billbug[1]	1.25	5.64 fl. oz. or 166.7 mL
	Chinch bug Corn flea beetle Corn leaf aphid Cutworm, black Grape colaspis Seedcorn maggot Southern corn leaf beetle Southern corn rootworm Southern green stinkbug Storage pests[2] (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) Sugarcane beetle White grub (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Thrips Wireworm	0.25	1.13 fl. oz or 33.3 mL
	Corn flea beetle (through first true seed leaf) Seedcorn maggot[3] Storage pests[2] (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) White grub[3] (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Wireworm[3]	0.125	0.57 fl. oz or 16.7 mL

CROP	INSECT PESTS	RATE PONCHO™ 600	REMARKS
Canola Rapeseed	Flea beetle Wireworm	3.84 fl. oz per 100 lbs. seed or 250 mL per 100 kg seed	Use this rate under **low to moderate** flea beetle pressure.
		5.12 fl. oz per 100 lbs. seed or 333 mL per 100 kg seed	Use this rate under **moderate** flea beetle pressure.
		10.23 fl. oz per 100 lbs. seed or 666 mL per 100 kg seed	Use this rate under **high to extreme** flea beetle pressure where extended control is required.

[1] Follow-up foliar sprays of a locally registered insecticide may be needed under heavy pest pressure. Consult your local Extension office for recommendations.

[2] It is recommended that seed with existing populations of storage pests be fumigated prior to treating and bagging seed.

[3] For seed protection only.

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.

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 should 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: 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. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: 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: 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™ 600 (PENDING) Submitted 11/17/04.

Justification for Revised Plantback Intervals for Potatoes and Sugarcane Planted after Corn and Canola Receiving a Seed Treatment of Clothianidin (Poncho)

7 copies of Justification Document

Richard W. Heintzelman, Ph.D.
Bayer CropScience
RTP, NC 27709

December 2, 2004

I. Introduction

Bayer CropScience (BCS) received a request from growers to reduce the plantback interval for potatoes grown after corn or canola which had received a seed-treatment of clothianidin. BCS also received a request for a reduction in the plantback interval for sugarcane grown after corn (especially sweet corn) receiving a seed-treatment of clothianidin. Bayer CropScience believes that shorter plantback intervals are justified based on the available data. The available data support a 30 day plantback interval for potatoes planted after corn or canola and an eight month plantback interval for sugarcane planted after corn. Details of the justification are given below.

II. Justification for the Requested Plantback Intervals

Plantback Interval for Potatoes after Corn or Canola

The limited field rotational crop study showed no residues of clothianidin greater than the LOQ of 0.01 ppm in turnip roots at any of the plantback intervals (1, 4, 8 or 12 months) at any of the test sites (See attached Table 6 from the EPA Summary of Analytical and Residue Data[1] in Attachment 1). Identified residues in turnip roots in the confined rotational crop study were also less than 0.01 ppm. Residues greater than 0.01 ppm were seen in the turnip tops in the limited field rotational crop study. However, since potato tops are not a livestock feed item residues in the turnip tops would not be relevant.

Bayer CropScience would therefore request a 30 day plantback interval for potatoes planted after corn or canola having a clothianidin seed treatment.

Plantback Interval for Sugarcane after Corn

Potential clothianidin residues in sugarcane rotated after corn receiving a seed treatment of clothianidin can be estimated by evaluating the difference in biomass between sugarcane and the wheat matrices from the rotational crop study. The limited field rotational crop study for clothianidin showed maximum clothianidin residues in wheat commodities at any rotational interval as follows (See Attachment 1):

Wheat forage:	0.019 ppm
Wheat hay:	0.0246 ppm
Wheat straw:	<0.01 ppm

Sugarcane rotated after the harvest of corn treated with clothianidin would have significantly greater biomass than the wheat grown in the limited field rotational crop

study. According to The Florida Sugar Cane League, Inc. the average yield of sugarcane from 1979 to 1999 was approximately 36 tons per acre with a low yield of approximately 30 tons per acre and a high yield of approximately 43 tons per acre. See attached spread sheet (Attachment 2) and website at:

http://www.canalpoint.sugarcane.usda.gov/florida_sugar_industry_productio.htm).

By comparison, available data for wheat straw production suggest that wheat produces approximately one to two tons of wheat straw per acre (See Attachment 3). [Attempts were made to locate data for production of wheat forage, hay and straw but data was found only for wheat straw. Specifically, the wheat straw data from the State of Washington:

(http://www.fiberfutures.org/pages/WAwheat.html)

indicates that wheat straw production is approximately two tons per acre. In a document on the use of wheat straw:

(www.ontariocorn.org/ocprmag/magh801pg6.htm)

the author indicates that "a quick rule of thumb for a wheat crop is that the straw will yield one 40 lb straw bale for each bushel of grain." According to the Kansas Wheat Commission:

(http://www.kswheat.com/general.asp?id=1)

the "annual average wheat production in Kansas for the past five years has been about 374 million bushels harvested from an average 9 million acres." This would yield approximately 42 bushels of wheat grain per acre. Assuming 40 lbs of straw per bushel of wheat grain (from above) would result in approximately 1662 lbs of wheat straw per acre or approximately 0.8 tons of straw per acre. Therefore, the available data would suggest approximately one to two tons of wheat straw per acre.]

Assuming an average sugarcane yield of 36 tons per acre and an average wheat straw yield of two tons per acre the ratio would be 18:1.

Calculation of potential clothianidin residues in rotational sugarcane based on the available wheat straw residue data from the limited field rotational crop study and the 18:1 ratio calculated above results in residues of approximately 0.001 ppm or less based on all of the wheat matrices at all plantback intervals (See Attachment 4). Therefore, no measurable residues of clothianidin would be anticipated in sugarcane rotated after corn (field or sweet) treated with clothianidin even with a plantback interval of 30 days.

Therefore, Bayer CropScience requests an eight month plantback interval for sugarcane after corn (field or sweet).

IV. Conclusions

The available data support a 30 day plantback interval for potatoes after corn or canola treated with clothianidin and an eight month plantback interval for sugarcane planted after corn treated with clothianidin. Therefore, Bayer CropScience requests these changes to the Poncho™ label.

V. References

1. Donovan, Y., Loranger, R. A., PP# 1F06315. TI-435 (Clothianidin) on Corn and Canola. Summary of Analytical Chemistry and Residue Data. D282446. PC Code: 044309, May 1, 2003.

Attachment 1: Table 6 from the EPA Summary of Analytical and Residue Data[1]

TABLE 6. Summary of Residue Data in Rotational Crops Following Primary Crop Treatment with TI-435.

Commodity	Applic. Rate, to the Primary Crop	PBI (days)	Analyte	Residue Levels (ppm)				
				Min.	Max.	HAFT	Mean	Std. Dev.
Mustard greens, leaves	2 mg a.i./seed 0.147-0.152 lb a.i./A (0.165-0.170 kg a.i./ha)	30-32	TI-435	<0.01	0.0108	<0.0104	<0.0102	0.0004
		122-131		<0.01	0.013	0.0121	<0.0107	0.0012
		243-247		<0.01	0.0232	0.0189	<0.0138	0.0049
		360-366		<0.01	<0.01	<0.01	<0.01	0
		30-32	TZNG	<0.01	<0.01	<0.01	<0.01	0
Turnip tops	2 mg a.i./seed 0.147-0.171 lb a.i./A (0.165-0.192 kg a.i./ha)	30-40	TI-435	<0.01	0.0144	0.0123	<0.0108	0.0018
		122-131		<0.01	0.0116	<0.0108	<0.0103	0.0007
		243-247		<0.01	0.0215	<0.0158	<0.0119	0.0047
		360-366		<0.01	<0.01	<0.01	<0.01	0
		30-40	TZNG	<0.01	<0.01	<0.01	<0.01	0
Turnip roots	2 mg a.i./seed 0.147-0.171 lb a.i./A (0.165-0.192 kg a.i./ha)	30-40	TI-435	<0.01	<0.01	<0.01	<0.01	0
		122-131		<0.01	<0.01	<0.01	<0.01	0
		243-247		<0.01	<0.01	<0.01	<0.01	0
		360-366		<0.01	<0.01	<0.01	<0.01	0
		30-40	TZNG	<0.01	<0.01	<0.01	<0.01	0

TABLE 6. Summary of Residue Data in Rotational Crops Following Primary Crop Treatment with TI-435.

Commodity	Applic. Rate, to the Primary Crop	PBI (days)	Analyte	Residue Levels (ppm)				
				Min	Max.	HAFT	Mean	Std. Dev.
Wheat forage	2 mg a.i./seed 0.144-0.163 lb a.i./A (0.162-0.182 kg a.i./ha)	27-30	TI-435	<0.01	0.0145	0.0125	<0.0114	0.0021
		121-125		<0.01	0.0121	0.0115	<0.0106	0.0009
		242-247		<0.01	0.019	0.0162	<0.0121	0.0036
		357-364		<0.01	<0.01	<0.01	<0.01	0
		27-30	TZNG	<0.01	<0.01	<0.01	<0.01	0
Wheat hay	2 mg a.i./seed 0.144-0.163 lb a.i./A (0.162-0.182 kg a.i./ha)	27-30	TI-435	<0.01	0.0246	0.0219	<0.0159	0.0072
		121-125		<0.01	0.0167	0.0167	<0.0122	0.0035
		242-247		<0.01	0.0196	0.0177	<0.0126	0.0042
		357-364		<0.01	<0.01	<0.01	<0.01	0
		27-30	TZNG	<0.01	<0.01	<0.01	<0.01	0
Wheat straw	2 mg a.i./seed 0.144-0.163 lb a.i./A (0.162-0.182 kg a.i./ha)	27-30	TI-435	<0.01	<0.01	<0.01	<0.01	0
		121-125		<0.01	<0.01	<0.01	<0.01	0
		242-247		<0.01	<0.01	<0.01	<0.01	0
		357-364		<0.01	<0.01	<0.01	<0.01	0
		27-30	TZNG	<0.01	<0.01	<0.01	<0.01	0
Wheat grain	2 mg a.i./seed 0.144-0.163 lb a.i./A (0.162-0.182 kg a.i./ha)	27-30	TI-435	<0.01	<0.01	<0.01	<0.01	0
		121-125		<0.01	<0.01	<0.01	<0.01	0
		242-247		<0.01	<0.01	<0.01	<0.01	0
		357-364		<0.01	<0.01	<0.01	<0.01	0
		27-30	TZNG	<0.01	<0.01	<0.01	<0.01	0

Attachment 2: Sugarcane Yields Per Acre

FLORIDA SUGAR INDUSTRY PRODUCTION
1979-1998
(Prepared by the Florida Sugar Cane League, Inc.)

Acreage			Sugarcane For Sugar				Sugar Produced				Yield	Molasses
Crop Year	Total Acres	Acres Harvested for Sugar	Cane Ground Gross Tons	Avg Cane Per Acre	Cane Ground Net Tons	Avg Cane per Acre	96° Basis Short Tons	Raw Value Basis Short Tons	Per Harvested Acre	Raw Value Made Per Net Ton of Cane	96° Sugar % Gross Cane Ground	Gallons 80° Brix
	-1000	-1000	-1000	(Gross Tons)	-1000	(Net Tons)	-1000	-1000	(Short Tons Raw Value)	(Pounds)	(Weighted Average)	-1000
1979-80	332.1	316.5	10,609	33.5	9,990	31.5	1,028	1,047	3.3	210	9.69	68,394
1980-81	339.1	320.7	10,623	33.1	10,137	31.6	1,103	1,121	3.5	216	10.38	66,718
1981-82	348.9	335.2	10,146	30.3	9,696	28.9	948	963	2.87	199	9.34	79,015
1982-83	355.3	341.4	12,840	37.6	12,158	35.6	1,284	1,307	3.83	215	10	81,028
1983-84	367.6	361	12,056	33.4	11,459	31.7	1,202	1,223	3.39	213	9.97	77,695
1984-85	387	371.8	12,864	34.6	12,252	33	1,367	1,412	3.8	231	10.76	85,409
1985-86	398.7	383.4	13,174	34.4	12,615	32.9	1,389	1,413	3.69	224	10.54	92,546
1986-87	405.1	380	13,713	35.2	12,918	33.1	1,450	1,476	3.78	228	10.57	92,299
1987-88	417.7	402.2	13,743	34.2	12,990	32.3	1,490	1,517	3.77	234	10.84	89,501
1988-89	421.1	404.1	13,583	33.6	12,756	31.6	1,538	1,566	3.88	246	11.32	91,670
1989-90	419.9	404.9	13,435	33.2	12,695	31.4	1,375	1,399	3.46	220	10.23	100,042
1990-91	433.4	418.6	15,888	38	14,876	35.5	1,774	1,805	4.31	243	11.17	104,131
1991-92	442.4	427.2	16,114	37.7	14,918	34.9	1,800	1,833	4.29	246	11.17	101,441
1992-93	442.6	425.8	15,351	36.1	14,132	33.2	1,679	1,710	4.02	242	10.94	93,686
1993-94	443.9	425.2	15,818	37.2	14,512	34.1	1,739	1,770	4.16	244	10.99	99,632
1994-95	443.0	422.5	15,987	36.9	14,216	33.7	1,695	1,726	4.08	243	10.87	93,658
1995-96	438.7	417.2	15,703	37.6	14,445	34.6	1,738	1,771	4.25	245	11.07	94,682
1996-97	436.4	417	14,905	35.7	13,790	33.1	1,646	1,679	4.03	244	11.04	89,937
1997-98	440.3	421.1	16,942	40.2	15,526	36.9	1,885	1,923	4.57	248	11.13	101,377
1998-99	447.1	426.4	18,418	43.2	17,092	40.1	2,084	2,127	4.99	249	11.32	109,573

http://www.canalpoint.sugarcane.usda.gov/florida_sugar_industry_productio.htm

Avg Yield (1979-1998): 35.8

Avg Yield (1990-1998): 38.1

Attachment 3: Wheat Straw Production for the State of Washington

County	Harvested Acres*	Crop Production in tons per year (tpy)*	Straw Yields (tons/A)
Whitman	534,300	1,291,067	2.42
Lincoln	404,900	768,225	1.90
Walla Walla	235,600	608,273	2.58
Adams	317,700	545,833	1.72
Grant	246,900	518,615	2.10
Douglas	237,500	284,353	1.20
Columbia	109,900	284,263	2.59
Spokane	127,500	258,663	2.03
Franklin	121,000	248,621	2.05
Benton	147,400	207,824	1.41
Garfield	94,700	199,131	2.10
Yakima	43,900	71,523	1.63
Klickitat	57,800	65,558	1.13
Asotin	26,500	48,112	1.82
Stevens	13,400	26,109	1.95
Other Counties	26,000	49,550	1.91
STATE***	2,745,000	5,475,720	1.99

http://www.fiberfutures.org/pages/WAwheat.html

Average Wheat Straw Yields: 1.91

Attachment 4: Potential Clothianidin Residues in Sugarcane

Limited Field Rotational Crop Data

	Maximum Residues (ppm)		Projected Sugarcane Residues (ppm)[1]	
Wheat forage				
one month pbi	0.0145		0.0008	0.001
four month pbi	0.0121		0.0007	0.001
eight month pbi	0.019		0.0011	0.001
one year pbi	0.01	←Actually less than 0.01	0.0006	0.001
Wheat hay				
one month pbi	0.0246		0.0014	0.001
four month pbi	0.0167		0.0009	0.001
eight month pbi	0.0196		0.0011	0.001
one year pbi	0.01	←Actually less than 0.01	0.0006	0.001
Wheat straw				
one month pbi	0.01	←Actually less than 0.01	0.0006	0.001
four month pbi	0.01	←Actually less than 0.01	0.0006	0.001
eight month pbi	0.01	←Actually less than 0.01	0.0006	0.001
one year pbi	0.01	←Actually less than 0.01	0.0006	0.001

[1]Based on an 18:1 biomass ratio between sugarcane and wheat straw.

Conclusion: No measurable residues were seen in the wheat straw. Maximum residues in the wheat hay were 0.0246 ppm at a one month pbi and in wheat forage were 0.019 ppm at an eight month ppb. All projected sugarcane residues are approximately 0.001 ppm or less even assuming maximum residues in any of the wheat matrices.

[1]Based on an 18:1 biomass ratio between sugarcane and wheat straw. Data presented with four decimal places as well as three.

E-Mail Communication between Bayer CropScience (R. W. Heintzelman) and EPA/HED (Rick Loranger) (Included with the Permission of Rick Loranger)

E-Mail Communication concerning the plantback interval for sugarcane after corn.

November 15, 2004

Dick,

I have finally gotten to responding to your message. My conclusion is that your proposal is reasonable and confirms my initial thoughts on the much higher biomass of sugarcane. I suggest you submit the request for the shorter plantback interval along with your rationale.

Rick Loranger
HED/OPP/EPA
Phone: 703-305-6912
FAX: 703-305-5147
E-mail: loranger.richard@epa.gov

Visit http://www.epa.gov/pesticides/

Dick
Heintzelman/MOVIM/US/BCS/BAYE
R

To
Loranger.Richard@epamail.epa.gov
cc

08/02/2004 02:15 PM

Subject
Re: Clothianidin Plantback Interval from Corn to Sugarcane Link

Rick,

Recently I sent you a request for a reduction in the plantback interval for sugarcane rotated after sweet corn treated with clothianidin. As you correctly pointed out I made a mistake in my calculation of the potential residues in sugarcane if it were assumed that all of the clothianidin was taken up by the sugarcane.

You suggested I evaluate the potential residues in sugarcane taking into account the differences in biomass yield of wheat matrices and sugarcane. Specifically, you suggested:

> I suggest you go back and look at the results of the available

rotational crop data for whichever small grain you studied (probably wheat). Taking into account the residues seen in the various wheat matrices at different PBI's and the relative yields to sugarcane, you could project a theoretical residue in the cane. For example, consider the residues in wheat straw at various PBI's and adjust them for the higher mass of sugarcane per acre. I can't guarantee this will eliminate the need for field trials, but I believe there is a good chance it will do so.

We have searched for data on wheat straw, hay and forage yields per acre for comparison with the sugarcane yields. We have located data on wheat straw but no literature on wheat hay or forage. The wheat straw data from the State of Washington

http://www.fiberfutures.org/pages/WAwheat.html

indicates that wheat straw production is approximately two tons per acre. In a document on the use of wheat straw

http://www.ontariocorn.org/ocpmag/magh801pg6.htm

the author indicates that "a quick rule of thumb for a wheat crop is that the straw will yield one 40 lb straw bale for each bushel of grain."

According to the Kansas Wheat Commission

http://www.kswheat.com/general.asp?id=1

the "annual average wheat production in Kansas for the past five years has been about 374 million bushels harvested from an average 9 million acres." This would yield approximately 42 bushels of wheat grain per acre. Assuming 40 lbs of straw per bushel of wheat (from above) would result in approximately 1662 lbs of wheat straw per acre or approximately 0.8 tons of straw per acre. Therefore, the available data would suggest approximately one to two tons of wheat straw per acre.

According to The Florida Sugar Cane League, Inc. the average yield of sugarcane from 1979 to 1999 was approximately 36 tons per acre with a low yield of approximately 30 tons per acre and a high yield of approximately 43 tons per acre. (See attached spread sheet and website at
http://www.canalpoint.sugarcane.usda.gov/florida_sugar_industry_productio.htm).

Assuming an average sugarcane yield of 36 tons per acre and an average wheat straw yield of two tons per acre the ratio would be 18:1.

Calculation of potential clothianidin residues in rotational sugarcane based on the available wheat straw residue data from the limited field rotational crop study and the 18:1 ratio calculated above results in residues of 0.001 ppm or less based on all of the wheat matrices at all

plantback intervals. Therefore, no measurable residues of clothianidin would be anticipated in sugarcane rotated after corn (field or sweet) treated with clothianidin even with a plantback interval of 30 days. Therefore, Bayer CropScience requests an eight month plantback interval for sugarcane after corn (field or sweet). (Note that we are requesting an 8 month pbi since the available data in the limited rotational crop study was collected at 1, 4 and 8 months as well as one year. A ten month pbi would be acceptable to the sweet corn growers and Bayer CropScience.

Please let me know if you have any questions or comments on this proposal. If it seems reasonable to you we will submit the required label amendment to the Agency.

Thank you very much for your assistance on this issue.

Regards,

Dick

Richard W. Heintzelman, Ph.D.
Product Safety Manager
Bayer CropScience
Phone: 919-549-2561
Fax: 919-549-2924
Mobile: 919-270-0935

(See attached file: Wheat Straw Production and projected sugarcane residues.xls)

E-Mail Communication concerning the plantback interval for potatoes after corn and canola.

November 15, 2004

Dick,

Provided the residues in turnip roots are less than 0.01 ppm (I did not go back to our reviews to confirm this), the proposed 30 day PBI for potatoes should be acceptable.

Rick
HED/OPP/EPA
Phone: 703-305-6912
FAX: 703-305-5147
E-mail: loranger.richard@epa.gov

Visit http://www.epa.gov/pesticides/

Dick Heintzelman
<dick.heintzelman@bayercropscience.com>

08/02/2004 04:57 PM

To
Richard Loranger/DC/USEPA/US@EPA

cc

Subject
Clothianidin Plantback Interval for Potatoes Rotated After Corn and Canola

Rick,

This is a follow-up to the e-mail that I just sent you on clothianidin plantback intervals. Bayer CropScience has received a request for a reduced pbi for planting potatoes after growing corn or canola which had a seed-treatment of clothianidin. We believe that the available data support a 30 day pbi for potatoes after corn or canola having a seed treatment of clothianidin. This conclusion is based on the following data.

The limited field rotational crop study showed no residues of clothianidin greater than the LOQ of 0.01 ppm in turnip roots at any of the plantback intervals (1, 4, 8 or 12 months) at any of the test sites (Georgia, Indiana, or Kansas). Identified residues in turnip roots in the confined rotational crop study were also less than 0.01 ppm. Residues of 0.01 ppm were seen in the turnip tops at two of the sites in the limited field rotational crop study. However, since potatoe tops are not a feed item residues in the turnip tops would not be relevant.

Bayer CropScience would therefore like to request a 30 day plantback interval for potatoes planted after corn or canola having a clothianidin seed treatment.

Please let me know if you have any questions on this request. If it appears acceptable to you we will submit the appropriate label amendment request to the Agency.

Again, thank you for your assistance on this issue.

Regards,

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Richard W. Heintzelman, Ph.D.
Product Safety Manager
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Mobile: 919-270-0935

Justification for Revised Plantback Intervals for Potatoes and Sugarcane Planted after Corn and Canola Receiving a Seed Treatment of Clothianidin (Poncho)

Richard W. Heintzelman, Ph.D.
Bayer CropScience
RTP, NC 27709

December 2, 2004

I. Introduction

Bayer CropScience (BCS) received a request from growers to reduce the plantback interval for potatoes grown after corn or canola which had received a seed-treatment of clothianidin. BCS also received a request for a reduction in the plantback interval for sugarcane grown after corn (especially sweet corn) receiving a seed-treatment of clothianidin. Bayer CropScience believes that shorter plantback intervals are justified based on the available data. The available data support a 30 day plantback interval for potatoes planted after corn or canola and an eight month plantback interval for sugarcane planted after corn. Details of the justification are given below.

II. Justification for the Requested Plantback Intervals

Plantback Interval for Potatoes after Corn or Canola

The limited field rotational crop study showed no residues of clothianidin greater than the LOQ of 0.01 ppm in turnip roots at any of the plantback intervals (1, 4, 8 or 12 months) at any of the test sites (See attached Table 6 from the EPA Summary of Analytical and Residue Data[1] in Attachment 1). Identified residues in turnip roots in the confined rotational crop study were also less than 0.01 ppm. Residues greater than 0.01 ppm were seen in the turnip tops in the limited field rotational crop study. However, since potato tops are not a livestock feed item residues in the turnip tops would not be relevant.

Bayer CropScience would therefore request a 30 day plantback interval for potatoes planted after corn or canola having a clothianidin seed treatment.

Plantback Interval for Sugarcane after Corn

Potential clothianidin residues in sugarcane rotated after corn receiving a seed treatment of clothianidin can be estimated by evaluating the difference in biomass between sugarcane and the wheat matrices from the rotational crop study. The limited field rotational crop study for clothianidin showed maximum clothianidin residues in wheat commodities at any rotational interval as follows (See Attachment 1):

Wheat forage:	0.019 ppm
Wheat hay:	0.0246 ppm
Wheat straw:	<0.01 ppm

Sugarcane rotated after the harvest of corn treated with clothianidin would have significantly greater biomass than the wheat grown in the limited field rotational crop

study. According to The Florida Sugar Cane League, Inc. the average yield of sugarcane from 1979 to 1999 was approximately 36 tons per acre with a low yield of approximately 30 tons per acre and a high yield of approximately 43 tons per acre. See attached spread sheet (Attachment 2) and website at:

http://www.canalpoint.sugarcane.usda.gov/florida_sugar_industry_productio.htm).

By comparison, available data for wheat straw production suggest that wheat produces approximately one to two tons of wheat straw per acre (See Attachment 3). [Attempts were made to locate data for production of wheat forage, hay and straw but data was found only for wheat straw. Specifically, the wheat straw data from the State of Washington:

(http://www.fiberfutures.org/pages/WAwheat.html)

indicates that wheat straw production is approximately two tons per acre. In a document on the use of wheat straw:

(www.ontariocorn.org/ocpmag/magh801pg6.htm)

the author indicates that "a quick rule of thumb for a wheat crop is that the straw will yield one 40 lb straw bale for each bushel of grain." According to the Kansas Wheat Commission:

(http://www.kswheat.com/general.asp?id=1)

the "annual average wheat production in Kansas for the past five years has been about 374 million bushels harvested from an average 9 million acres." This would yield approximately 42 bushels of wheat grain per acre. Assuming 40 lbs of straw per bushel of wheat grain (from above) would result in approximately 1662 lbs of wheat straw per acre or approximately 0.8 tons of straw per acre. Therefore, the available data would suggest approximately one to two tons of wheat straw per acre.]

Assuming an average sugarcane yield of 36 tons per acre and an average wheat straw yield of two tons per acre the ratio would be 18:1.

Calculation of potential clothianidin residues in rotational sugarcane based on the available wheat straw residue data from the limited field rotational crop study and the 18:1 ratio calculated above results in residues of approximately 0.001 ppm or less based on all of the wheat matrices at all plantback intervals (See Attachment 4). Therefore, no measurable residues of clothianidin would be anticipated in sugarcane rotated after corn (field or sweet) treated with clothianidin even with a plantback interval of 30 days.

Therefore, Bayer CropScience requests an eight month plantback interval for sugarcane after corn (field or sweet).

IV. Conclusions

The available data support a 30 day plantback interval for potatoes after corn or canola treated with clothianidin and an eight month plantback interval for sugarcane planted after corn treated with clothianidin. Therefore, Bayer CropScience requests these changes to the Poncho™ label.

V. References

1. Donovan, Y., Loranger, R. A., PP# 1F06315. TI-435 (Clothianidin) on Corn and Canola. Summary of Analytical Chemistry and Residue Data. D282446. PC Code: 044309, May 1, 2003.

Attachment 1: Table 6 from the EPA Summary of Analytical and Residue Data[1]

TABLE 6. Summary of Residue Data in Rotational Crops Following Primary Crop Treatment with TI-435.

Commodity	Applic. Rate, to the Primary Crop	PBI (days)	Analyte	Residue Levels (ppm)				
				Min.	Max.	HAFT	Mean	Std. Dev.
Mustard greens, leaves	2 mg a.i./seed 0.147-0.152 lb a.i./A (0.165-0.170 kg a.i./ha)	30-32	TI-435	<0.01	0.0108	<0.0104	<0.0102	0.0004
		122-131		<0.01	0.013	0.0121	<0.0107	0.0012
		243-247		<0.01	0.0232	0.0189	<0.0138	0.0049
		360-366		<0.01	<0.01	<0.01	<0.01	0
		30-32	TZNG	<0.01	<0.01	<0.01	<0.01	0
Turnip tops	2 mg a.i./seed 0.147-0.171 lb a.i./A (0.165-0.192 kg a.i./ha)	30-40	TI-435	<0.01	0.0144	0.0123	<0.0108	0.0016
		122-131		<0.01	0.0116	<0.0108	<0.0103	0.0007
		243-247		<0.01	0.0215	<0.0158	<0.0119	0.0047
		360-366		<0.01	<0.01	<0.01	<0.01	0
		30-40	TZNG	<0.01	<0.01	<0.01	<0.01	0
Turnip roots	2 mg a.i./seed 0.147-0.171 lb a.i./A (0.165-0.192 kg a.i./ha)	30-40	TI-435	<0.01	<0.01	<0.01	<0.01	0
		122-131		<0.01	<0.01	<0.01	<0.01	0
		243-247		<0.01	<0.01	<0.01	<0.01	0
		360-366		<0.01	<0.01	<0.01	<0.01	0
		30-40	TZNG	<0.01	<0.01	<0.01	<0.01	0

TABLE 6. Summary of Residue Data in Rotational Crops Following Primary Crop Treatment with TI-435.

Commodity	Applic. Rate, to the Primary Crop	PBI (days)	Analyte	Residue Levels (ppm)				
				Min.	Max.	HAFT	Mean	Std. Dev.
Wheat forage	2 mg a.i./seed 0.144-0.163 lb a.i./A (0.162-0.182 kg a.i./ha)	27-30	TI-435	<0.01	0.0145	0.0125	<0.0114	0.0021
		121-125		<0.01	0.0121	0.0116	<0.0106	0.0009
		242-247		<0.01	0.019	0.0162	<0.0121	0.0036
		357-364		<0.01	<0.01	<0.01	<0.01	0
		27-30	TZNG	<0.01	<0.01	<0.01	<0.01	0
Wheat hay	2 mg a.i./seed 0.144-0.163 lb a.i./A (0.162-0.182 kg a.i./ha)	27-30	TI-435	<0.01	0.0246	0.0219	<0.0159	0.0072
		121-125		<0.01	0.0157	0.0167	<0.0122	0.0035
		242-247		<0.01	0.0156	0.0177	<0.0126	0.0042
		357-364		<0.01	<0.01	<0.01	<0.01	0
		27-30	TZNG	<0.01	<0.01	<0.01	<0.01	0
Wheat straw	2 mg a.i./seed 0.144-0.163 lb a.i./A (0.162-0.182 kg a.i./ha)	27-30	TI-435	<0.01	<0.01	<0.01	<0.01	0
		121-125		<0.01	<0.01	<0.01	<0.01	0
		242-247		<0.01	<0.01	<0.01	<0.01	0
		357-364		<0.01	<0.01	<0.01	<0.01	0
		27-30	TZNG	<0.01	<0.01	<0.01	<0.01	0
Wheat grain	2 mg a.i./seed 0.144-0.163 lb a.i./A (0.162-0.182 kg a.i./ha)	27-30	TI-435	<0.01	<0.01	<0.01	<0.01	0
		121-125		<0.01	<0.01	<0.01	<0.01	0
		242-247		<0.01	<0.01	<0.01	<0.01	0
		357-364		<0.01	<0.01	<0.01	<0.01	0
		27-30	TZNG	<0.01	<0.01	<0.01	<0.01	0

Attachment 2: Sugarcane Yields Per Acre

FLORIDA SUGAR INDUSTRY PRODUCTION
1979-1998
(Prepared by the Florida Sugar Cane League, Inc.)

Acreage			Sugarcane For Sugar				Sugar Produced				Yield	Molasses
Crop Year	Total Acres	Acres Harvested for Sugar	Cane Ground Gross Tons	Avg Cane Per Acre	Cane Ground Net Tons	Avg Cane per Acre	96° Basis Short Tons	Raw Value Basis Short Tons	Per Harvested Acre	Raw Value Made Per Net Ton of Cane	96° Sugar % Gross Cane Ground	Gallons 80° Brix
	-1000	-1000	-1000	(Gross Tons)	-1000	(Net Tons)	-1000	-1000	(Short Tons Raw Value)	(Pounds)	(Weighted Average)	-1000
1979-80	332.1	316.0	10,608	33.6	9,980	31.5	1,028	1,047	3.3	210	9.69	68,394
1980-81	339.1	320.7	10,623	33.1	10,137	31.6	1,103	1,121	3.5	218	10.38	68,718
1981-82	348.9	335.2	10,146	30.3	9,696	28.9	948	963	2.87	199	9.34	79,015
1982-83	355.3	341.4	12,840	37.6	12,156	35.6	1,284	1,307	3.83	215	10	81,028
1983-84	357.8	361	12,058	33.4	11,459	31.7	1,202	1,223	3.39	213	9.97	77,695
1984-85	387	371.8	12,864	34.6	12,252	33	1,387	1,412	3.8	231	10.78	85,409
1985-86	390.7	383.4	13,174	34.4	12,615	32.9	1,389	1,413	3.69	224	10.54	92,546
1986-87	405.1	390	13,713	35.2	12,918	33.1	1,450	1,476	3.78	228	10.57	92,299
1987-88	417.7	402.2	13,743	34.2	12,990	32.3	1,490	1,517	3.77	234	10.84	89,501
1988-89	421.1	404.1	13,583	33.6	12,756	31.6	1,538	1,566	3.88	246	11.32	91,670
1989-90	419.9	404.9	13,435	33.2	12,695	31.4	1,376	1,399	3.48	220	10.23	100,042
1990-91	433.4	418.6	15,888	38	14,876	35.5	1,774	1,806	4.31	243	11.17	104,131
1991-92	442.4	427.2	16,114	37.7	14,919	34.9	1,800	1,833	4.29	246	11.17	101,441
1992-93	442.8	425.8	15,351	36.1	14,132	33.2	1,679	1,710	4.02	242	10.94	93,686
1993-94	443.9	425.2	15,818	37.2	14,512	34.1	1,739	1,770	4.16	244	10.99	98,832
1994-95	443.9	422.5	15,587	36.9	14,216	33.7	1,695	1,725	4.08	243	10.87	93,658
1995-96	436.7	417.2	15,783	37.6	14,445	34.6	1,738	1,771	4.25	245	11.07	84,882
1996-97	438.4	417	14,905	35.7	13,790	33.1	1,646	1,679	4.03	244	11.04	89,937
1997-98	440.3	421.1	16,942	40.2	15,526	36.9	1,885	1,923	4.57	248	11.13	101,377
1998-99	447.1	426.4	18,418	43.2	17,092	40.1	2,084	2,127	4.99	249	11.32	109,573

http://www.canalpoint.sugarcane.usda.gov/florida_sugar_industry_productio.htm

Avg Yield (1979-1998): 35.8

Avg Yield (1996-1998): 38.1

Attachment 3: Wheat Straw Production for the State of Washington

County	Harvested Acres*	Crop Production in tons per year (tpy)*	Straw Yields (tons/A)
Whitman	534,300	1,291,067	2.42
Lincoln	404,900	768,225	1.90
Walla Walla	235,600	608,273	2.58
Adams	317,700	545,833	1.72
Grant	246,900	518,615	2.10
Douglas	237,500	284,353	1.20
Columbia	109,900	284,263	2.59
Spokane	127,500	258,663	2.03
Franklin	121,000	248,621	2.05
Benton	147,400	207,824	1.41
Garfield	94,700	199,131	2.10
Yakima	43,900	71,523	1.63
Klickitat	57,800	65,558	1.13
Asotin	26,500	48,112	1.82
Stevens	13,400	26,109	1.95
Other Counties	26,000	49,550	1.91
STATE***	2,745,000	5,475,720	1.99

http://www.tiberfutures.org/pages/WAwheat.html

Average Wheat Straw Yields: **1.91**

Attachment 4: Potential Clothianidin Residues in Sugarcane

Limited Field Rotational Crop Data

	Maximum Residues (ppm)		Projected Sugarcane Residues (ppm)[1]	
Wheat forage				
one month pbi	0.0145		0.0008	0.001
four month pbi	0.0121		0.0007	0.001
eight month pbi	0.019		0.0011	0.001
one year pbi	0.01	←Actually less than 0.01	0.0006	0.001
Wheat hay				
one month pbi	0.0246		0.0014	0.001
four month pbi	0.0167		0.0009	0.001
eight month pbi	0.0196		0.0011	0.001
one year pbi	0.01	←Actually less than 0.01	0.0006	0.001
Wheat straw				
one month pbi	0.01	←Actually less than 0.01	0.0006	0.001
four month pbi	0.01	←Actually less than 0.01	0.0006	0.001
eight month pbi	0.01	←Actually less than 0.01	0.0006	0.001
one year pbi	0.01	←Actually less than 0.01	0.0006	0.001

[1]Based on an 18:1 biomass ratio between sugarcane and wheat straw.

Conclusion: No measurable residues were seen in the wheat straw. Maximum residues in the wheat hay were 0.0246 ppm at a one month pbi and in wheat forage were 0.019 ppm at an eight month ppb. All projected sugarcane residues are approximately 0.001 ppm or less even assuming maximum residues in any of the wheat matrices.

[1]Based on an 18:1 biomass ratio between sugarcane and wheat straw. Data presented with four decimal places as well as three.

E-Mail Communication between Bayer CropScience (R. W. Heintzelman) and EPA/HED (Rick Loranger)
(Included with the Permission of Rick Loranger)

E-Mail Communication concerning the plantback interval for sugarcane after corn.

November 15, 2004

Dick,

I have finally gotten to responding to your message. My conclusion is that your proposal is reasonable and confirms my initial thoughts on the much higher biomass of sugarcane. I suggest you submit the request for the shorter plantback interval along with your rationale.

Rick Loranger
HED/OPP/EPA
Phone: 703-305-6912
FAX: 703-305-5147
E-mail: loranger.richard@epa.gov

Visit http://www.epa.gov/pesticides/

Dick
Heintzelman/MOVIM/US/BCS/BAYE
R

08/02/2004 02:15 PM

To
Loranger.Richard@epamail.epa.gov
cc

Subject
Re: Clothianidin Plantback Interval from Corn to Sugarcane
Link

Rick,

Recently I sent you a request for a reduction in the plantback interval for sugarcane rotated after sweet corn treated with clothianidin. As you correctly pointed out I made a mistake in my calculation of the potential residues in sugarcane if it were assumed that all of the clothianidin was taken up by the sugarcane.

You suggested I evaluate the potential residues in sugarcane taking into account the differences in biomass yield of wheat matrices and sugarcane. Specifically, you suggested:

> I suggest you go back and look at the results of the available

rotational crop data for whichever small grain you studied (probably wheat). Taking into account the residues seen in the various wheat matrices at different PBI's and the relative yields to sugarcane, you could project a theoretical residue in the cane. For example, consider the residues in wheat straw at various PBI's and adjust them for the higher mass of sugarcane per acre. I can't guarantee this will eliminate the need for field trials, but I believe there is a good chance it will do so.

We have searched for data on wheat straw, hay and forage yields per acre for comparison with the sugarcane yields. We have located data on wheat straw but no literature on wheat hay or forage. The wheat straw data from the State of Washington

http://www.fiberfutures.org/pages/WAwheat.html

indicates that wheat straw production is approximately two tons per acre. In a document on the use of wheat straw

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Calculation of potential clothianidin residues in rotational sugarcane based on the available wheat straw residue data from the limited field rotational crop study and the 18:1 ratio calculated above results in residues of 0.001 ppm or less based on all of the wheat matrices at all

plantback intervals. Therefore, no measurable residues of clothianidin would be anticipated in sugarcane rotated after corn (field or sweet) treated with clothianidin even with a plantback interval of 30 days. Therefore, Bayer CropScience requests an eight month plantback interval for sugarcane after corn (field or sweet). (Note that we are requesting an 8 month pbi since the available data in the limited rotational crop study was collected at 1, 4 and 8 months as well as one year. A ten month pbi would be acceptable to the sweet corn growers and Bayer CropScience.

Please let me know if you have any questions or comments on this proposal. If it seems reasonable to you we will submit the required label amendment to the Agency.

Thank you very much for your assistance on this issue.

Regards,

Dick

Richard W. Heintzelman, Ph.D.
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(See attached file: Wheat Straw Production and projected sugarcane residues.xls)

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Provided the residues in turnip roots are less than 0.01 ppm (I did not go back to our reviews to confirm this), the proposed 30 day PBI for potatoes should be acceptable.

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Visit http://www.epa.gov/pesticides/

Dick Heintzelman
<dick.heintzelman@bayercropscience.com>

08/02/2004 04:57 PM

To
Richard Loranger/DC/USEPA/US@EPA

cc

Subject
Clothianidin Plantback Interval for Potatoes Rotated After Corn and Canola

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Again, thank you for your assistance on this issue.

Regards,

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Richard W. Heintzelman, Ph.D.
Product Safety Manager
Bayer CropScience
Phone: 919-549-2561
Fax: 919-549-2924
Mobile: 919-270-0935

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 264-789
2. EPA Product Manager: L. Arrington
3. Proposed Classification: [x] None [ ] Restricted
4. Company/Product (Name): Poncho 600
PM#: Notifications
5. Name and Address of Applicant (Include ZIP Code)
Bayer CropScience
1400 Preston Road, Suite 400
Plano, Texas 75093
[ ] Check if this is a new address
6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

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

NOTIFICATION
JUN 16 2005

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

Submitting a notification to revise the warranty statement and add another EPA Establishment number.

"This notification is consistent with the provisions of PR Notice 86-5 and EPA regulations at 40 CFR 152.44, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 86-5 and 40 CFR 152.44, the product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Dennis McFadden

Section - III

1. Material This Product Will Be Packaged In:

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

3. Location of Net Contents Information: [ ] Label [ ] Container
4. Size(s) Retail Container
5. Location of Label Directions
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)
Dennis McFadden	Reg. Mgr. - Seed Treatment Products	972-985-8877

Certification

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

6. Date Application Received (Stamped)

2. Signature: Dennis McFadden
3. Title: Reg. Mgr. - Seed Treatment Products
4. Typed Name: Dennis McFadden
5. Date: 5/23/05

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

NOTIFICATION

JUN 16 2005

Poncho™ 600

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insect pests.
All seed treated with this product must be conspicuously coloured at the time of treatment.

ACTIVE INGREDIENT:
Clothianidin 48.0%
INERT INGREDIENTS: 52.0%
Contains 5 lbs. active ingredient per gallon. TOTAL 100.0%

E.P.A. Reg. No. 264-789 **E.P.A. Est. No. 7501-IA-01, 7501-ID-01, 264-MO-002**

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:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • 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.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577. Have the 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.

PRECAUTIONARY STATEMENTS

CAUTION
HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables, 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. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment 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. Contain any product spills or equipment leaks and dispose of wastes according to disposal instructions on this label. Do not contaminate water when disposing of equipment washwaters.

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 by commercial treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting. This product is to be used in commercial liquid or slurry treaters. Mix thoroughly before use or use entire container at one time.

All seed treated with this product must be conspicuously coloured at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by *40 CFR 153.155* must be strictly adhered to when using this product.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SEED QUALITY AND STORAGE OF TREATED SEED

Treatment of highly mechanically damaged seed, or seed of known low vigor or 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.

LABELLING OF TREATED SEED

Seed commercially treated with Poncho™ 600 must be labelled in compliance with the *Federal Seed Act*.

All bags containing treated seed must be labelled or tagged as follows:

- This seed has been treated with Poncho™ 600 seed protectant, which contains clothianidin.
- Do not use treated seed for feed, food or oil processing.
- Rapeseed greens and seed grown or harvested from Poncho™ 600-treated seed must not be used for feed or human consumption. *Rapeseed grown and harvested from Poncho™ 600-treated seed is only for industrial uses and can not be used for* edible oil or any other human/feed consumption.
- Store away from feeds and other foodstuffs.
- Wear long-sleeved shirt, long pants and waterproof gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be doublesown 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.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, and dried beans. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

GENERAL INFORMATION

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insects.

For use in commercially available equipment designed for seed treatment only. Not for use in hopper-box, slurry-box, or similar seed treatment applications used at planting. This product is to be used in liquid or slurry treaters. Mix thoroughly before use or use entire

container at one time. All tank mixes should be pre-tested to determine physical compatibility between formulations. Observe all cautions and limitations on labeling of all products used in mixtures.

For Early Season Protection Against Certain Insects:

Poncho™ 600 will aid in the protection of seeds and seedlings against injury by certain early season insects.

RECOMMENDED APPLICATIONS

CROP	INSECT PESTS	RATE PONCHO™ 600	
		mg a.i./Kernel	80,000 Unit of Seed
Corn (including field, sweet and pop)	Corn rootworm (including Northern, Western, Southern and Mexican) Southern corn billbug[1]	1.25	5.64 fl. oz. or 166.7 mL
	Chinch bug Corn flea beetle Corn leaf aphid Cutworm, black Grape colaspis Seedcorn maggot Southern corn leaf beetle Southern corn rootworm Southern green stinkbug Storage pests[2] (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) Sugarcane beetle White grub (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Thrips Wireworm	0.25	1.13 fl. oz or 33.3 mL
	Corn flea beetle (through first true seed leaf) Seedcorn maggot[3] Storage pests[2] (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) White grub[2] (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Wireworm[3]	0.125	0.57 fl. oz or 16.7 mL

[1] Follow-up foliar sprays of a locally registered insecticide may be needed under heavy pest pressure. Consult your local Extension office for recommendations.

[2] It is recommended that seed with existing populations of storage pests be fumigated prior to treating and bagging seed.

[3] For seed protection only.

CROP	INSECT PESTS	RATE PONCHO™ 600	REMARKS
Canola Rapeseed	Flea beetle Wireworm	3.84 fl. oz per 100 lbs. seed or 250 mL per 100 kg seed	Use this rate under low to moderate flea beetle pressure.
		5.12 fl. oz per 100 lbs. seed or 333 mL per 100 kg seed	Use this rate under moderate flea beetle pressure.
		10.23 fl. oz per 100 lbs. seed or 666 mL per 100 kg seed	Use this rate under high to extreme flea beetle pressure where extended control is required.

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.

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

Treatment of highly mechanically damaged seed, 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 commitment to treat and/or to treat seed with normal treatment. Due to seed quality conditions beyond the control of Bayer CropScience, no claims are made to bird/rodent repellation or carry-over seed.

CONDITIONS: The directions for use of this product are believed to be adequate and should 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: 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. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: 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: 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™ 600 (MASTER) EPA Approved 10/20/03, Notification 2/5/04, Notification 05/12/05

Gustafson

May 23, 2005

Ms. Linda Arrington, Notifications
Office of Pesticide Programs
Document Processing Desk (NOTIF)
1801 S. Bell St.
Arlington, VA 22202

Subject: PONCHO 600, 264-789

Dear Ms. Arrington,

We are submitting a notification for the above named product to revise the warranty statement and add an additional EPA establishment number.

Please sign the note and send back in the envelope so that we can get acknowledgement that the notification is approved.

Sincerely,

Dennis McFadden

Dennis McFadden

Reg. Mgr. – Seed Treatment Products

Gustafson LLC • P.O. Box 660065 • Dallas, Texas 75266-0065 • Phone: (972) 985-8877 • FAX: (972) 985-1696 • www.gustafson.com

66330.65

Material to be added to an e-Jacket

Reg. No. 264-789

1. Placement within the e-Jacket:

   Default: chronological top
   Other: (PDF page number, i.e., "before page 45")

2. Is this material:

   Newly stamped accepted label
   Notification
   New CSF
   Final Printed Label
   Other: _____

   Issue to - 66330.65 Sent to [illegible]

3. Attach this notice on top of the material. It must be clipped all together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Stephanie Nguyen

Phone: 703-605-0702 Division: OPP/IRB

Date: 4/26/06

164-789

Bayer

Agriculture Division

Bayer Corporation
8400 Hawthorn Road
P.O. Box 4913
Kansas City, MO 64120-0013
Phone: 816 242-2000

April 2, 1996

Dr. Tina Levine
Office of Pesticide Programs (7505C)
U.S. EPA
401 M St., SW
Washington, DC 20460

Subject: New Bayer Insecticide, TI-435;
Assignment of a Product Manager and Request for Meeting

Dear Dr. Levine:

Bayer Corporation and Takeda Chemicals Ltd. are jointly developing a new chloronicotinyl insecticide identified as TI-435.

The subchronic studies with rats and mice have been completed and we are in the process of planning the start of oncogenicity studies during April. Prior to initiation of further studies, we would like to meet with EPA to discuss dose selection for long-term studies and proposed mechanistic studies to address interference in hormonal regulation.

The proposed agenda is attached along with the appropriate background material on this active ingredient.

We propose that five toxicologists from Takeda, Bayer AG and Bayer Corporation in addition to myself will participate in this meeting along with the appropriate Toxicology and regulatory representatives from EPA.

Our preference for a meeting time would be April 30, or as a second choice, April 29, 1997.

Please contact me at (816) 242-2255 or Mr. Jim Kunstman (816) 242-2838 to finalize arrangements for this meeting.

Yours very truly,

BAYER CORPORATION
AGRICULTURE DIVISION

John S. Thornton

John S. Thornton
Director, Product Registrations
and Regulatory Affairs

JST2034

cc: G. K. Sangha
Reg. Book

Bayer

Agriculture Division

Bayer Corporation
8400 Hawthorn Road
P.O. Box 4913
Kansas City, MO 64120-0013
Phone: 816 242-2000

March 30, 1998

Dr. Elizabeth Haeberer
Office of Pesticide Programs (7505C)
U.S. ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, DC 20460

SUBJECT: **TI 435, A new insecticide candidate being developed by BAYER Corporation and Takeda Chemical Industries, Request for meeting to discuss Environmental Fate Issues**

Dear Ms. Haeberer:

As discussed briefly on the phone, BAYER would like to come in along with representatives of Takeda to discuss registration issues relative to environmental fate studies and proposals for new studies for our new insecticide candidate, TI 435.

I have attached a one page data sheet to provide some brief background information on this new chemical. A brief agenda for this meeting would be as follows:

1. Registration Strategy (proposed uses, formulations, application methods, etc.)
2. Summarize preliminary results of ongoing and studies completed to date
3. Proposed Soil dissipation study:
   a. locations
   b. crops
   c. soils
   d. climates
   e. seed treatment vs. soil applied
4. Proposed soil analytical residue method

If possible, please arrange a meeting on one of the following days: April 14 - 16 or April 28 - 30. If you need further information or have any additional questions on this matter - please feel free to contact me at (816) 242-2838.

BAYER CORPORATION
AGRICULTURE DIVISION

James Lee Kunstman
Manager, Registrations

attachment

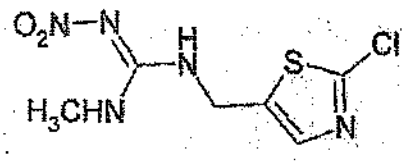
Data Sheet – TI 435

Common Name : chlothianidine (ISO proposed)

Chemical Name : (E)-1-(2-chlorothiazol-5-ylmeyhyl)-3-methyl-2-nitroguanidine

Emperical Formula : $C_6H_8ClN_5O_2S$

Molecular Weight : 249.68



Physical and Chemical Properties

Appearance : pale yellow powder

Odor : none

Melting Point : 176 – 178 °C

Vapor Pressure : 5.7×10^{-8} Pa (20 °C)

Solubility : in water; 0.27 g/l (20 °C)
in organic solvents; g/l (20 °C)
ethanol – 2.62
xylene – 0.012
ethyl acetate – 1.77
hexane – 9.6×10^{-7}

Partition Coefficient : Log $P_{o/w}$ = 1.05 (24 °C)

Dissociation Constant : pKa 11.5

Stability : chemical stability ; stable at 25°C for 4 months (pH 4-9)
storage stability ; stable at 40°C for 3 months

Formulations : 600 FS (proposed for seed treatments), 200SC (proposed for spray applications)

Markets : TI 435 is being jointly developed by TAKEDA and BAYER in the US as a seed treatment to control soil insects in corn and canola, and as a foliar spray to control piercing/sucking insects in apples and pears.

Bayer CropScience

January 30, 2006

Dan Kenny, INS-ROD Br.
Office of Pesticide Programs
Document processing Desk (Final label)
Room 266A, Crystal Mall 2
1801 S. Bell St.
Arlington, VA 22202

Subject: PONCHO 600, 264-789

Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709
Phone: 919 549-2000

Dear Mr. Kenny,

Enclosed is the final printed label for Poncho 600 stamped on 1/26/06.

Sincerely,

Dennis McFadden

Dennis McFadden

Reg. Mgr.-Seed Treatment Products

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 264-789
2. EPA Product Manager: D. Kenny
3. Proposed Classification: [x] None [ ] Restricted
4. Company/Product (Name): PONCHO 600
PM#: INS-ROD Br.
5. Name and Address of Applicant (Include ZIP Code):
Bayer CropScience
2 T. W. Alexander Drive
Research Triangle Park, NC 27709
[ ] Check if this is a new address
6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[x] Final printed labels in response to Agency letter dated 1/26/06
[ ] "Me Too" Application.
[ ] Other - Explain below.

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

Final printed label.

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: [ ] Label [ ] Container
4. Size(s) Retail Container
5. Location of Label Directions: [ ]
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)
Dennis McFadden	Reg. Mgr.-Seed Treatment Products	919-549-2427

Certification

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

6. Date Application Received (Stamped)

2. Signature: Dennis McFadden
3. Title: reg. mgr.-Seed Treatment Products
4. Typed Name: Dennis McFadden
5. Date: 1/27/06

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated
JAN 2 6 2005

Bayer CropScience

Poncho™ 600

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed, and corn for the control of certain insect pests.
All seed treated with this product must be conspicuously coloured at the time of treatment.

ACTIVE INGREDIENT:
Clothianidin 48.0%
INERT INGREDIENTS: 52.0%
Contains 5 lbs. active ingredient per gallon. TOTAL 100.0%

E.P.A. Reg. No. 264-789 **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:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • 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.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577. Have the 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.

PRECAUTIONARY STATEMENTS

CAUTION

HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables, 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. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment 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. Contain any product spills or equipment leaks and dispose of wastes according to disposal instructions on this label. Do not contaminate water when disposing of equipment washwaters.

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 by commercial treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting. This product is to be used in commercial liquid or slurry treaters. Mix thoroughly before use or use entire container at one time.

All seed treated with this product must be conspicuously coloured at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by *40 CFR 153.155* must be strictly adhered to when using this product.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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LABELLING OF TREATED SEED

Seed commercially treated with Poncho™ 600 must be labelled in compliance with the *Federal Seed Act*.

All bags containing treated seed must be labelled or tagged as follows:

- This seed has been treated with Poncho™ 600 seed protectant, which contains clothianidin.
- Do not use treated seed for feed, food or oil processing
- Rapeseed greens and seed grown or harvested from Poncho™ 600-treated seed must not be used for feed or human consumption. Rapeseed grown and harvested from Poncho™ 600-treated seed is only for industrial uses and can not be used for edible oil or any other human/feed consumption
- Store away from feeds and other foodstuffs.
- Wear long-sleeved shirt, long pants and waterproof gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be doublesown 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.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.

ROTATIONAL CROP PLANT-BACK INTERVALS					
Crop Planted	Immediate Plant-back	30-Day Plant-back	4-Month Plant-back	8-Month Plant-back	12-Month Plant-back
Field corn, popcorn	Field corn, popcorn, sweet corn, rapeseed, canola	Cereal grains, grasses, non-grass animal feeds, soybeans, dry beans, root and tuber vegetables		Sugar cane	Any crops without an earlier plant-back interval
Sweet corn, canola, rapeseed	Field corn, popcorn, sweet corn, rapeseed, canola (sorghum when registered)	Cereal grains, grasses, non-grass animal feeds, soybeans, dried beans, root and tuber vegetables	Any crop without an earlier plant-back interval		

GENERAL INFORMATION

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insects.

For use in commercially available equipment designed for seed treatment only. Not for use in hopper-box, slurry-box, or similar seed treatment applications used at planting. This product is to be used in liquid or slurry treaters. Mix thoroughly before use or use entire container at one time. All tank mixes should be pre-tested to determine physical compatibility between formulations. Observe all cautions and limitations on labeling of all products used in mixtures.

For Early Season Protection Against Certain Insects:

Poncho™ 600 will aid in the protection of seeds and seedlings against injury by certain early season insects.

RECOMMENDED APPLICATIONS

CROP	INSECT PESTS	RATE PONCHO™ 600	
		mg a.i./Kernel	80,000 Unit of Seed
Field corn and popcorn	Corn rootworm (including Northern, Western, Southern and Mexican) Southern corn billbug[1]	1.25	5.64 fl. oz. or 166.7 mL
Corn (including field, sweet and pop)	Chinch bug Corn flea beetle Corn leaf aphid Cutworm, black Grape colaspis Seedcorn maggot Southern corn leaf beetle Southern corn rootworm Southern green stinkbug Storage pests[2] (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) Sugarcane beetle White grub (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Thrips Wireworm	0.25	1.13 fl. oz or 33.3 mL

[1] Follow-up foliar sprays of a locally registered insecticide may be needed under heavy pest pressure. Consult your local Extension office for recommendations.

[2] It is recommended that seed with existing populations of storage pests be fumigated prior to treating and bagging seed.

[3] For seed protection only.

CROP	INSECT PESTS	RATE PONCHO™ 800	REMARKS
Canola Rapeseed	Flea beetle Wireworm	3.84 fl. oz per 100 lbs. seed or 250 mL per 100 kg seed	Use this rate under low to moderate flea beetle pressure.
		5.12 fl. oz per 100 lbs. seed or 333 mL per 100 kg seed	Use this rate under moderate flea beetle pressure.
		10.23 fl. oz per 100 lbs. seed or 666 mL per 100 kg seed	Use this rate under high to extreme flea beetle pressure where extended control is required.

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 should 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: 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. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: 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: 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.bayercropscience.us.com

01/26/06

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JAN 26 2006
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 264-789

Poncho™ 600

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed, and corn for the control of certain insect pests.
All seed treated with this product must be conspicuously coloured at the time of treatment.

ACTIVE INGREDIENT:
Clothianidin 48.0%
INERT INGREDIENTS: 52.0%
Contains 5 lbs. active ingredient per gallon. TOTAL 100.0%

E.P.A. Reg. No. 264-789 **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:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • 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.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577. **Have the 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.

PRECAUTIONARY STATEMENTS

CAUTION
HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables, 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. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment 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. Contain any product spills or equipment leaks and dispose of wastes according to disposal instructions on this label. Do not contaminate water when disposing of equipment washwaters.

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 by commercial treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting. This product is to be used in commercial liquid or slurry treaters. Mix thoroughly before use or use entire container at one time.

All seed treated with this product must be conspicuously coloured at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by *40 CFR 153.155* must be strictly adhered to when using this product.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SEED QUALITY AND STORAGE OF TREATED SEED

Treatment of highly mechanically damaged seed, or seed of known low vigor or 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.

LABELLING OF TREATED SEED

Seed commercially treated with Poncho™ 600 must be labelled in compliance with the *Federal Seed Act*.

All bags containing treated seed must be labelled or tagged as follows:

- This seed has been treated with Poncho™ 600 seed protectant, which contains clothianidin.
- Do not use treated seed for feed, food or oil processing.
- Rapeseed greens and seed grown or harvested from Poncho™ 600-treated seed must not be used for feed or human consumption. Rapeseed grown and harvested from Poncho™ 600-treated seed is only for industrial uses and can not be used for edible oil or any other human/feed consumption.
- Store away from feeds and other foodstuffs.
- Wear long-sleeved shirt, long pants and waterproof gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be doublesown 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.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.

ROTATIONAL CROP PLANT-BACK INTERVALS					
Crop Planted	Immediate Plant-back	30-Day Plant-back	4-Month Plant-back	9-Month Plant-back	18-Month Plant-back
Field corn, popcorn	Field corn, popcorn, sweet corn, rapeseed, canola	Cereal grains, grasses, non-grass animal feeds, soybeans, dry beans, root and tuber vegetables		Sugar beets	Any crops without an earlier plant-back interval
Sweet corn, canola, rapeseed	Field corn, popcorn, sweet corn, rapeseed, canola (sorghum when registered)	Cereal grains, grasses, non-grass animal feeds, soybeans, dried beans, root and tuber vegetables	Any crop without an earlier plant-back interval		

GENERAL INFORMATION

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insects.

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For Early Season Protection Against Certain Insects:

Poncho™ 600 will aid in the protection of seeds and seedlings against injury by certain early season insects.

RECOMMENDED APPLICATIONS

CROP	INSECT PESTS	RATE PONCHO™ 600	
		mg a.i./Kernel	80,000 Unit of Seed
Field corn and popcorn	Corn rootworm (including Northern, Western, Southern and Mexican) Southern corn billbug[1]	1.25	5.64 fl. oz. or 166.7 mL
Corn (including field, sweet and pop)	Chinch bug Corn flea beetle Corn leaf aphid Cutworm, black Grape colaspis Imported Fire Ant Seedcorn maggot Southern corn leaf beetle Southern corn rootworm Southern green stinkbug Storage pests[2] (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) Sugarcane beetle White grub (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Thrips Wireworm	0.25	1.13 fl. oz or 33.3 mL
Corn (including field, sweet and pop)	Corn flea beetle (through first true seed leaf) Seedcorn maggot[3] Storage pests[2] (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) White grub[3] (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Wireworm[3]	0.125	0.57 fl. oz or 16.7 mL

[1] Follow-up foliar sprays of a locally registered insecticide may be needed under heavy pest pressure. Consult your local Extension office for recommendations.

[2] It is recommended that seed with existing populations of storage pests be fumigated prior to treating and bagging seed.

CROP	INSECT PESTS	RATE PONCHO™ 600	REMARKS
Canola Rapeseed	Flea beetle Wireworm	3.84 fl. oz per 100 lbs. seed or 250 mL per 100 kg seed	Use this rate under low to moderate flea beetle pressure.
		5.12 fl. oz per 100 lbs. seed or 333 mL per 100 kg seed	Use this rate under moderate flea beetle pressure.
		10.23 fl. oz per 100 lbs. seed or 666 mL per 100 kg seed	Use this rate under high to extreme flea beetle pressure where extended control is required.

IMPORTANT: READ BEFORE USE

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CONDITIONS: The directions for use of this product are believed to be adequate and should 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: 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. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: 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: 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™ 600 (PENDING) Submitted 01/06/06

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Dennis McFadden
Bayer CropScience LP
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

JAN 26 2006

Dear Mr. McFadden:

Subject: Labeling Amendment; Plant-Back Intervals
Poncho 600
EPA Registration No. 264-789
Submission Date: March 29, 2005

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable with the following provision:

1) The target insect "Imported Fire Ant" must be deleted from the label. To have the label amended to include the "Imported Fire Ant" supportive efficacy data must be submitted or cited.

A stamped copy is enclosed for your records. Please submit one (1) final printed copy for the referenced label, incorporating the above changes, before releasing the product for shipment. If you have any questions regarding this letter, please contact Kable Bo Davis at (703) 206-0415.

Sincerely,

Daniel C. Kenny
Product Manager (01)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

Gustafson

March 28, 2005

Mr. Dan Kenny, INS-ROD Br.
Office of pesticide Programs
Document Processing Desk (AMEND)
Room 266A, Crystal Mall 1
1801 S. Bell St.
Arlington, VA 22202

Subject: PONCHO 600, 264-789
Lower sweet corn application rate/reduce plant-back intervals

Dear Mr. Kenny,

We are submitting a label amendment to lower the application rate for sweet corn and to shorten plant-back intervals for various crops. A rotational study is not needed. Please see attached justification for shortening plant-back intervals.

We believe this action is R35, non-fast track, $10,000. Please send the invoice to my e-mail address, mcfadden@gustafson.com or FAX to my attention at 972-985-1696.

Sincerely,

Dennis McFadden

Dennis McFadden

Manager, Toxicology and Regulatory Affairs

Gustafson LLC • P.O. Box 660065 • Dallas, Texas 75266-0065 • Phone: (972) 985-8877 • FAX: (972) 985-1696 • www.gustafson.com

Justification for Revised Plant-back Intervals followed by Clothianidin-treated Seed

I. Introduction:

Application rate reduction for sweet corn

It has been identified that 0.25 mg. ai./seed is an optimal application rate for sweet corn. We are proposing to lower the highest application rate from 1.25 mg.ai./seed to 0.25 mg.ai./seed.

Plant-Back Interval (PBI) followed by:

- Sweet corn
  - A 4-month PBI is proposed reflecting the reduced application rate.
- Canola, rapeseed and sorghum
  - A 4-month PBI is proposed based on low chemical loading per acre.
- Corn, popcorn, sweet corn, canola, rapeseed, and sorghum
  - A 30-day PBI is proposed for root and vegetable based on turnip root residue profile.

II. Justification for the Requested Plant-Back Intervals

Fact

The highest residue levels from the limited field rotation crop study is 0.0246 ppm (30 days in wheat hay) based on the 2 mg. al./seed (equivalent rate up to 0.163 lb.ai./A).

(See Table 6 from EPA Summary of Analytical and Residue Data – Barcode D282446 reprint is listed on page 2 of 5)

- Sweet corn
  - Based on the reduced rate of 0.25 mg.ai/seed, the theoretical residues from table 6 can be divided by 8 (2 mg.ai/0.25 mg.ai). This puts all residues below LOQ of 0.01 ppm.
- Canola and rapeseed
  - The equivalent chemical loading /A based on the highest canola seeding rate (8 lb/A from EPA Exp SOP #15) and highest application rate (6.4 oz.ai/cwt) is 0.032 lb.ai/A. This is only a small fraction (1 / 5.34x) of 0.171 lb.ai/A. The theoretical residue followed by canola and rapeseed can be adjusted by 5.34x, this puts all residue below LOQ of 0.01 ppm.
- Sorghum
  - The equivalent chemical loading /A based on the highest canola seeding rate (10 lb/A from EPA Exp SOP #15) and highest application rate (4 oz.ai/cwt) is 0.025 lb.ai/A. This is only a small fraction (1/ 6.84x) of 0.171 lb.ai/A. The theoretical residue followed by sorghum can be adjusted by 6.84x. This puts all residues below LOQ of 0.01 ppm.
- Field corn, popcorn, sweet corn, canola, rapeseed and sorghum
  - Since the residue in turnip roots at any of the plant-back intervals at any of the test sites is below the LOQ of 0.01 ppm, this would justify the proposal of 30 days PBI for root and tuber vegetables.

(The proposed justifications have been consulted with Dr. Richard Loranger at HED. A copy of confirmation e-mail is included on page 3 of 5.)

TABLE 6. Summary of Residue Data in Rotational Crops Following Primary Crop Treatment with TI-435.								
Commodity	Applic. Rate, to the Primary Crop	PBI (days)	Analyte	Residue Levels (ppm)				
				Min.	Max.	HAFT	Mean	Std. Dev.
Mustard greens, leaves	2 mg a.i./seed 0.147-0.152 lb a.i./A (0.165-0.170 kg a.i./ha)	30-32	TI-435	<0.01	0.0108	<0.0104	<0.0102	0.0004
		122-131		<0.01	0.013	0.0121	<0.0107	0.0012
		243-247		<0.01	0.0232	0.0189	<0.0138	0.0049
		360-366		<0.01	<0.01	<0.01	<0.01	0
		30-32	TZNG	<0.01	<0.01	<0.01	<0.01	0
Turnip tops	2 mg a.i./seed 0.147-0.171 lb a.i./A (0.165-0.192 kg a.i./ha)	30-40	TI-435	<0.01	0.0144	0.0123	<0.0108	0.0018
		122-131		<0.01	0.0116	<0.0108	<0.0103	0.0007
		243-247		<0.01	0.0215	<0.0156	<0.0119	0.0047
		360-366		<0.01	<0.01	<0.01	<0.01	0
		30-40	TZNG	<0.01	<0.01	<0.01	<0.01	0
Turnip roots	2 mg a.i./seed 0.147-0.171 lb a.i./A (0.165-0.192 kg a.i./ha)	30-40	TI-435	<0.01	<0.01	<0.01	<0.01	0
		122-131		<0.01	<0.01	<0.01	<0.01	0
		243-247		<0.01	<0.01	<0.01	<0.01	0
		360-366		<0.01	<0.01	<0.01	<0.01	0
		30-40	TZNG	<0.01	<0.01	<0.01	<0.01	0

TABLE 6. Summary of Residue Data in Rotational Crops Following Primary Crop Treatment with TI-435.								
Commodity	Applic. Rate, to the Primary Crop	PBI (days)	Analyte	Residue Levels (ppm)				
				Min.	Max.	HAFT	Mean	Std. Dev.
Wheat forage	2 mg a.i./seed 0.144-0.163 lb a.i./A (0.162-0.182 kg a.i./ha)	27-30	TI-435	<0.01	0.0145	0.0125	<0.0114	0.0021
		121-125		<0.01	0.0121	0.0116	<0.0106	0.0009
		242-247		<0.01	0.019	0.0162	<0.0121	0.0036
		357-364		<0.01	<0.01	<0.01	<0.01	0
		27-30	TZNG	<0.01	<0.01	<0.01	<0.01	0
Wheat hay	2 mg a.i./seed 0.144-0.163 lb a.i./A (0.162-0.182 kg a.i./ha)	27-30	TI-435	<0.01	0.0246	0.0219	<0.0159	0.0072
		121-125		<0.01	0.0167	0.0167	<0.0122	0.0035
		242-247		<0.01	0.0196	0.0177	<0.0126	0.0042
		357-364		<0.01	<0.01	<0.01	<0.01	0
		27-30	TZNG	<0.01	<0.01	<0.01	<0.01	0
Wheat straw	2 mg a.i./seed 0.144-0.163 lb a.i./A (0.162-0.182 kg a.i./ha)	27-30	TI-435	<0.01	<0.01	<0.01	<0.01	0
		121-125		<0.01	<0.01	<0.01	<0.01	0
		242-247		<0.01	<0.01	<0.01	<0.01	0
		357-364		<0.01	<0.01	<0.01	<0.01	0
		27-30	TZNG	<0.01	<0.01	<0.01	<0.01	0
Wheat grain	2 mg a.i./seed 0.144-0.163 lb a.i./A (0.162-0.182 kg a.i./ha)	27-30	TI-435	<0.01	<0.01	<0.01	<0.01	0
		121-125		<0.01	<0.01	<0.01	<0.01	0
		242-247		<0.01	<0.01	<0.01	<0.01	0
		357-364		<0.01	<0.01	<0.01	<0.01	0
		27-30	TZNG	<0.01	<0.01	<0.01	<0.01	0

-----Original Message-----
From: Loranger.Richard@epamail.epa.gov
[mailto:Loranger.Richard@epamail.epa.gov]
Sent: Tuesday, March 22, 2005 6:10 PM
To: sshen@gustafson.com
Cc: Kenny.Dan@epamail.epa.gov
Subject: Re: FW: Confirmation -Clothianidin seed treatment

Sue,

Ironically, I was in the process of printing out your message when you called a short time ago. I agree with the basic concepts as summarized in your e-mail. That is, we would adjust the residues observed in the rotational crop studies for the 4x exaggeration rate. I start getting uncomfortable when you talk about the 8x adjustment in the latest message, but it is not needed in this case as the 4x puts residues below 0.01 ppm. Therefore, the proposed label distinctions in plantback intervals for field/pop corn versus sweet corn/canola/ rapeseed appear to be supported. Note that I did not go back to our actual reviews to confirm the rotational crop residues, although they do jive with my recollection of being roughly in the range of 0.01-0.02 ppm.

Rick Loranger

Sue Shen
<sshen@gustafson
.com>

03/22/2005 12:52
AM

Please respond
to
sshen@gustafson.
com

To
Richard Loranger/DC/USEPA/US@EPA
cc
Subject
FW: Confirmation -Clothianidin
seed treatment

Dr. Loranger :

For your information, we have decided to further reduce the maximal rate down to 0.25 mg/seed.

So the theoretical uptake from the rotational study (see below) can be divided by 8 (3 mg.ai /0.25 mg.ai) instead of 4 (2 mg.ai / 0.5 mg/seed).

The confirmation of being able to shortening the plant back interval for sweet corn, canola and rapeseed is appreciated.

The existing label calls for

"Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, and dried beans. Do not plant any other crop in the treated area for at least one year after treated seeds are planted. "

Suggested label :
" Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, root vegetable group and dried beans. Do not plant any other crop in the treated area for at least one year after treated field corn and popcorn seeds are planted. Do not plant any other crop in the treated area for at least four months after treated canola, rapeseed or sweet corn seeds are planted"

Thanks,

Sue Shen

Sue Shen
Director, Regulatory and Government Affairs
Gustafson LLC
1400 Preston Road, Suite 400
Plano, TX 75093
Tel: (972)985-5637
Fax: (972)985-5737
sshen@gustafson.com

-----Original Message-----
From: Sue Shen [mailto:sshen@gustafson.com]
Sent: Wednesday, March 14, 2006 6:58 PM
To: Richard Loranger (loranger.richard@epamail.epa.gov)
Subject: Confirmation of Rotational Plant Back Restriction -Clothianidin

Dear Dr. Loranger:

Thank so much for taking the time to discuss the above subject with me.

To confirm our phone conversation this afternoon, we understand that the plant back restriction followed by Clothianidin sweet corn can be reduced from 12 months down to 4 months if we lower the maximum application label rate for sweet corn from 1.25 mg.ai to 0.5 mg.ai/seed. Four months plant back restriction can also apply to canola and rapeseed since the equivalent chemical loading (0.032 lb.ai/A) is significantly lower than the one from corn (0.171 lb.ai/A).

Since the rate of application and equivalent chemical loading /A for sweet corn, canola and rapeseeds are lower than the one for corn and popcorn, we would like to propose two separate plant back restricitons statements.

The existing label calls for

"Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, and dried beans. Do not plant any other crop in the treated area for at least one year after treated seeds are planted. "

For corn and popcorn: (Since there is no update in the turnip root, we would suggest inserting the root vegetable groups)

"Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, root vegetable groups, and dried beans. Do not plant any other crop in the treated area for at least one year after treated corn or popcorn seeds are planted. "

For sweet corn, canola and rapeseed (reflecting the lower application rate of 0.5 mg.ai/seed for sweet corn).

"Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, root vegetable groups, and dried beans. Do not plant any other crop in the treated area for at least four months after treated canola; rapeseed or sweet corn seeds are planted"

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Supporting data and rational:

The rotational studies on

Mustard green leaves (Max. Residue for 1, 4, 8 months are 0.0108, 0.016 and 0.0232 ppm),

Turnip tops (Max. residue for 1, 4, 8 months are 0.0144, 0.0116 and 0.0215 ppm),

Turnip roots (all less than 0.01 ppm),

Wheat forage (Max. residue for 1, 4, 8 months are 0.0145, 0.0121, 0.013 ppm)

Wheat hay (max residue for 1, 4, 8 months are 0.0246, 0.0167 and

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA United States Environmental Protection Agency Washington, DC 20460

[ ] Registration
[x] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 264-789
2. EPA Product Manager: D. Kenny
3. Proposed Classification: [x] None [ ] Restricted
4. Company/Product (Name): PONCHO 600
PM#: INS-ROD Br.
5. Name and Address of Applicant (Include ZIP Code):
Gustafson LLC
1400 Preston Road, Suite 400
Plano, Texas 75093
[ ] 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

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

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

Submission of label amendment to lower the application rate for sweet corn and to shorten plant back interval for various crops. We believe this action is R35, non-fast track, $10,000. Please e-mail the Invoice to my e-mail address, mcfadden@gustafson.com or FAX to my attention at 972-985-1696.

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: [ ] Label [ ] Container
4. Size(s) Retail Container
5. Location of Label Directions: [ ]
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)
Dennis McFadden	Mgr. Tox. & Reg. Affairs	972-985-5877

Certification

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

5. Date Application Received (Stamped)

2. Signature: Dennis McFadden
3. Title: Mgr. Tox. & Reg. Affairs
4. Typed Name: Dennis McFadden
5. Date: 3/29/2005

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

15 B 1.1 Jacket

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

December 13, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-351931
EPA File Symbol or Registration Number: 264-789
Product Name: PONCHO 600
EPA Receipt Date: 07-Dec-2004
EPA Company Number: 264
Company Name: BAYER CROPSCIENCE LP

Jamin Huang, Ph.D.
BAYER CROPSCIENCE LP
2 T.W. ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, NC 27709

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. 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: R35

NON-FAST TRACK (CHANGES TO REI;PPE;PHI;RATE AND NUMBER OF APPLICATIONS;ADD AERIAL APPLICATION;MODIFY GW/SW ADVISORY STATEMENT;

Please remit payment in the amount of: $ 10,000 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

By Courier:
U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
Telephone: (412) 236-2294

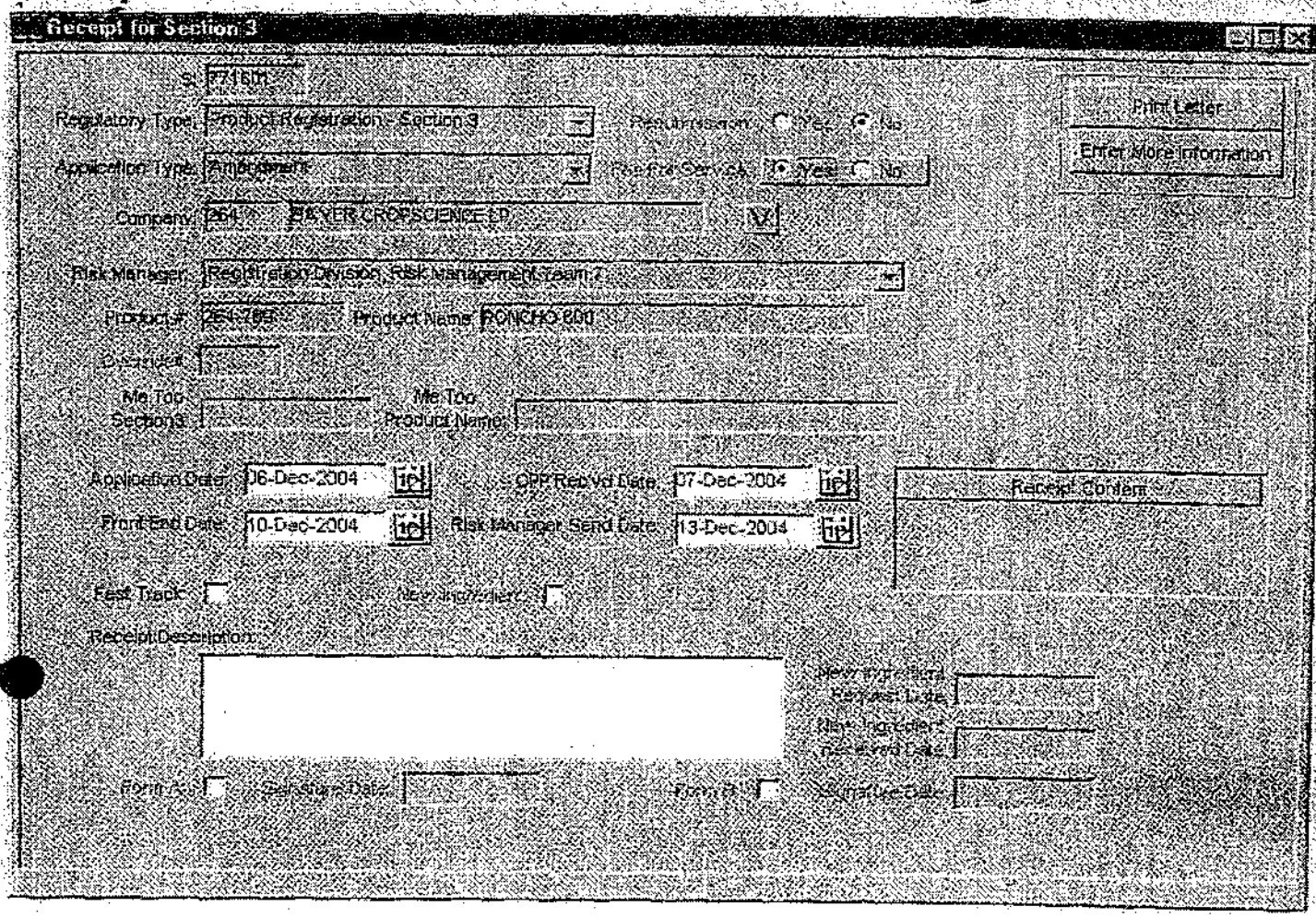
All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or 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 soley 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.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 305-6249.

Sincerely,

Front End Processing Staff
Information Resources and Services Division


Receipt for Section 3
S: 771601
Regulatory Type: Product Registration - Section 3
Application Type: Amendment
Company: 264 BAYER CROPSCIENCE LP
Risk Manager: Registration Division, Risk Management Team 7
Product #: 264-789
Product Name: PONCHO 600
Me Too Section3
Me Too Product Name:
Application Date: 06-Dec-2004
OPP Rec'vd Date: 07-Dec-2004
Front End Date: 10-Dec-2004
Risk Manager Send Date: 13-Dec-2004
Fast Track:
Receipt Description:
Print Letter
Enter More Information
Receipt Content

JUN - 7 2004

Mr. Jamin Huang, Ph.D.
Product Registration Manager
BAYER CROPSCIENCE
P.O. BOX 12014
Research Triangle Park, NC 27709

Dear Dr. Huang:

The Agency has reviewed your application for four (4) alternate confidential statements of formula (CSF) for **EPA Registration 264-789**. The proposed CSFs dated 4-13-04, 4-14-04, 4-15-04, and 4-16-04 **are acceptable**. A copy of each CSF has been added to the registration file for the subject product.

Sincerely,

/S/

Sherada D. Hobgood
Minor Formulation Review Coordinator
Registration Division (7505C)

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 264-789
2. EPA Product Manager: Daniel C. Kenny
3. Proposed Classification: ☐ None ☐ Restricted
4. Company/Product (Name): PONCHO 600
PM#: Team 01
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 response to Agency letter dated _____
☐ "Me Too" Application.
☑ Other - Explain below.

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

REGFEE: Fast-track review (45 days). Minor Formulation Amendment per PR Notice 98-10. No fee is required per an e-mail dated April 15, 2004 from Ms. Sharada Hobgood (Minor Formulation Amendment Review Coordinator/Acting Ombudsperson) to Sue Shen of Gustafson (a copy attached as Attachment 1)

See Attached

Section - III

1. Material This Product Will Be Packaged In:

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

3. Location of Net Contents Information: ☐ Label ☐ Container
4. Size(s) Retail Container
5. Location of Label Directions: ☐
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)
Jamin Huang	Product Registration Manager, Insecticides	(919) 549-2634

Certification

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

6. Date Application Received (Stamped)

2. Signature: Jamin Huang
3. Title: Product Registration Manager, Insecticides
4. Typed Name: Jamin Huang
5. Date: April 19, 2004

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Reg. # 264-789 Vol. 2

Page _____ is not included in this copy.

Pages 91 through 92 are not included in this copy.

The material not included contains the following type of information:

✓ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-Client work product.

_____ Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Bayer CropScience

April 19, 2004

Ms. Stephanie Nguyen
Document Processing Desk
Office of Pesticide Programs (7504C)
Registration Division
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202-4501

Re: **Poncho 600 (EPA Reg. No.: 264-789)**

Alternate Confidential Statements of Formula – Minor Formulation Amendment per PR Notice 98-10

Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709
Phone: 919 549-2000

Dear Ms. Nguyen, [illegible]

Bayer CropScience is herein submitting four (4) alternate Confidential Statements of Formula for Poncho 600 for your review and approval. All of the changes made are listed below. None of the previously approved nominal concentrations and certified limits for the active ingredient and inerts (except the [redacted] is changed relative to the basic CSF dated June 1, 2003, which was submitted to the Agency on October 22, 2003 and approved on December 24, 2003.

Based on an e-mail dated April 15, 2004 from Ms. Sherada Hobgood (Minor Formulation Amendment Review Coordinator/Acting Ombudsperson) to Sue Shen of Gustafson (Attachment I), minor formulation amendment changes pursuant to PR Notice 98-10 are exempt from the payment of fees for service and it is business as usual. We believe these four alternate CSFs meet the criteria for minor formulation amendment review per PR Notice 98-10.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Reg. 264-789 Vol. 2

Page 94 is not included in this copy.

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

✓ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-Client work product.

_____ Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

In support of the above-described update, we are herein submitting the following:

1. Application for Pesticide Amendment (EPA Form 8570-1) dated April 19, 2004.

2. Five (5) copies of each of the new alternate CSFs for Poncho 600 dated 4/13/2004 (CSF ID # 789.A140), 4/14/2004 (CSF ID # 789.A150), 4/15/2004 (CSF ID # 789.A160) and 4/16/2004 (CSF ID # 789.A170).

3. One (1) copy of the approved basic CSF for Poncho 600 dated June 1, 2003, which was submitted to the Agency on October 22, 2003 and approved on December 24, 2003, for your convenient comparison with the new alternate CSFs listed above.

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

Sincerely,

Jamin Huang, Ph.D.
Product Registration Manager

Attachments

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

May 20, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-343513
EPA File Symbol or Registration Number: 264-789
Product Name: PONCHO 600
EPA Receipt Date: 02-Dec-2003
EPA Company Number: 264
Company Name: BAYER CROPSCIENCE LP

Jamin Huang
BAYER CROPSCIENCE LP
2 T.W. ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, NC 27709

SUBJECT: Receipt of Registration Service Fee Voluntary Payment Notice

Dear Registrant:

The Office of Pesticide Programs has received your Notice of Intent to Submit Voluntary Payment for the action described below.

The Action has been identified as Action Code: R17

NEW USE;EACH ADDITIONAL NEW FOOD USE;

The net amount due was calculated by determining the fee associated with this action (from the March 17, 2004 Federal Register Notice), calculating the amount of work that has been completed on the particular action, and reducing the basic fee by the appropriate percentage of work completed. This amount was further reduced by the amount of any tolerance fee paid in association with this action if applicable.

You may be eligible for a full or partial waiver of the registration service if, for example, you qualify as a small business or are applying for a minor use. 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 below. OPP wil not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please remit payment in the amount of: $ 27,825 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

By Courier:
U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor

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.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,

Lois Rossi

Lois Rossi, Director
Registration Division

No Decision has ever been created for this use - it is not on 2004 workplan. Data submitted in Nov.

Code Should be R17

New Use $50,000

(Never cleared - No Discount)

(minus petition fee paid - see attachment)

$ 50,000
- 22,175
27,825

[illegible] it was [illegible] to [illegible] [illegible], so I'd say no 10% [illegible]

$27,825

[illegible] $ [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible]

☐ New FFS Action

Fee for Service

☐ Voluntary Payment Request

[redacted]

01

264-789

4/9/04

Action Code: R17

Amount Due: $ ~~50,000~~ $27,825 (see Remarks

☐ Waiver Request: No

☐ Small Business 100% ☐ IR-4 ☐ Federal/State
☐ Small Business 50% ☐ Minor Use

D343513

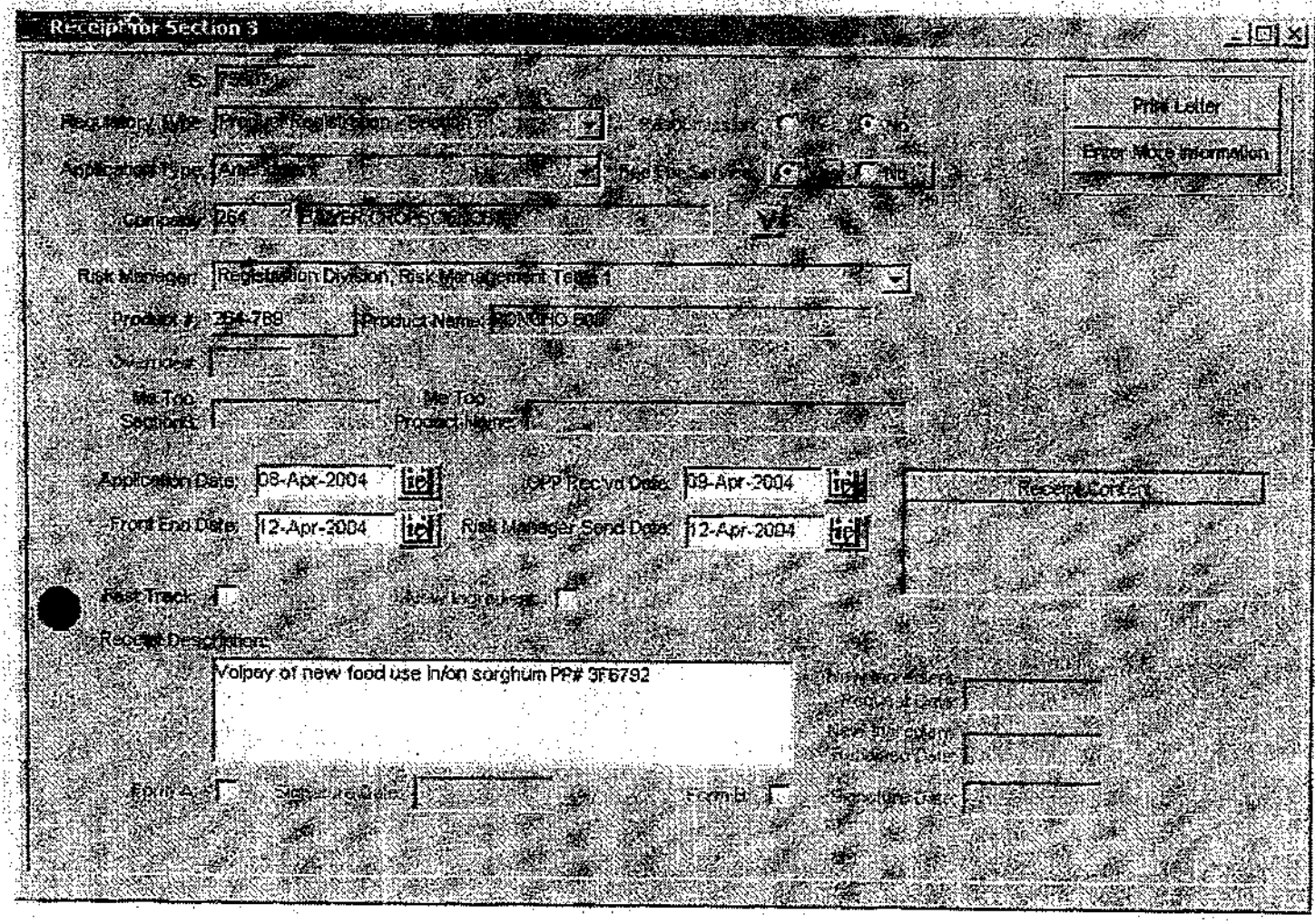
Voluntary Payment Reduction Amount:

☑ 0% ☐ 30% ☐ 70%
☐ 10% ☐ 40% ☐ 75%
☐ 20% ☐ 50% ☐ 80%
☐ 25% ☐ 60% ☐ 90%

Original Decision #: D337611 if this is on the petition; D3 if this is ~~on the product~~ and D#

Reviewer: Bazuin Date: 4/12/04

Remarks: Company will VOLPAY $50,000. They don't state Action Code but since it is one (only) new use and no indication is given of Reduced Risk, I'd call it an R17. Company says they already paid $22,175 for the petition (this leaves $27,825 more).


Receipt for Section 3
Print Letter
Enter More Information
Company: 264
Risk Manager: Registration Division, Risk Management Team 1
Product #: 264-789
Product Name:
Me Too Section3:
Me Too Product Name:
Application Date: 08-Apr-2004
OPP Rec'vd Date: 09-Apr-2004
Receipt Content
Front End Date: 12-Apr-2004
Risk Manager Send Date: 12-Apr-2004
Fast Track:
Receipt Description:
Volpay of new food use in/on sorghum PP# 3F6792
Form A:
Form B:

Bayer CropScience

April 8, 2004

Ms. Meredith Laws
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Document Processing Desk (VOLPAY)
Crystal Mall Building 2, Room 266A
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Re: Voluntary Payment of Registration Fee for Poncho 600 (EPA Reg. No.: 264-789)
Petition for Tolerance, PP#3F6792

Dear Ms. Laws:

We hereby inform the Agency that we would like to make a voluntary registration fee payment for our pending application for the proposed use Poncho 600 on sorghum *via* seed treatment use (a.i.: clothianidin).

Bayer CropScience
T.W. Alexander Drive
Research Triangle Park, NC 27709
Phone: 919 549-2000

Enclosed with this letter are the following documents:

1. An application form, EPA 8570-1 dated April 8, 2004.
2. A copy of the submission cover letter dated December 1, 2003.
3. A copy of the certified check in the amount of $ 22,175.00, already paid to cover petition tolerance fee.

If you have any questions, please contact me either by telephone at 919-549-2634 or by e-mail at jamin.huang@bayercropscience.com.

Sincerely,

Jamin Huang
Product Registration manager
Regulatory Affairs

Attachments

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 264-789

2. EPA Product Manager: Daniel C. Kenny

3. Proposed Classification: ☑ None ☐ Restricted

4. Company/Product (Name): Poncho 600

PM#: 01

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

Bayer Cropscience
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)(ii), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

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

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

VOLPAY: We are interested in obtaining registration and would like to make voluntary payment of fee.
Fee Category: new food use. Amount due: $ 50,000.00 (already paid $ 22,175.00 in tolerance fees with the December 1, 2003 submission - copy of certified check attached)
Submitted Petition for Tolerance, PP # 3F6792. Contact person: jamin.huang@bayercropscience.com

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging: ☐ Yes ● ☐ No
** Certification must be submitted*

Unit Packaging: ☐ Yes ☐ No
If "Yes" Unit Packaging wgt. | No. per container

Water Soluble Packaging: ☐ Yes ☐ No
If "Yes" Package wgt | No. per container

2. Type of Container: ☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____

3. Location of Net Contents Information: ☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions: ☐ ON 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)
Jamin Huang, Ph.D.	Registration Product Manager	919-549-2534

Certification

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

6. Date Application Received (Stamped)

2. Signature: Jamin Huang

3. Title: Registration Product Manager

4. Typed Name: Jamin Huang, Ph.D.

5. Date: April 8, 2004

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

White - EPA File Copy (original) Yellow - Applicant Copy

Bayer CropScience

December 1, 2003

Mr. Daniel C. Kenny
Product Manager 01
Document Processing Desk
Office of Pesticide Programs (7504C)
Registration Division
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202-4501

Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709
Phone: 919 549-2000

Re: Poncho 600 (EPA Reg. No.: 264-789)

Petition to Propose Tolerances for Residues of Clothianidin in/on Sorghum

Dear Mr. Kenny,

Bayer CropScience is herein submitting the enclosed petition pursuant to Section 408(d)(1) of the Federal Food, Drug and Cosmetic Act (FFDCA) as amended to propose tolerances for clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on sorghum.

Clothianidin is utilized as an active ingredient in Poncho 600 which has been approved by the Agency for seed treatment use on corn and canola to control a number of pests and, as a result, several residue tolerances have been established. Enclosed hereto, in duplicate and constituting a part of this petition, are the following:

Section A: The name, chemical identity and composition of the pesticide clothianidin and its crop-use product.

Section B: The amount, frequency and time of application of the pesticide product.

Section C: A summary of the toxicology database for clothianidin.

Section D: Residue chemistry data and analytical methodology used in support of the proposed tolerances.

Section E: Practical methods for removing residues in excess of the proposed tolerance.

Section F: The proposed tolerances for residues of clothianidin in or on sorghum.

Section G: Reasonable grounds in support of this petition. This section summarizes the proposed tolerances for clothianidin for the crop use and the supporting data.

Also included with this submission is a Notice of Filing summary document consistent with section 408(d) of FFDCA, as amended by the Food Quality Protection Act. Bayer CropScience also authorizes for this summary to be published in the Federal Register in a notice of receipt of the petition. While the summary represents Bayer's evaluation of the chemical, we understand that EPA has not evaluated the sufficiency of the submitted data or whether the data fully support this petition.

In accordance with CFR 40 §180.33(b) and the latest fee schedule, the fee required to accompany this petition proposing the establishment of tolerances on additional raw agricultural commodities at lower numerical levels than tolerances already established for the same pesticide chemical is $ 22,175 [68 FR 24370]. A check payable to the Environmental Protection Agency for the amount of $22,175 was mailed together with a copy of this letter to the following address:

Environmental Protection Agency
Headquarters Accounting Operations Branch
Office of Pesticide Programs (Tolerance Fees)
P.O. Box 360277M
Pittsburgh, PA 15251

The following documents are enclosed pursuant to the tolerances proposed in this petition:

(1) A copy of check # 640761668 payable to US Environmental Protection Agency, in the amount of $ 22,175 for tolerance petition fee.

(2) Transmittal document.

(3) Application for amendment to registration of Poncho 600 (EPA Reg. No. 264-789), including 5 copies of the proposed product label dated November 17, 2003, and a completed and signed "Certification with Respect to Citation of Data"

(4) Petition for Tolerances (2 copies)

(5) Notice of Filing (paper and electronic copy)

(6) Data matrix for clothianidin and Poncho 600 (2 copies – the public copy and the Agency internal use copy)

(7) Two study reports listed in Transmittal Document in support of this petition (3 copies each).

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

Sincerely,

Jamin Huang, Ph.D.
Product Registration Manager

Attachments

OFFICIAL CHECK

[redacted]

640761668

0005497

WACHOVIA

11/19/2003

Pay To The Order Of ENVIROMENTAL PROTECTION AGENCY
FOR:TOLERANCE PETITION FEES

$ $22,175.00

*TWENTY TWO THOUSAND ONE HUNDRED SEVENTY FIVE DOLLARS AND 00 CENTS

Dollars

DRAWER: Wachovia Bank, National Association

BAYER CROPSCIENCE LP

Remitter

Issued by Integrated Payment Systems Inc., Englewood, Colorado
Bank One, NA Drawer, Colorado

Authorized Signature

[redacted] 6800640761668 1

COMMERCIAL/FINANCIAL INFORMATION IS NOT INCLUDED

Mike Rexrode

08/03/2004 03:41 PM

To: Stephanie Nguyen/DC/USEPA/US@EPA
cc: Allen Vaughan/DC/USEPA/US@EPA, Mah Shamim/DC/USEPA/US@EPA
Subject: clothianidin acute sediment requirement

Stephanie, 8/02/04

This is in response to the registrants (Bayer) E-mail regarding clarification of the acute sediment toxicity testing on clothianidin. EFED is referring to the OPPTS 850.1735 study that uses whole spiked sediment.

Chironomus riparius may be used as a substitute for C. tentans. The duration of the study is 10 days and emergence is not an endpoint.

850.1735: ***Acute Sediment (freshwater)***

- Test organism: Hyalella azteca or Chironomus tentans.
- Duration: 10 days, endpoint is survival and growth.

Miachel Rexrode Ph. D.
Senior Aquatic Biologist
EPA/OPP/EFED/ERB5

Jamin Huang
<jamin.huang@bayercropscience.com>

06/08/2004 06:55 AM

To: Stephanie Nguyen/DC/USEPA/US@EPA
cc: Alison Chalmers <alison.chalmers@bayercropscience.com>
Subject: question - clothianidin - whole sediment acute toxicity - freshwater invertebrate

Dear Stephanie,

In the clothianidin risk assessment dated 2/20/03, one of the requested studies was an acute sediment test -

"OPPTS 850.1735: Whole Sediment Acute Toxicity Invertebrates, Freshwater. This is a 28 day test that measures survival, growth and emergence of *Chironomus riparius* that have been exposed to pesticide spiked sediment. EFED is requesting this acute sediment toxicity test because clothianidin is toxic to aquatic invertebrates, persistent in the environment, and binds to sediment over time."

However, OPPTS 850.1735 gives guidelines for a 10-day sediment test using *Chironomus tentans* (" (d) Test method. (1).....Whole sediment toxicity tests are outlined for the amphipod, *Hyalella azteca* and the midge, *Chironomus tentans*.....".)

Before we start the test, we would like to clarify with the Agency whether the intention was for BCS to carry out this *Chironomus tentans* study or if the request was intended to be for a 28-day *Chironomus riparius* test carried out under OECD guidelines (Guideline 218). Please note that we have already submitted several studies with *Chironomus riparius*, including MRID # 45422509: Heimbach, F. (1999) 'Influence of TI 435 Technical on Development and Emergence of Larvae of *Chironomus riparius* in a Water-Sediment System' and MRID # 45422414: Mattock, S. (2001) TI-435: 'Comparison Acute Toxicity Test of Chironomus riparius with TZMU, MU, TZNG and MNG')

Your assistance to clarify this particular request is appreciated.

Best Regards,
Jamin

Jamin Huang, Ph.D.
Registration Product Manager
Bayer CropScience

tel: 919-549-2634
e-mail: jamin.huang@bayercropscience.com

[Federal Register: June 16, 2004 (Volume 69, Number 115)]
[Notices]
[Page 33635-33638]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr16jn04-49]

[[Page 33635]]

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0087; FRL-7350-6]

Clothianidin; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments identified by docket identification (ID) number OPP-2004-0087, must be received on or before July 16, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Stephanie Nguyen, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 605-0702; e-mail address: nguyen.stephanie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

Crop production (NAICS 111)
Animal production (NAICS 112)
Food manufacturing (NAICS 311)
Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining

whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Copies of this Document and Other Related Information?

1. Docket. EPA has established an official public docket for this action under docket ID number OPP-2004-0087. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall 2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. Electronic access. You may access this Federal Register document electronically through the EPA Internet under the ``Federal Register'' listings at http://www.epa.gov/fedrgstr/.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that areavailable electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ``search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in EPA's Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPAidentifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the

copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ``late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. Electronically. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk

[[Page 33636]]

or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. EPA Dockets. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket/ , and follow the online instructions for submitting comments.

Once in the system, select ``search,'' and then key in docket ID number OPP-2004-0087. The system is an ``anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. E-mail. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP-2004-0087. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ``anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. Disk or CD ROM. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These

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electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. By mail. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2004-0087.

3. By hand delivery or courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall 2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP-2004-0087. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under FOR FURTHER INFORMATION CONTACT.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however,

EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 27, 2004.
Lois Rossi,
Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Bayer CropScience

PP 3F6792

EPA has received a pesticide petition (3F6792) from Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of clothianidin in or on the raw agricultural commodities sorghum, grain at 0.01 part per million (ppm); sorghum, forage at 0.01 ppm; and sorghum, stover at 0.01 ppm, respectively. EPA has determined that the petition contains data or information regarding the elements set forth in

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section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. Plant metabolism. In plants, the metabolism of clothianidin is adequately understood for the purposes of establishing these proposed tolerances. Unchanged parent clothianidin was the predominant residue in all crop matrices (14.4% to 64.5% in corn, 66.1% to 96.6% in tomatoes, 4.3% to 24.4% in sugar beets, and 24.3% to 63.3% in apples), with the exception of sugar beet leaves. In sugar beet leaves, the main components were the methylguanidine and thiazolylmethylguanidine metabolites, accounting for 28.6% and 27.7%, respectively. All metabolites found in plants were also found in the animal metabolism studies. In animals, parent clothianidin was the major component in liver, muscle, and fat. Based on the available metabolism data, parent clothianidin, thiazolyl-guanidine (TZG), thiazolyl-urea (TZU), and (ATMG-Pyr) aminothiazolyl methylguanidine-pyridine are proposed to be

considered as the residues of concern in livestock matrices.

2. Analytical method. In plants and plant products, the residue of concern, parent clothianidin, can be determined using high performance liquid chromotography (HPLC) with electrosprey mass spectroscopy/mass molecular size (MS/MS) detection. In an extraction efficiency testing, the plant residues method has also demonstrated the ability to extract aged clothianidin residue.

Although the plant residues lethal dose (LC)-MS/MS method is highly suitable for enforcement method, an LC-ultraviolet (UV) method has also been developed which is suitable for enforcement (monitoring) purposes in all relevant matrices.

3. Magnitude of residues in sorghum. A total of 12 field trials was conducted to evaluate the quantity of clothianidin in sorghum forage, stover, and grain. Sorghum seed was treated with TI-435 600 fecal streptococci (FS) at a rate of 250 grams active ingredient/100 kilograms (kg) seed. The highest average field trial was less than 0.01 ppm in sorghum forage, stover, and grain when collected at normal harvest of 97 to 167 days after planting of treated seed. In a sorghum processing study sorghum seed was treated at a 2X rate of 500 grams active ingredient/100 kg seed. No residues at or above the limit of quantitation (LOQ) of 0.01 ppm were found in the sorghum grain. Therefore, a sorghum processing study was not conducted.

B. Toxicological Profile

1. Acute toxicity. The acute oral lethal dose (LD)50 was >5,000 milligrams/kilogram/body weight (mg/kg/bwt) for both male and female rats. The acute dermal LD50 was greater than 2,000 mg/kg/bwt in rats. The 4-hour inhalation LC50 was 5.538 miligrams/Liters (mg/L) for male and female rats. Clothianidin was not irritating to rabbit skin and only slightly irritating to the eyes and did not cause skin sensitization in guinea pigs.

2. Genotoxicity. Extensive mutagenicity studies were conducted with clothianidin. Based on the weight of evidence clothianidin was considered negative for genotoxicity.

3. Reproductive and developmental toxicity. In a 2-generation reproduction study, rats were administered dietary levels of 0, 150, 500, and 2,500 ppm. The no observed effect level (NOAEL) for reproductive parameters was 500 ppm (31.2/36.8 mg/kg/day; for male and female), while the NOAEL for developmental effects was 150 ppm (9.8/11.5 mg/kg/day; for male and female. The parental systemic NOAEL was 500 ppm (31.2/36.8 mg/kg/day; for male and female).

A developmental toxicity study was conducted in rats with clothianidin using dose levels of 0, 10, 50, and 125 mg/kg/bwt by gavage. The NOAEL for maternal toxicity was established at 10 mg/kg/bwt and for developmental effects it was >125 mg/kg bwt. Additionally, a developmental toxicity study was conducted with rabbits treated orally by gavage at 0, 10, 25, 75, and 100 mg/kg/bwt. The NOAEL for maternal toxicity was 25 mg/kg/bwt and for developmental toxicity it was 75 mg/kg/bwt. Developmental toxicity studies showed no primary developmental toxicity and no teratogenic potential was evident.

4. Subchronic toxicity. A 90-day feeding study was conducted in rats and dogs. The rat study was conducted at dietary levels of 0, 150, 500, and 3,000 ppm and the dog study was conducted at 0, 325, 650, and 1,500 ppm. The NOAELs were established at 500 ppm (27.9/34.0 mg/kg/day; for the male and female rat, and 650 ppm (19.3 mg/kg/day) for the male dog, and 1,500 ppm (42.1 mg/kg/day) for the female dog.

5. Chronic toxicity. A 2-year combined rat chronic/oncogenicity study conducted at dietary levels of 0, 150, 500, 1,500, and 3,000 ppm demonstrated a NOAEL of 500 ppm (27.9/34.0 mg/kg/day) based on reduced

weight gains and non-neoplastic histomorphological changes. A 78-week mouse oncogenicity study conducted at dose levels of 0, 100, 350, 1,250, and 2,000, and 1,800 ppm for males and females, respectively, revealed a NOAEL of 350 ppm (47.2/65.1 mg/kg/day) for males and females based on reduced body weight gains and increased incidence of hypercellular hypertrophy. No evidence of oncogenicity was seen in the rat or the mice. A 52-week chronic toxicity study in dogs conducted at dietary levels of 0, 325, 650, 1,500, and 2,000 ppm revealed a NOAEL of 2,000 ppm (46.4 mg/kg/day) for the male dog and 1,500 ppm (40.1 mg/kg/day) for the female dog.

6. Animal metabolism. The nature of the clothianidin residue in livestock is adequately understood. In animals, parent clothianidin was the major component in liver, muscle, and fat. Based on the available metabolism data, parent clothianidin, TZG, TZU, and ATMG-Pyr are proposed to be considered as the residues of concern in livestock matrices.

7. Metabolite toxicology. Eight in vivo metabolites of clothianidin identified in the rat were investigated for acute oral endpoint mutagenic activity. None of the metabolites were mutagenic either with or without activation and the LD50 values range from <500 to >2,000 mg/kg, showing low to moderate toxicity.

8. Endocrine disruption. All guideline studies conducted to characterize toxicological profile showed no endocrine related toxicity or tumorgenicity. No effects on triiodothyronine (T3), throxine (T4), or thyroid stimulating hormone (TSH) were observed in the subchronic rat study. In a 2-generation reproduction study in rat, and rat and rabbit teratology studies, clothianidin did not show reproductive or teratogenic effects. The extensive data base shows that clothianidin has no endocrine properties.

C. Aggregate Exposure

1. Dietary exposure. There are no residential uses for clothianidin, therefore aggregate exposure consists of dietary (food and drinking water) exposures. The acute population adjusted dose (PAD) of 0.025 mg/kg bwt/day based on an acute NOAEL of 25 with an uncertainty factor (UF) of 1,000 was used to assess acute dietary exposure. The chronic (PAD) of 0.0098 mg/kg/bwt/day based on a chronic NOAEL of 9.8 with an UF of 1,000 was used to assess chronic exposure.

i. Food. In the clothianidin pesticide tolerance action for corn and canola, the

[[Page 33638]]

Federal Register notice of May 30, 2003 (68 FR 32390) (FRL-7306-8), EPA conducted Tier I acute and chronic dietary assessments for clothianidin. These assessments included residues of clothianidin that arise from the uses of thiamethoxam which has clothianidin as a common metabolite. Based on these assessments, a tolerance of 0.01 ppm for sorghum use for clothianidin was added to the analysis. No significant contribution was seen from this use. The U.S. population utilized 8.4% (0.002111 mg/kg/bwt/day, 95\th\ percentile) of the acute PAD and 6.5% (0.000635 mg/kg/bwt/day) of the chronic PAD. The most highly exposed subpopulation is children 1 to 2 at 19.1% (0.004772 mg/kg/bwt/day, 95\th\ percentile) of the acute PAD and 19.1% (0.001874 mg/kg/bwt/day) of the chronic PAD.

ii. Drinking water. EPA's Standard Operating Procedure (SOP) for drinking water exposure and risk assessments was used to perform the drinking water assessment. This SOP uses a variety of tools to conduct drinking water assessment. These tools include water models such as

Screening Concentration in Groundwater (SCI-GROW), FQPA Index Reservoir Screening Tool (FIRST), EPA's Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), and monitoring data. If monitoring data are not available then the models are used to predict potential residues in surface water and ground water and the highest is assumed to be the drinking water residue. In the case of clothianidin, monitoring data do not exist therefore SCI-GROW and FIRST were used to estimate a water residue. The calculated drinking water levels of comparison (DWLOC) for acute chronic exposure for all adults and children exceed the drinking water estimated concentrations (DWEC) from the models. The chronic DWLOC for adults is 321 parts per billion (ppb) and the acute DWLOC is 801 ppb. The chronic DWLOC for children 1 to 2 is 79 ppb and the acute DWLOC is 202 ppb. The DWEC for the worst case chronic scenario is 2.14 ppb FIRST and the acute DWEC FIRST is 2.97 ppb. The DWLOC are based on conservative dietary (food) exposures and are expected to be much higher in real world situations.

2. Non-dietary exposure. Clothianidin products are not labeled for residential uses (food or non-food), thereby eliminating the potential for residential exposure or non-occupational exposure.

D. Cumulative Effects

Clothianidin is a metabolite of thiamethoxam. Therefore, residues of clothianidin resulting from use of thiamethoxam were included in the above risk assessment. There are no data available to indicate that toxic effects produced by clothianidin are cumulative with those of any other compound.

E. Safety Determination

1. U.S. population. Using the conservative exposure assumptions described above and based on the completeness of the toxicity data, it can be concluded that aggregate exposure to residues of clothianidin present a reasonable certainty of no harm. Exposure from residues in crops utilize 8.4% of the acute PAD and 6.5% of the chronic PAD. EPA generally has no concerns for exposures below 100% of the PAD. DWLOC are well above the estimated drinking water concentrations as calculated by conservative models. There are no residential uses so aggregate exposure consists of food and drinking water exposures. The conservative Tier I assessments demonstrate a reasonable certainty of no harm will result from uses of clothianidin for the U.S. population.

2. Infants and children. In assessing the potential for additional sensitivity of infants and children to residues of clothianidin, the data from developmental toxicity studies in both the rat and rabbit, a 2-generation reproduction study in rats and a developmental neurotoxicity study in rats have been considered.

The developmental toxicity studies evaluate potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates effects from exposure to the pesticide on the reproductive capability of mating animals through 2-generations, as well as any observed systemic toxicity.

The developmental neurotoxicity studies evaluate the neurobehavioral and neurotoxic effects on the developing animal resulting from the exposure of the mother. FFDCA section 408 provides that EPA may apply an additional UF for infants and children based on the threshold effects to account for prenatal and postnatal effects and the completeness of the toxicity data base. Based on the current toxicological data requirements the toxicology data base for clothianidin relative to prenatal and postnatal development is

complete, including the developmental neurotoxicity study. None of the studies indicated the offsprings to be more sensitive. All effects were secondary to severe maternal toxicity. Therefore, no additional safety or UF is justified.

F. International Tolerances

No CODEX maximum residue levels have been established for residues of clothianidin on any crops at this time.

[FR Doc. 04-13411 Filed 6-15-04; 8:45 am]

BILLING CODE 6560-50-S

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Jamin Huang, Ph.D
Registration Product Manager
Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

JUN 1 6 2004

Subject: EPA Reg. No.: 264-789
Poncho 600
Alternate Confidential Statements of Formula
Submission Dated April 7, 2004

Dear Dr. Huang:

The Agency has reviewed your submission for the six Confidential Statements of Formula dated March 4, 5, 6, 7, 8 and 9, 2004 for the alternate formulations in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act.

It has been determined that the Confidential Statements of Formula agree with the label claim in compliance with PR Notice 91-2 and are acceptable. The Confidential Statements of Formula have been added to your file as part of the record. A detailed review of the Confidential Statements of Formula is also enclosed for your records.

If you have any questions or comments about this letter, please contact Stephanie Nguyen at 703-605-0702.

Sincerely,

Daniel C. Kenny
Product Manager (01)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

DATE OUT: 20/MAY/2004

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [ ] End-Use Product [X]
DP BARCODE #:D301325 EPA RECEIVED DATE:12/APR/2004 FILE SYMBOL/REG #264-789
PRODUCT NAME: Poncho 600 FOOD USES [X]
COMPANY NAME: Bayer CropScience LP MRIDs: None ACTION CODE: 345
PPC NUMBER OF THE TGAI IN THE PRODUCT: 044309 DECISION NO.: 341875

FROM: Sami Malak, Chemist
Technical Review Branch/RD (7505C)

TO: 01 Daniel Kenny/Stephanie Nguyen
Insecticide/Rodenticide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 07/APR/2004, the applicant requested review for acceptability six alternate CSFs dated 04, 05, 06, 07, 08 & 09/MAR/2004.

FINDINGS:

1. The submitted six alternate CSFs dated 04, 05, 06, 07, 08 & 09/MAR/2004 for subject product are substantially similar in composition to the current basic and one alternate CSFs dated 01 & 02/JUN/2003, respectively. Exceptions: Minor changes in the intentionally added inert ingredients, also the use of wider limits for certain inerts with acceptable explanations as specified in the attached letter dated 07/APR/2004 in compliance with the regulations of 40CFR§158.175(c)(2) No other changes were noted regarding the source technical, Reg. No. 74207-1, the nominal concentration of 48% clothianidin, or in the physical/chemical properties.

2. The submitted six alternate CSFs dated 04, 05, 06, 07, 08 & 09/MAR/2004 were filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2) & 40CFR§158.175(c)(2) All ingredients claimed in the CSF are cleared for use in pesticide formulations intended for food uses.

CONCLUSIONS:

TRB has no objections for approval of the submitted six alternate CSFs dated 04, 05, 06, 07, 08 & 09/MAR/2004.

cc: S. Malak and Central File (Reg. No. 264-789).
7505C:RD:TRB:CM-2:Rm.268:s.m.:20/MAY/2004:703-308-9365:<264-789 >.

CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC) REQUEST FORM*

GRA 04-0269

REQUESTOR NAME: Sami Malak REQUEST DATE: 5/19/04
TEL.: (703) 308-9365 ORG.: RAITRB (DIV./BR./SEC.) ROOM: 268 MAIL CODE: 7505C

CSF ATTACHED:

- [x] YES If CSF is attached complete Item A and the chemical name in Item B.
- [ ] NO If CSF is not attached complete Items A through C.

A. INFORMATION REQUIRED:

✓Check Applicable Category

- [x] Provide PCC and Tolerance Exemption Status For Food-Use Inert Ingredient(s)
- [x] Provide PCC for Non-Food Use Inert Ingredient (s)
- [ ] Provide PCC for Active Ingredient(s)
- [ ] Provide PCC for Dye
- [ ] Determine if Fragrance is Acceptable for Use in Formulation
- [ ] Other (Describe): _____

B. INGREDIENT INFORMATION: INERT INGREDIENT INFORMATION IS NOT INCLUDED

Ingredient No. 1:

Chem. Name: [redacted]

Trade Name: [redacted]

CAS Reg. No.: not available

Ingredient No. 2:

Chem. Name: _____

Trade Name: _____

CAS Reg. No.: _____

Ingredient No. 3:

Chem. Name: _____

Trade Name: _____

CAS Reg. No.: _____

Ingredient No. 4:

Chem. Name: _____

Trade Name: _____

CAS Reg. No.: _____

C. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No./File Symbol: 264-789 ProductName: Poncho 600
Registrant: Bayer CropScience Food-Use Pesticide: [x] YES [x] NO
Percent in Formulation (For Fragrance/Dyes only): _____

INFORMATION REPORTED: INERT INGREDIENT INFORMATION IS NOT INCLUDED

Ingredient No. 1: [redacted]
PCC:
TOL. STATUS:
OTHER INF.:

Ingredient No. 2:
PCC:
TOL. STATUS:
OTHER INF.:

Ingredient No. 3:
PCC:
TOL. STATUS:
OTHER INF.:

Ingredient No. 4:
PCC:
TOL. STATUS:
OTHER INF.:

Completed By: LINDA FAN Date Completed: 05/25/2004

*Once completed, this form may be entitled to treatment as CBI under section 10 of FIFRA. If so, a red FIFRA CBI cover should be affixed to the request form and the document handled accordingly.

Reg.# 264-789 Vol. 2

Page _____ is not included in this copy.

Pages 121 through 125 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

✓ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-Client work product.

_____ Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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

April 12, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JAMIN HUANG PhD
BAYER CROPSCIENCE LP
2 T.W. ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, NC 27709

PRODUCT NAME: PONCHO 600
COMPANY NAME: BAYER CROPSCIENCE LP
EPA FILE SYMBOL: 264-789
EPA RECEIPT DATE: 04/09/04

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 1, at (703) 305-7546.

Sincerely,

Patricia A Moore
Front End Processing Staff
Information Services Branch
Information Resources and Services Division

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [✓] Amendment
- [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 264-789	2. EPA Product Manager Daniel C. Kenny	3. Proposed Classification [ ] None [ ] Restricted
4. Company/Product (Name) PONCHO 600	PM# Team 01	
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.
- [ ] Other - Explain below.

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

REGFEE: EPA No. R34, Non-Fast Track. Alternate confidential statements of formula (CSF). Fee amount due $ 3,000

Justification: submission of alternate confidential statements of formula (CSF) with minor formulation amendment on inerts per PR Notice 98-10, no data being submitted, proposed amendments are based on the approved basic CSF for Poncho 600 (EPA Reg. No.: 264-789) dated June 1, 2003. See attached.

Section - III

1. Material This Product Will Be Packaged In:

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

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] 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)
Jamin Huang, Ph.D.	Product Registration Manager, Insecticides	(919) 549-2634

Certification

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

6. Date Application Received (Stamped)

2. Signature	3. Title Product Registration Manager, Insecticides
4. Typed Name Jamin Huang, Ph. D.	5. Date April 7, 2004

Reg.# 264-789 Vol. 2

Page _____ is not included in this copy.

Pages 128 through 130 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-Client work product.

✓ Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Bayer CropScience

April 7, 2004

Ms. Stephanie Nguyen
Document Processing Desk
Office of Pesticide Programs (7504C)
Registration Division
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202-4501

Re: Poncho 600 (EPA Reg. No. 264-739)

Alternate Confidential Statements of Formula – Minor Formulation Amendment per PR Notice 98-10

Bayer CropSciences
2 T.W. Alexander Drive
Research Triangle Park, NC 27709
Phone: 919 549-2000

(NEW ENCLOSURE INFORMATION IS NOT INCLUDED)

Dear Ms. Nguyen,

Bayer CropScience is herein submitting six (6) alternate Confidential Statements of Formula for Poncho 600 for your review and approval. The only changes made are listed below. All other contents remain unchanged relative to the basic CSF dated June 1, 2003, which was submitted to the Agency on October 22, 2003 and approved on December 24, 2003.

A. The common changes for all of the six CSFs in this submission are outlined below:

1) The lower certified limit for [redacted] is lowered from [redacted] by weight. This value is lowered [redacted] of the product and allow the performance properties to remain unchanged.

2) [redacted] is added as an alternate to the [redacted]

3) The upper certified limit for the inert [redacted] is increased from [redacted] by weight. This adjustment enhances the [redacted] and [redacted] of the product.

4) [redacted] is added as an alternate to [redacted]

5) The lower certified limit for [redacted] is lowered from [redacted] % by weight.

6) [redacted] is added as an alternate to [redacted]

7) [redacted] is added as an alternate to [redacted]

8) Supplier names and addresses are updated where necessary.

9) The diluent values are adjusted slightly to accommodate the full range of ingredients used to formulate the product when necessary. The certified limits are adjusted to allow for the minor adjustments to the inerts as allowed by 40 CFR 158.175.

B. The specific changes for each of the six CSFs in this submission are outlined below:

CSF ID # 789.A080

1) The lower certified limit for the inert [redacted] is lowered from [redacted] by weight. This adjustment allows for the final adjustment of the pH to the product.

2) The upper certified limit for [redacted] is increased from [redacted] by weight.

CSF ID # 789.A090

1) The [redacted] is removed from this CSF. Otherwise, its contents are identical to those in Alternate CSF ID# 789.A080. The diluent is adjusted to compensate for the deletion.

2) The upper certified limit for [redacted] is increased from [redacted] by weight.

CSF ID # 789.A100

1) The lower certified limit for the inert [redacted] is lowered from [redacted] by weight.

2) The inert [redacted] is added as [redacted] Otherwise, its contents are identical to those in Alternate CSF ID# 789.A080. The diluent is adjusted to compensate for the deletion.

3) The upper certified limit for [redacted] is increased from [redacted] by weight.

CSF ID # 789.A110

1) The [redacted] is removed from this CSF. Otherwise, its contents are identical to those in Alternate CSF ID# 789.A100. The diluent is adjusted to compensate for the deletion.

2) The upper certified limit for [redacted] is increased from [redacted] by weight.

CSF ID # 789.A120

1) The lower certified limit for the inert [redacted] is lowered from [redacted] by weight.

2) The amount of [redacted] used is changed from [redacted] by weight. The certified limits are set wider [redacted] by weight) to allow for slightly more or less [redacted] to be used based upon [redacted] the production process.

3) The inert [redacted] is added to the formula as an additional surfactant that [redacted] of the product. Beside the above changes, its contents are identical to those in Alternate CSF ID# 789.A100. The diluent is adjusted to compensate for the deletion.

CSF ID # 789.A130

1) The [redacted] is removed from this CSF. Otherwise, its contents are identical to those in Alternate CSF ID# 789.A120. The diluent is adjusted to compensate for the deletion.

The MSDS for [redacted] are enclosed with this application. All of the inerts added are exempt from tolerance and are used in other approved formulations.

In support of the above-described update, we are herein submitting the following:

1. Application for Pesticide Amendment (EPA Form 8570-1) dated April 7, 2004.

2. Five (5) copies of each of the new alternate CSFs for Poncho 600 dated 3/4/2004 (CSF ID # 789.A080), 3/5/2004 (CSF ID # 789.A090), 3/6/2004 (CSF ID # 789.A100), 3/7/2004 (CSF ID # 789.A110), 3/8/2004 (CSF ID # 789.A120), 3/9/2004 (CSF ID # 789.A130).

3. One (1) copy of the approved basic CSF for Poncho 600 dated June 1, 2003, which was submitted to the Agency on October 22, 2003 and approved on December 24, 2003, for your convenient comparison with the new alternate CSFs listed above.

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

Sincerely,

Jamin Huang, Ph.D.
Product Registration Manager

Attachments

Jamin Huang
<jamin.huang@bayercropscience.com>

05/06/2004 07:49 AM

To: Stephanie Nguyen/DC/USEPA/US@EPA
cc: Dan Kenny/DC/USEPA/US@EPA, Roy Lidstone <roy.lidstone@bayercropscience.com>, Alison Chalmers <alison.chalmers@bayercropscience.com>, David Fischer <david.fischer@bayercropscience.com>, Karen Cain <karen.cain@bayercropscience.com>
Subject: Poncho - request to postpone the bee field study to 2005

Dear Stephanie,

Thank you for the review and detailed response to the protocol we submitted for the honeybee field study with Poncho-treated canola. We appreciate the inputs and will rewrite the protocol to incorporate necessary changes. Both agencies requested adding additional fields to the study. By the time we received these comments in early April we were unable to find suitable fields in time for the 2004 growing season. Therefore, we are advising you that we will delay the study until the 2005 growing season.

Please let us know if you have questions. A similar message is being sent to PMRA

Best Regards,
Jamin

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Jamin Huang, Ph.D.
Registration Product Manager
Bayer CropScience

tel: 919-549-2634
e-mail: jamin.huang@bayercropscience.com

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

OFFICE OF PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM March 11, 2004

Subject: EFED Review of Bayer CropScience's Draft Protocol of a Honeybee Field Study - Poncho 600 (264-789) [Clothianidin (044309), D295318]

To: Meredith F. Law, Chief-Insecticide Branch
Dan Kenny, PM Team 4A
Stephanie Nguyen, Reviewer
Registration Division (RD) (7505C)

From: Gabe Patrick, Biologist
Environmental Risk Branch V
Environmental Fate and Effects Division (EFED) (7507C)

Through: Mah Shamim, Ph.D., Chief
Environmental Risk Branch V
Environmental Fate and Effects Division (7507C)

This memo provides EFED's changes to the Bayer CropScience's (BCS's) draft honeybee field study protocol. The protocol title is: An Investigation of the Potential Long-Term Impact of Clothianidin Seed Treated Canola on Honey Bees, *Apis mellifera* L. EFED recommends that RD assign an MRID No. to this protocol and later submissions. The table below reflects an update of the schedule for completion of this study. EFED proposed this schedule in a 4-7-03 addendum to EFED's Risk Assessment on clothianidin's use as a seed treatment on corn and canola.

Proposed Date	Action	Actual Date
Start (April/May 2003)	Conditional Registration of Clothianidin 600 FS	5/30/03

Proposed Date	Action	Actual Date
60 days (June/July 2003)	Registrant submission of draft protocol	11/28/03 (received by EFED)
120 days (August/September 2003)	EPA response with proposed changes to draft protocol	2/17/04 - 1st reviewer completed review 3/5/04 - 2nd reviewer completed review 3/8/04 - EFED's response completed
180 days (October/November 2003)	Registrant submission of final protocol for approval	
210 days (December 2003/January 2004)	EPA and registrant concur on study	
540 days (1.5 yrs.) (December 2004)	Final completed study submitted to EPA for review	May, 2005 (Bayer requested extension)

Overall we feel good about this protocol and believe it will yield valuable data about clothianidin's long-term effects on honeybee colonies. However, we do have some comments, questions, and changes that BCS needs to address before wrapping up this protocol. As pointed out in schedule, we are behind the proposed completion dates. By the design provided in this protocol, the clothianidin treated seed, plant dates would probably occur the last week of April, 2004 or the first week of May, 2004. The honeyflow and pollen production from theses sites would begin during the first week of July, 2004. BCS, in a 9/30/2003 memo, requested an extension until May, 2005 to complete the study. BCS is seeking this extension to allow time for samples analysis and writing the final report. EFED does not oppose this extension.

These dates mean that it is still possible to have a final agreement on the protocol before implementation which would allow this field study to occur during the 2004 crop growing year. However, should this not prove possible, EFED would recommend delaying this field study until the 2005 growing season. EFED wants usable data to decide the potential adverse effects to bees from clothianidin's seed treatment use and opposes rushing the study and having deficient information.

cc: Christine Cairns, Life Scientist
U. S. Environmental Protection Agency - Region 4

The specific comments, questions, and changes that need to be addressed by the registrant are as follows:

Trial Design

1. BCS recommends using canola as the representative seed treatment crop with test crops located in Ontario, Canada. Ontario is a major canola growing region in North America. Specifically, the test crops' locations are at the University of Guelph's Elora Research Station, Elora, Ontario. Normally EFED would prefer to have representative test crops in the United States (US). US field testing would account for variables caused by farming practices, meteorological conditions and soil conditions unique to the US. However, EFED feels the practices and conditions in Ontario are similar to those in US canola growing regions. The results from this study should provide satisfactory data to make an adverse effect determination for US concerns. EFED also agrees to the use of canola as the test crop since this crop is attractive to bee and will provide bee exposure from both pollen and nectar. An alternative crop, such as corn, which is less attractive to bees as a forage crop, would provide exposure from pollen, only.

2. BCS must include a map in this study which will show the locations of all the test fields and apiaries (including the full apiary). This map will provide the distances between apiaries as well as the distances between apiaries and test canola fields. This map will also provide the locations of any other forage attractions available to the bees within a 10 km radius of each apiary. The map must provide the blooming or pollinating status of the plants during the test period and distances from the test apiaries. EFED assumes the 10 km distance is an unlikely flight distance for foragers but would be a possible flight range given a dearth in forage.

3. BCS states the canola seed treatment rate will be at the proposed US commercial rate. The clothianidin seed treatment rate used in study must be the maximum allowable labeled rate per area for clothianidin. BCS must provide this rate in the study as pounds active ingredient per acre (lb ai/A) or kilograms active ingredient per hectare (kg ai/ha) or both.

4. The protocol mentioned various other pesticide treatments (such as, fungicide, herbicides, and insecticides). When known, BCS must provide the application rates for any pesticides used for any treatment relevant to this study. BCS must provide these rates expressed as pounds active ingredient per acre (lb ai/A) or kilograms active ingredient per hectare (kg ai/ha) or both. At a minimum, BCS must provide the chemical's common name and percent active ingredient of the product used (for example, trifluralin, 44.5% for the product, Treflan®) for all pesticides mentioned. If the product is a multiple active ingredient product, then BCS must provide all active ingredients in the product with their respective active ingredient percentages. BCS must show these other treatments on the map filed with this study.

5. BCS proposes using 6, one hectare size fields of spring canola in this study. BCS will use

three of these fields as clothianidin seed treated fields and will use the remaining three fields as controls. EFED is strongly recommending BCS add an another test field and a control field to this study thus having 4 treatment fields and 4 control fields. Field studies are unpredictable and the use of the extra fields would provide a backup in case something goes wrong with one of the test plots. The extra fields would also increase the statistical significance of this study.

Planting Requirements

EFED has no comments, changes or questions.

Honey Bees

1. BCS intends to place the test hives at the edge of the test canola fields when 20% bloom occurs and remove the test hives when bloom has ended. The study must provide the method used for deciding when 20% canola bloom occurs and when the bloom has ended.

2. BCS will use "beekeeping techniques typical for southern Ontario." The study must provide a summary of these techniques. This summary should include bee management techniques used, the equipment (such as, Langstroth hives, queen excluders, or other) used, number of supers (that is, boxes) for each colony, and the number of frames in each super. BCS must also provide the estimated population sizes of all colonies at critical times during the study, and any extra feeding provided. EFED believes periodic population estimates of each colony is useful in assessing the health of the colonies including mortality rates. EFED assumes a normal colony has about 50,000 bees (Pacific Northwest Extension, 1993).

Colony Assessments

1. To measure bee mortality, BCS proposes counting the number of dead bees in front of each colony every 7 days beginning on Day 7 through the end of the study. BCS will perform this count by laying a linen sheet in front of each colony and counting the dead bees on this sheet. EFED believes mortality measurement to be an important value in this study. The proposed method will not account for dead bees lost to scavengers (for example, birds, mammals, and insects) and wind. EFED wants dead bees counted and collected twice daily at roughly 06:30 and 17:30 to better estimate mortality. These daily collections should begin on Day 1 (when BCS places bees next to the test fields) and continue to the end of the study. BCS needs to collect a sample of the bees and save the sample for possible laboratory analysis. As an alternative to these frequent collections from a sheet, EFED is recommending the use of dead bee traps for the collections. EFED is also recommending BCS use mortalities per day classifications from Todd and Reed (1969). Todd and Reed (1969) proposed the death of 100 bees/day near or inside the hive is "normal", 200-400 bees/day represent "low mortality"; 500-900 "moderate" and more than 1,000 "high mortality".

Worker Assessments

1. To decide how long worker bees are living, BCS states "100 young (48 hr old), marked worker bees will be introduced to each of the colonies at the 6 field locations." BCS will survey these marked worker bees every 10 days until BCS finds no more marked worker bees. At that point, BCS will introduce a second group of marked worker bees to the hives and survey every 10 days until BCS finds none. It is not clear to EFED how BCS will introduce these marked worker bees to the hives or how BCS will conduct the survey. Does BCS intend to remove sealed brood from a hive, mark emerging workers, then reintroduce theses marked workers to the same hive? The marked worker bees origin is not clear to EFED. EFED feels this would be a useful measure of an adult bee's exposure to the clothianidin at the treated sites and after removal from the sites. BCS needs to elaborate on this method and reasoning behind this assessment technique.

2. BCS must supply a method for evaluating the potential disorientation of the forage bees. Are forage bees becoming disoriented and failing to return to the hive from their exposure to clothianidin because of clothianidin's seed treatment use on canola? EFED feels that some assessments in this protocol (such as, the worker longevity assessment, worker mortality assessment and overall colony health assessments) indirectly address this issue. However, EFED wants BCS to devise a more direct measurement for this possible disorientation effect on the bees and include an analysis in this study.

Queen Assessments

EFED has no comments, changes or questions.

Residue Assessment

1. This protocol shows collections of nectar, pollen and beeswax for residue analysis will begin on Day 1 (when BCS places the bees next to the test fields). EFED feels BCS must perform baseline sampling and analysis of nectar, pollen and beeswax before BCS places the bees next to the test fields. In other words, EFED must know the residue levels in the nectar, pollen and beeswax before testing exposure. EFED noted, under the section titled **Honey Bees**, the registant refers to Day 1 as the day the colonies are placed on the edge of test fields. However, under **Colony Assessments**, BCS refers to Day 1 as "24 hours prior to placement in canola." EFED assumes BCS will clarify this inconsistency in the final protocol and BCS intends to perform baseline sampling and analysis.

2. There is no mention of honey residue assessment in this protocol. Past field studies from clothianidin seed treatment uses have shown the presence of clothianidin in nectar from foraging bees' honey stomachs (MRID No. 45422431) and in the stored nectar samples from hives (MRID No. 45422435). The water content of nectar can be as high as 80% whereas the water content of honey is less than 20%. EFED needs to know what, if any,

the clothianidin concentration is in the honey as well as the nectar, pollen and beeswax. BCS must perform sampling and analysis of the honey according to the regimen used for the nectar, pollen and beeswax.

3. BCS must include sampling and analysis of the pollen from the canola, nectar from the canola blooms and nectar from the foraging bees as part of this study. Previous studies (MRID Nos. 45422431 and 45422433) confirmed the presence of clothianidin from canola seed treatment uses in these sample sources. EFED feels BCS must sample and analyze canola nectar and nectar from foraging bees to understand the bees' clothianidin exposure in these studies. EFED believes BCS's use of the Ontario Agricultural College (OAC) pollen trap should adequately assess the residue in the pollen on the test plots. Thus BCS would not need to sample pollen from the canola plants.

Added Inclusions

1. BCS must include weather during test plot planting and later during the honeybee foraging time period on the test plots. BCS must report daily temperatures ranges, daily wind speeds and directions, daily percent cloud cover estimates, and daily precipitation during the foraging time period. During planting BCS must report the daily temperature ranges, daily precipitation and the average soil moisture. BCS can use weather from acceptable local weather reporting stations as a source for this information.

2. BCS must include a characterization of the soil in the test plots which will include the soil type (for example, sandy loam), the percent organic matter and the soil pH.

3. BCS must provide Quality Assurance and Good Laboratory Practices (GLP) compliance statements for the laboratory analysis portion of study. BCS must provide a summary of methods taken to avoid contamination and degradation of the field samples taken during this study. This summary must include how and when BCS delivers the samples to the laboratory for analysis.

4. The study must include signed and dated reports of each of the individual scientists or other professionals involved in the study.

5. BCS must provide all raw data collected with the final report.

References

MRID No. 45422431. Schmuck R. and R. Schöning. 2000. Residues of TI-435 in Nectar Blossoms, Pollen and Honey Bees Sampled from a Summer Rape Field in Sweden and Effects of These Residues on Foraging Honey Bees. Bayer AG, Crop Protection-Development, Leverkusen-Bayerwerk, Germany. Bayer AG, GB Plant Protection, Marketing-Seed Treatment (Dr. Krohn/Altmann), D-40789 Monheim

MRID No. 45422433. Schmuck R. and R. Schöning. 2000. Residues of TI-435 in Nectar Blossoms, Pollen and Honey Bees Sampled from a French Summer Rape Field and Effects of These Residues on Foraging Honey Bees. Bayer AG, Crop Protection-Development, Leverkusen-Bayerwerk, Germany

MRID No. 45422435. Scott-Dupree C.; Spivak, M., Bruns, G.; Blenkinsop, C.; & Nelson, S. 2001. The Impact of GAUCHO® and TI-435 Seed Treated Canola on Honey Bees, *Apis mellifera* L. University of Guelph, Guelph, Ontario, Canada; University of Minnesota, St. Paul, Minnesota, USA; Enviro-Test Laboratories, Edmonton, Alberta, Canada. Bayer Corporation, Agriculture Division, Stilwell, Kansas

Pacific Northwest Extension. Nov. 1993. PNW 245. Evaluating Honey Bee Colonies for Pollination. A Guide for Growers and Beekeepers. Pacific Northwest Extension Publication URL. http://eesc.orst.edu/AgComWebFile/EdMat/PNW245.pdf

Todd, F.K. and C.B. Reed. 1969. Pollen Gathering of honey bees reduced by pesticide sprays. Journal of Economic Entomology. Vol 62 (4). Pp 865-867.

Memorandum

2-17-04

To: Gabe Patrick
From: Christine Cairns
Date: 2/5/04
Subject: Review of clothianidin field study protocol

I have had a chance to review the clothianidin field study protocol, and overall, I feel very good about this protocol as it is. I believe it will yield some very good data on the long term effects on honeybee colonies. However, I do have a few questions and comments about this study that I feel the researcher should address before the study protocol is finalized:

1. They should specify the location of the fall apiary with a brief description of landscape and food source(s). Saying they will use "beekeeping techniques typical for southern Ontario" isn't enough for me to know exactly how the bees will be managed at that point. However, this is mainly due to the fact that my own experience has been in the tropics. If others reviewing this protocol are familiar with what is typical for southern Ontario it may not be necessary for the researcher to expand on that, but for myself it would be.

2. They state that the colonies will be removed from the study fields when canola bloom has ended. I feel they should be a bit more specific because when the canola bloom ends may depend on various factors, and it could be slightly different for each field. It would be a better idea to simply remove all hives after a given number of days, so that at each site the hives will be placed there when 20% of blooms are open and removed *x* days later. Another possibility would be to remove the hives after a given percent of the blooms have dropped. The number of days chosen should give the bees a chance to exhaust a significant portion of the field but not exhaust it totally. If the resources are near exhausted, and you have four hives competing for the remaining nectar and pollen, then some bees will go off and forage elsewhere rather than compete. Although it is stated that no flowering crops will be planted in the vicinity, bees can forage as far as 10 km from the hive. This could pose a risk of cross-contamination in the study if bees start foraging in other fields. Not knowing a lot about the flowering phenology of canola, it is hard for me to suggest an exact number of days or to know how long it would take before the flowers are near tapped, but these are things the researcher should consider.

3. For statistical purposes it may be better to have two additional study fields for a total of N=8 (one more control and one more treated field) so that in case something goes wrong in one of the plots they would have backup and still be able to do a solid analysis on the remaining plots. Six is the absolute minimum for a study like this, so eight would increase statistical significance and decrease the problems that would occur if something did go wrong. Field studies are always a bit unpredictable and it is difficult to exact total control over everything that happens, and since they will only get one shot at this during a very narrow time frame of the canola flowering season, it would be better for them to hedge their bets and go with a higher number of reps. However, if six is the most they can afford to do with their existing resources and manpower then so be it.

4. For the mortality measure, they plan to count the number of dead bees which fall on a light colored linen sheet in front of each colony every seven days. I wondered if they have considered the role of natural predators - isn't it possible that something could eat the dead bees before they get to count them? This would effect the accuracy of the mortality assessment. In my experience you don't normally see lots of dead bees accumulating around a hive. Anything from ants to small reptiles and birds may carry them off. Again, my experience is in the tropics where there may be more of these types of predators and perhaps it is not so much of an issue in southern Ontario, but the researcher should address it and figure out a way to mitigate predation on dead bees if it is a problem. Perhaps using sticky pads instead of just a sheet is a possibility, or counting more frequently than once a week. They can review methodologies of other studies that have tried to keep a measure of hive mortality if they have not already done so.

5. In terms of the longevity assessment, they plan to introduce 100 young marked worker bees on day 4 to track their longevity, and another 100 after the hive has been removed form the canola field. If we are measuring longevity, shouldn't it be based on the bees native to that hive? The first set of bees could be introduced from another hive since at that time the hive will not have been exposed to the canola field for very long, but the second set I would think should be native to the hive, they should be young workers who were raised from the larval stage on honey and pollen extracted from the canola fields. I wasn't clear on where they are planning to get the 100 worker bees they are introducing. At the very least, this should be made clear.

Again, I believe the study overall will yield good results. They are clearly looking at multiple dimensions of the effects of clothianidin including evaluations of bees at all stages, residue analysis, observing queen health, colony weight gain, honey yield, mortality etc. The primary researcher may have already considered some of these issues I just addressed and may have reasons for doing it they way she has chosen to, but if that is the case we should at least know what the reasoning is for choosing to do it this way. Feel free to contact me if you wish to discuss any of my comments or have any questions.

U. S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES (OPPTS)
1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460

DOCKET VERIFICATION AND CERTIFICATION FORM

For Internal OPPTS Use Only

Title of Action:

RIN #: 2070-	Docket ID #: OPP-2004-0087	FRL#:
Docket Title: Notice of Filing		
Contact Information:	Name: Stephanie Nguyen	Phone: 605-0702
Legacy Information:		

Program Lead's Verification: I have reviewed the docket and verified the following:

- ☐ All of the documents identified in the attached Docket Index have been submitted to the appropriate Docket Manager for inclusion in the docket identified above.
- ☐ Documents containing copyrighted, CBI or otherwise protected information have been identified to allow for "special" processing by the docket.
- ☐ The material has been assembled in a useable form to support the document being published in the FEDERAL REGISTER.
- ☒ Comments: No support Documents

Date: 3/9/04	Initials:	Phone: 703-605-0702

Docket Manager's Verification and Sign-off: I hereby confirm the following:

- ☐ The Docket ID # identified above matches our records.
- ☐ The documents identified in the attached Docket Index have been received by the Docket.
- ☐ The documents have been properly processed for inclusion in EPA Dockets, as appropriate.
- ☐ The documents either already are in the docket or are being process for inclusion in the docket.
- ☒ Comments: No Support Documents

Date: 3/9/04	Signature: Monica Daniels	Phone: 308-0410

Program Lead's Certification: I hereby certify that:

- ☐ I have completed the verification above.
- ☐ I have submitted to the DM all of the documents that I identified needed to be updated, or added to the docket.
- ☐ I have obtained the DM's sign-off.
- ☐ The docket is complete and ready for public release.
- ☐ Comments:

Date:	Signature:	Phone:

Attachment: List of Documents Included in this Docket

Poncho™ 600

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insect pests.
All seed treated with this product must be conspicuously coloured at the time of treatment.

ACTIVE INGREDIENT:
Clothianidin 48.0%
INERT INGREDIENTS: 52.0%
Contains 5 lbs. active ingredient per gallon. **TOTAL** 100.0%

E.P.A. Reg. No. 264-789 **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:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • 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.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.
Have the 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.

PRECAUTIONARY STATEMENTS

CAUTION
HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables, 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. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment 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. Contain any product spills or equipment leaks and dispose of wastes according to disposal instructions on this label. Do not contaminate water when disposing of equipment washwaters.

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 by commercial treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting. This product is to be used in commercial liquid or slurry treaters. Mix thoroughly before use or use entire container at one time.

All seed treated with this product must be conspicuously coloured at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by *40 CFR 153.155* must be strictly adhered to when using this product.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SEED QUALITY AND STORAGE OF TREATED SEED

Treatment of highly mechanically damaged seed, or seed of known low vigor or 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.

LABELLING OF TREATED SEED

Seed commercially treated with Poncho™ 600 must be labelled in compliance with the *Federal Seed Act*.

All bags containing treated seed must be labelled or tagged as follows:

- This seed has been treated with Poncho™ 600 seed protectant, which contains clothianidin.
- Do not use treated seed for feed, food or oil processing.
- Rapeseed greens and seed grown or harvested from Poncho™ 600-treated seed must not be used for feed or human consumption. Rapeseed grown and harvested from Poncho™ 600-treated seed is only for industrial uses and can not be used for edible oil or any other human/feed consumption.
- Store away from feeds and other foodstuffs.
- Wear long-sleeved shirt, long pants and waterproof gloves when handling treated seed
- Dispose of all excess treated seed. Left over treated seed may be doublesown 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.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, and dried beans. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

GENERAL INFORMATION

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insects.

For use in commercially available equipment designed for seed treatment only. Not for use in hopper-box, slurry-box, or similar seed treatment applications used at planting. This product is to be used in liquid or slurry treaters. Mix thoroughly before use or use entire

container at one time. All tank mixes should be pre-tested to determine physical compatibility between formulations. Observe all cautions and limitations on labeling of all products used in mixtures.

For Early Season Protection Against Certain Insects:

Poncho™ 600 will aid in the protection of seeds and seedlings against injury by certain early season insects.

RECOMMENDED APPLICATIONS

CROP	INSECT PESTS	RATE PONCHO™ 600	
		mg a.i./Kernel	80,000 Unit of Seed
CORN (INCLUDING FIELD, SWEET AND POP)	Corn rootworm (including Northern, Western, Southern and Mexican) Southern corn billbug[1]	1.25	5.64 fl. oz. or 166.7 mL
	Chinch bug Corn flea beetle Corn leaf aphid Cutworm, black Imported Fire Ant Grape colaspis Seedcorn maggot Southern corn leaf beetle Southern corn rootworm Southern green stinkbug Storage pests[2] (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) Sugarcane beetle White grub (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Thrips Wireworm	0.25	1.13 fl. oz or 33.3 mL
	Corn flea beetle (through first true seed leaf) Imported Fire Ant Seedcorn maggot[3] Storage pests[2] (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) White grub[3] (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Wireworm[3]	0.125	0.57 fl. oz or 16.7 mL

CROP	INSECT PESTS	RATE PONCHO™ 600	REMARKS
CANOLA RAPESEED	Flea beetle Wireworm	3.84 fl. oz per 100 lbs. seed or 250 mL per 100 kg seed	Use this rate under **low to moderate** flea beetle pressure.
		5.12 fl. oz per 100 lbs. seed or 333 mL per 100 kg seed	Use this rate under **moderate** flea beetle pressure.
		10.23 fl. oz per 100 lbs. seed or 666 mL per 100 kg seed	Use this rate under **high to extreme** flea beetle pressure where extended control is required.

[1] Follow-up foliar sprays of a locally registered insecticide may be needed under heavy pest pressure. Consult your local Extension office for recommendations.

[2] It is recommended that seed with existing populations of storage pests be fumigated prior to treating and bagging seed.

[3] For seed protection only.

CROP	INSECT PESTS	RATE PONCHO™ 600	REMARKS
SORGHUM	Black granulate cutworm Aphid (including Greenbug, Yellow sugarcane aphid, Corn leaf aphid and English grain aphid) Chinch bugs Imported fire ants White grubs Wireworms	5.1 to 6.4 fl. oz per 100 lbs. seed	Apply prior to planting as a slurry treatment to provide early season protection of seedlings. Ensure thorough coverage.

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.

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 should 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: 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. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: 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 CROPSCIENCES ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS: 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™ 600 (PENDING) Submitted 11/17/03.

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

December 30, 2003

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

BAYER CROPSCIENCE LP
2 T.W. ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, NC 27709

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 02-DEC-03. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Tolerance Petition

Registration Division, Risk Management Team 1

Fee Waived: Yes No Fee:

Petition Type: F - Raw Agricultural Commodity

Application Date: 01-Dec-2003 OPP Rec'vd Date: 02-Dec-2003

Front End Date: 03-Dec-2003 Risk Manager Send Date: 03-Dec-2003

Studies: New Ingredient:

Receipt Description:

Clothianidin in/on sorghum

Receipt for Section 3

Post Letter

Enter More Information

Registration Type: Product Registration - Section 3

Application Type: Amendment

Risk Manager: Registration Division, Risk Management Team 1

Product #: 284-789 Product Name: PONCHO 600

Me Too Section: Me Too Product Name:

Application Date: 01-Dec-2003 OPP Rec'vd Date: 02-Dec-2003

Front End Date: 05-Dec-2003 Risk Manager Send Date: 05-Dec-2003

Fast Track: Studies: New Ingredient:

Receipt Description:

FILE NAME: company.wpt (4/1/2001)

ATTENTION: All commodity terms must comply with the Food and Feed Commodity Vocabulary database (http://www.epa.gov/pesticides/foodfeed/).

COMPANY FEDERAL REGISTER DOCUMENT SUBMISSION TEMPLATE (4/1/2001)

EPA Registration Division contact: [Daniel C. Kenny, 703.305.7546.]

INSTRUCTIONS: Please utilize this outline in preparing tolerance petition documents. In cases where the outline element does not apply please insert "NA-Remove" and maintain the outline. The comment notes that appear on the left margin represent hidden typesetting codes designed to expedite the processing of the **Federal Register** document. Please do not remove or alter these comment notes or change the margins, font, or format in your document. Simply replace the instructions that appear in italics and brackets, i.e., "[*insert company name*]," with the information specific to your action.

[Insert petition number]

Summary of Petitions.

EPA has received a pesticide petition ([XXXXX]) from **[Bayer CropScience], [2.T. W. Alexander Drive, Research Triangle Park, NC 27709]** proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of **clothianidin** in or on the raw agricultural commodities **[sorghum, grain; sorghum, forage and sorghum, stover]** at **[0.01, 0.01, and 0.01]** parts per million (ppm), respectively. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* In plants, the metabolism of clothianidin is adequately understood for the purposes of establishing these proposed tolerances. Unchanged parent clothianidin was the predominant residue in all crop matrices (14.4% to 64.5% in corn, 66.1% to 96.6% in tomatoes, 4.3% to 24.4% in sugar beets and 24.3% to 63.3% in apples), with the exception of sugar beet leaves. In sugar beet leaves, the main components were the methylguanidine and

thiazolylmethylguanidine metabolites, accounting for 28.6% and 27.7%, respectively. All metabolites found in plants were also found in the animal metabolism studies. In animals, parent clothianidin was the major component in liver, muscle and fat. Based on the available metabolism data, parent clothianidin, thiazolyl-guanidine (TZG), thiazolyl-urea (TZU) , and (ATMG-Pyr) aminothiazolyl methylguanidine-pyridine are proposed to be considered as the residues of concern in livestock matrices.

2. *Analytical method.* In plants and plant products, the residue of concern, parent clothianidin, can be determined using High Performance Liquid Chromotography (HPLC) with Electrospray MS/MS detection. In an extraction efficiency testing, the plant residues method has also demonstrated the ability to extract aged clothianidin residue.

Although the plant residues LC-MS/MS method is highly suitable for enforcement method, an LC-UV method has also been developed which is suitable for enforcement (monitoring) purposes in all relevant matrices.

3. *Magnitude of residues in sorghum* - A total of 12 field trials was conducted to evaluate the quantity of clothianidin in sorghum forage, stover and grain. Sorghum seed was treated with TI-435 600 FS at a rate of 250 g ai/100 kg seed. The highest average field trial was less than 0.01 ppm in sorghum forage, stover and grain when collected at normal harvest of 97 to 167 days after planting of treated seed. In a sorghum processing study sorghum seed was treated at a 2X rate of 500 g ai/100 kg seed. No residues at or above the LOQ of 0.01 ppm were found in the sorghum grain. Therefore, a sorghum processing study was not conducted.

B. Toxicological Profile

1. *Acute toxicity.* The acute oral LD_{50} was >5,000 milligrams/ kilograms/ body weight (mg/kg bw) for both male and female rats. The acute dermal LD_{50} was greater than 2,000 mg/kg bw in rats. The 4-hour inhalation LC_{50} was 5.538 mg/L for male and female rats. Clothianidin was not irritating to rabbit skin and only slightly irritating to the eyes and did not cause skin sensitization in guinea pigs.

2. *Genotoxicty.* Extensive mutagenicity studies were conducted with clothianidin. Based on the weight of evidence clothianidin was considered negative for genotoxicity.

3. *Reproductive and developmental toxicity.* In a 2-generation reproduction study, rats were administered dietary levels of 0, 150, 500 and 2,500 ppm. The No Observed Effect Level (NOAEL) for reproductive parameters was 500 ppm (31.2/36.8 mg.kg/day; M/F) while the NOAEL for developmental effects was 150 ppm (9.8/11.5 mg/kg/day; M/F). The parental systemic NOAEL was 500 ppm (31.2/36.8 mg/kg/day; M/F).

A developmental toxicity study was conducted in rats with clothianidin using dose levels of 0,

10, 50 and 125 mg/kg bw by gavage. The NOAEL for maternal toxicity was established at 10 mg/kg bw and for developmental effects it was >125 mg/kg bw. Additionally, a developmental toxicity study was conducted with rabbits treated orally by gavage at 0, 10, 25, 75 and 100 mg/kg bw. The NOAEL for maternal toxicity was 25 mg/kg bw and for developmental toxicity it was 75 mg/kg bw.

Developmental toxicity studies showed no primary developmental toxicity and no teratogenic potential was evident.

4. *Subchronic toxicity.* Ninety-day feeding studies were conducted in rats and dogs. The rat study was conducted at dietary levels of 0, 150, 500 and 3,000 ppm and the dog study was conducted at 0, 325, 650 and 1,500 ppm. The NOAELs were established at 500 ppm (27.9/34.0 mg/kg/day; M/F) for rat and 650 ppm (19.3 mg/kg/day) for the female dog and 1,500 ppm (42.1 mg/kg/day) for the female dog.

5. *Chronic toxicity.* A 2- year combined rat chronic / oncogenicity conducted at dietary levels of 0, 150, 500, 1,500 and 3,000 ppm demonstrated a NOAEL of 500 ppm (27.9/34.0 mg/kg/day) based on reduced weight gains and non-neoplastic histomorphological changes. A 78-week mouse oncogenicity study conducted at dose levels of 0, 100, 350, 1,250 and 2,000, and 1,800 ppm for males and females, respectively, revealed a NOAEL of 350 ppm (47.2/65.1 mg/kg/day; M/F) based on reduced body weight gains and increased incidence of hypercellular hypertrophy. No evidence of oncogenicity was seen in the rat or the mice. A 52-week chronic toxicity study in dogs conducted at dietary levels of 0, 325, 650, 1,500 and 2,000 ppm revealed a NOAEL of 2,000 ppm (46.4 mg/kg/day) for the male dog and 1,500 ppm (40.1 mg/kg/day) for the female dog.

6. *Animal metabolism.* The nature of the clothianidin residue in livestock is adequately understood. In animals, parent clothianidin was the major component in liver, muscle and fat. Based on the available metabolism data, parent clothianidin, TZG, TZU, and ATMG-Pyr are proposed to be considered as the residues of concern in livestock matrices.

7. *Metabolite toxicology.* Eight *in vivo* metabolites of clothianidin identified in the rat were investigated for acute oral endpoint mutagenic activity. None of the metabolites were mutagenic either with or without activation and the LD_{50} values range from <500 to >2,000 mg/kg, showing low to moderate toxicity.

8. *Endocrine disruption.* All guideline studies conducted to characterize toxicological profile showed no endocrine related toxicity or tumorgenicity. No effects on triiodothyronine (T3), throxine (T4) or thyroid stimulating hormone (TSH) were observed in the subchronic rat study. In a 2-generation reproduction study in rat; and rat and rabbit teratology studies, clothianidin did not show reproductive or teratogenic effects. The extensive database shows that clothianidin has no endocrine properties.

C. Aggregate Exposure

1. *Dietary Exposure.* There are no residential uses for clothianidin therefore aggregate exposure consists of dietary (food and drinking water) exposures. The acute population adjusted dose (aPAD) of 0.025 mg/kg bw/day based on a acute NOAEL of 25 with an uncertainty factor of 1,000 was used to assess acute dietary exposure. The chronic population adjusted dose (cPAD) of 0.0098 mg/kg bw/day based on a chronic NOAEL of 9.8 with an uncertainty factor of 1,000 was used to assess chronic exposure.

i. *Food.* In the Clothianidin Pesticide Tolerance Action for Corn and Canola of May 30, 2003 EPA conducted Tier 1 acute and chronic dietary assessments for clothianidin. These assessments included residues of clothianidin that arise from the uses of thiamethoxam which has clothianidin as a common metabolite. Based on these assessments, a tolerance of 0.01 ppm for sorghum use for clothianidin was added to the analysis. No significant contribution was seen from this use. The US Population utilized 8.4% (0.00211 mg/kg bw/day, 95th percentile) of the aPAD and 6.5% (0.000635 mg/kg bw/day) of the cPAD. The most highly exposed sub-population is Children 1-2 at 19.1% (0.004772 mg/kg bw/day, 95th percentile) of the aPAD and 19.1% (0.001874 mg/kg bw/day) of the cPAD.

ii. Drinking Water. US EPA's Standard Operating Procedure (SOP) for Drinking Water Exposure and Risk Assessments was used to perform the drinking water assessment. This SOP uses a variety of tools to conduct drinking water assessment. These tools include water models such as SCI-GROW, FIRST, PRZM/EXAMS, and monitoring data. If monitoring data are not available then the models are used to predict potential residues in surface and ground water and the highest is assumed to be the drinking water residue. In the case of clothianidin monitoring data do not exist therefore SCI-GROW and FIRST were used to estimate a water residue. The calculated drinking water levels of comparison (DWLOC) for acute chronic exposure for all adults and children exceed the estimated drinking water concentrations (EDWC) from the models. The chronic DWLOC for adults is 321 ppb and the acute DWLOC is 801 ppb. The chronic DWLOC for children 1-2 is 79 ppb and the acute DWLOC is 202 ppb. The EDWC for the worst case chronic scenario is 2.14 ppb (FIRST) and the acute EDWC (FIRST) is 3.97 ppb. The drinking water levels of comparison are based on conservative dietary (food) exposures and are expected to be much higher in real world situations.

2. Non-dietary Exposure. Clothianidin products are not labeled for residential uses (food or non-food), thereby eliminating the potential for residential exposure or non-occupational exposure.

D. Cumulative Effects

Clothianidin is a metabolite of thiamethoxam. Therefore, residues of clothianidin resulting from use of thiamethoxam were included in the above risk assessment. There are no data available to indicate that toxic effects produced by clothianidin are cumulative with those of any other compound.

E. Safety Determination

1. *US Population.* Using the conservative exposure assumptions described above and based on the completeness of the toxicity data, it can be concluded that aggregate exposure to residues of clothianidin present a reasonable certainty of no harm. Exposure from residues in crops utilize 8.4% of the aPAD and 6.5% of the cPAD. EPA generally has no concerns for exposures below 100% of the Population Adjusted Doses. Drinking water levels of concern are well above the estimated drinking water concentrations as calculated by conservative models. There are no residential uses so aggregate exposure consists of food and drinking water exposures. The conservative Tier 1 assessments demonstrate a reasonable certainty of no harm will result from uses of clothianidin for the US Population.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of clothianidin, the data from developmental toxicity studies in both the rat and rabbit, a 2-generation reproduction study in rats and a developmental neurotoxicity study in rats have been considered.

The developmental toxicity studies evaluate potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates effects from exposure to the pesticide on the reproductive capability of mating animals through two generations, as well as any observed systemic toxicity.

The developmental neurotoxicity studies evaluate the neurobehavioral and neurotoxic effects on the developing animal resulting from the exposure of the mother. FFDCA Section 408 provides that EPA may apply an additional uncertainty factor for infants and children based on the threshold effects to account for prenatal and postnatal effects and the completeness of the toxicity database. Based on the current toxicological data requirements the toxicology database for clothianidin relative to prenatal and postnatal development is complete, including the developmental neurotoxicity study. None of the studies indicated the offsprings to be more sensitive. All effects were secondary to severe maternal toxicity. Therefore, no additional safety or uncertainty factor is justified.

F. International Tolerances

No CODEX Maximum Residue Levels (MRL's) have been established for residues of clothianidin on any crops at this time.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DEC 24 2003

Jamin Huang, Ph.D
Registration Product Manager
Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Subject: EPA Reg. No.: 264-789
Poncho 600
Updated Confidential Statements of Formula
Submission Dated October 22, 2003

Dear Dr. Huang :

The updated Confidential Statements of Formula (CSFs) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are acceptable.

If you have any questions or comments about this letter, please contact Stephanie Nguyen at 703-605-0702.

Sincerely,

Daniel C. Kenny
Product Manager (01)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

Bayer CropScience

October 22, 2003

Ms. Stephanie Nguyen
Document Processing Desk
Office of Pesticide Programs (7504C)
Registration Division
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202-4501

Re: Poncho 600 (EPA Reg. No. : 264-789)

Updated Confidential Statements of Formula

Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709
Phone: 919 549-2000

Dear Ms. Nguyen,

Bayer CropScience is herein submitting two updated Confidential Statements of Formula for Poncho 600 (1 basic and 1 alternate) for your review and approval. The only changes made are listed below. All other contents remain unchanged relative to the CSF dated March 28, 2001 (basic) or November 5, 2002 (alternate).

1) Company name and address in Boxes # 1 and 2 [from Bayer Corporation to Bayer CropScience]

2) Product name in Box # 3 [from Clothianidin 600FS to Poncho 600]

3) Registration number in Box # 4 [from 3125- to 264-789]

4) EPA product manager name in Box # 5 [to Daniel C. Kenny, to be consistent in all clothianidin CSFs].

5) Nominal concentration of Clothianidin Technical in Box # 10 [from 98% nominal concentration to 97.5%, per the October 20, 2003 approval]

6) Supplier name of clothianidin technical in Box # 11 [from Takeda Chemical Industries Ltd. to Sumitomo Chemical Takeda Agro Co. Ltd.]

160

7) EPA Reg. No. of clothianidin technical in Box # 12 [to 74207-1]

8) Each components in formulation for clothianidin technical in Box # 13 (page 1) to reflect the change in nominal concentration to 97.5% from 98% [amount: [redacted]

9) Each components in formulation for water in Box # 13 (page 2) to reflect the change in nominal concentration of clothianidin technical to 97.5% from 98% [amount: [redacted]

10) Purpose in Formulation for [redacted] in Box # 15 [from [redacted] per the suggestion # 4b in the June 24, 2003 Product Chemistry Review, DP Code: D288402]

11) BCS reference information in Boxes # 16, 18, 19, 20 and 21.

In support of the above-described update, we are herein submitting the following:

1. Application for Pesticide Amendment (EPA Form 8570-1) dated October 22, 2003.

2. Five copies of each of the updated CSF for Poncho 600 dated June 1, 2003 (basic), and June 2, 2003 (alternate).

3. One copy of each of the CSF for Poncho 600 dated March 28, 2001 (basic) and November 5, 2002 (alternate) respectively for your convenient comparison with the updated CSFs listed above. All of the boxes that were updated are highlighted in yellow.

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

Sincerely,

Jamin Huang, Ph.D.
Product Registration Manager

Attachments

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 264-789	2. EPA Product Manager: Daniel C. Kenny	3. Proposed Classification: ☑ None ☐ Restricted
4. Company/Product (Name): Poncho 600	PM# 01	
5. Name and Address of Applicant *(Include ZIP Code)*: Bayer Cropscience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709 ☐ *Check if this is a new address*	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

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

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

Two CSFs (1 basic and 1 alternate) for Poncho 600 are updated. All changes are the update of data such as company name (updated), Product name (to Poncho 600), EPA Reg. No. (to 264-789), Product Reg manager name, the nominal concentration of technical (to 97.5%) per the EPA Oct. 20, 2003 approval, etc..

Section - III

1. Material This Product Will Be Packaged In:

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

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ ON 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)
Jamin Huang, Ph.D.	Registration Product Manager	919-549-2634

Certification

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

2. Signature	3. Title: Registration Product Manager	6. Date Application Received (Stamped)
4. Typed Name: Jamin Huang, Ph.D.	5. Date: October 22, 2003	

Bayer CropScience

October 21, 2003

Ms. Stephanie Nguyen
Document Processing Desk
Office of Pesticide Programs (7504C)
Registration Division
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202-4501

Re: Revised Final Printed Label of Poncho 600 (EPA Reg. No. 264-789)

Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709
Phone: 919 549-2000

Dear Ms. Nguyen,

In compliance with your request in the October 20, 2003 approval of label amendment to add a new rate for Poncho 600 (EPA Registration Number 264-789), we are herein submitting one copy of the revised final printed label dated October 20, 2003 for your records.

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

Sincerely,

Jamin Huang, Ph.D.
Product Registration Manager

attachment

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated
OCT 20 2003

Poncho™ 600

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insect pests.
All seed treated with this product must be conspicuously coloured at the time of treatment.

ACTIVE INGREDIENT:
Clothianidin 48.0%
INERT INGREDIENTS: 52.0%
Contains 5 lbs. active ingredient per gallon. **TOTAL** 100.0%

E.P.A. Reg. No. 264-789 **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:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • 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.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.
Have the 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.

PRECAUTIONARY STATEMENTS

CAUTION
HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables, 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. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment 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. Contain any product spills or equipment leaks and dispose of wastes according to disposal instructions on this label. Do not contaminate water when disposing of equipment washwaters.

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 by commercial treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting. This product is to be used in commercial liquid or slurry treaters. Mix thoroughly before use or use entire container at one time.

All seed treated with this product must be conspicuously coloured at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by *40 CFR 153.155* must be strictly adhered to when using this product.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SEED QUALITY AND STORAGE OF TREATED SEED

Treatment of highly mechanically damaged seed, or seed of known low vigor or 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.

LABELLING OF TREATED SEED

Seed commercially treated with Poncho™ 600 must be labelled in compliance with the *Federal Seed Act*.

All bags containing treated seed must be labelled or tagged as follows:

- This seed has been treated with Poncho™ 600 seed protectant, which contains clothianidin.
- Do not use treated seed for feed, food or oil processing.
- Rapeseed greens and seed grown or harvested from Poncho™ 600-treated seed must not be used for feed or human consumption. Rapeseed grown and harvested from Poncho™ 600-treated seed is only for industrial uses and can not be used for edible oil or any other human/feed consumption.
- Store away from feeds and other foodstuffs.
- Wear long-sleeved shirt, long pants and waterproof gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be doublesown 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.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, and dried beans. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

GENERAL INFORMATION

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insects.

For use in commercially available equipment designed for seed treatment only. Not for use in hopper-box, slurry-box, or similar seed treatment applications used at planting. This product is to be used in liquid or slurry treaters. Mix thoroughly before use or use entire container at one time. All tank mixes should be pre-tested to determine physical compatibility between formulations. Observe all cautions and limitations on labeling of all products used in mixtures.

For Early Season Protection Against Certain Insects:

Poncho™ 600 will aid in the protection of seeds and seedlings against injury by certain early season insects.

RECOMMENDED APPLICATIONS

CROP	INSECT PESTS	RATE PONCHO™ 600	
		mg a.i./Kernel	80,000 Unit of Seed
Corn (including field, sweet and pop)	Corn rootworm (including Northern, Western, Southern and Mexican) Southern corn billbug[1]	1.25	5.64 fl. oz. or 166.7 mL
	Chinch bug Corn flea beetle Corn leaf aphid Cutworm, black Grape colaspis Seedcorn maggot Southern corn leaf beetle Southern green stinkbug White grub (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Thrips Wireworm	0.25	1.13 fl. oz or 33.3 mL
	Wireworm * White grub * Seedcorn maggot * Corn flea beetle (through first true seed leaf) * For seed protection only	0.125	0.57 fl. oz or 16.7 mL

CROP	INSECT PESTS	RATE PONCHO™ 600	REMARKS
Canola Rapeseed	Flea beetle Wireworm	3.84 fl. oz per 100 lbs. seed or 250 mL per 100 kg seed	Use this rate under low to moderate flea beetle pressure.
		5.12 fl. oz per 100 lbs. seed or 333 mL per 100 kg seed	Use this rate under moderate flea beetle pressure.
		10.23 fl. oz per 100 lbs. seed or 666 mL per 100 kg seed	Use this rate under high to extreme flea beetle pressure where extended control is required.

[1] Follow-up foliar sprays of a locally registered insecticide may be needed under heavy pest pressure. Consult your local Extension office for recommendations.

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.

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 should 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: 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. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: 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: 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™ 600 (MASTER) Approved 10/20/03.

IRB

Bayer CropScience

September 30, 2003

Ms. Stephanie Nguyen
Document Processing Desk
Office of Pesticide Programs (7504C)
Registration Division
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202-4501

Re: Poncho 600 (EPA Reg. No. 264-789)

Submission of Draft Protocol of a Honeybee Field Study for Review

Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709
Phone: 919 549-2000

Dear Ms. Nguyen,

Attached please find five (5) copies of a draft protocol for a research study to investigate any possible chronic effects of clothianidin on bees, as requested in the memo from EFED on April 7, 2003 and in the May 30, 2003 Notice of Pesticide Registration for Poncho 600.

We have developed the protocol in collaboration with Dr. Cynthia Scott Dupree, a very experienced bee researcher from the University of Guelph. We believe that this protocol covers all of the specific requirements and endpoints detailed in the April, 2003 memo. We recommend carrying out the study in canola, as this represents the 'worst case' exposure scenario for bees. We also recommend carrying out the study in Ontario, Canada, as this represents a major canola region in North America. The only change we need to make concerns the timing of the experiments. The original request was for completion of the study at the end of 2004. However, we cannot start the 'field' portion of the study until the canola starts to bloom (around beginning of July). We then need to keep the colonies for two full life cycles (approximately 130 days), which means that the last samples will not be collected until November/December, 2004. To allow time for sample analysis and writing the report, we request an extension until May 2005.

My counterpart in Canada, Roy Lidstone, will also provide PMRA this protocol. We would be happy to meet with you and scientists in EFED and discuss this protocol in more detail. We could also have a joint meeting with PMRA to discuss this protocol. Please let us know how you would like to proceed.

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

Sincerely,

Jamin Huang, Ph.D.
Product Registration Manager

Cc: Roy Lidstone (Bayer CropScience in Canada)

Attachment

Pamela Hurley
10/21/03 01:26 PM

To: Yan Donovan/DC/USEPA/US@EPA
cc: Stephanie Nguyen/DC/USEPA/US@EPA
Subject: Re: DERs for Clothiandin Reg. # 044309

Nope. Sorry, I cannot send the tox. DERs out. They are stuck in HED forever or until I retire or leave and someone just happens to find them in my bookcase. They are caught in the endless do loop of IHAD.

I don't have enough time between projects to get the DERs to the point that someone can put them into the IHAD database system. The ones for clothianidin were done by PMRA. Because of that, I have to redo each one putting in the TXR number and some other corrections or the person who puts them in will send them back to me. I have 3-4 chemicals waiting in line and will have to work weekends to get them in. So, clothianidin won't go out for months because I don't have time to get to them. Also, I cannot get them signed off by our contract person because PMRA did the DERs and didn't fill out the green sheets. He won't sign them unless I make up something ficticious on the green sheets. Because I cannot get signatures, I cannot get the person who puts stuff into IHAD to put them in. So, in the long run, I have to do it all myself. However, I still won't be able to get any signatures on them because they weren't done in the conventional way, so even then I don't know if I'll ever be able to get them out of here unless I am given a couple of months to do just IHAD and will then have the time to look at the original DERs from the contractor, compare them with the PMRA DERs and then write down every detailed change that PMRA made on the green sheets.

Yan Donovan

Yan Donovan
10/21/03 12:50 PM

To: Pamela Hurley/DC/USEPA/US@EPA
cc:
Subject: DERs for Clothiandin Reg. # 044309

Pam:

Can you send the tox DERs to Stephanie? Thanks

---- Forwarded by Yan Donovan/DC/USEPA/US on 10/21/2003 12:52 PM ----

Stephanie Nguyen
10/20/2003 01:51 PM

To: Yan Donovan/DC/USEPA/US@EPA
cc:
Subject: DERs for Clothiandin Reg. # 044309

Yan:

I am following up on the Registrant 's request concerning DERS in the toxicology and residue areas for the following product. AI # 044309, EPA Reg. #264-789.

Thanks
Stephanie

Jamin Huang
<jamin.huang@bayercropscience.com>

10/21/03 07:33 AM

To: Stephanie Nguyen/DC/USEPA/US@EPA
cc:
Subject: your fax - Poncho 600

Dear Stephanie,

Your fax has been received. Thank you for approving these two amendments - label and CSF.

A heads-up about clothianidin at BCS:

1. With the approval of the revised CSF for clothianidin technical (with 97.5% nominal concentration), we will submit a revised CSF for Poncho 600 with the only change on the nominal concentration of TGAI (from 98% to the current 97.5%) to you for approval. The purpose is to make the new value consistent across the board.

2. We are preparing a submission package to add the use of Poncho 600 on sorghum via seed treatment use. Hopefully, we could submit it by the end of November.

Best Regards,
Jamin

****

Jamin Huang, Ph.D.
Registration Product Manager
Bayer CropScience

tel: 919-549-2634
e-mail: jamin.huang@bayercropscience.com

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

OCT 20 2003

Jamin Huang, Ph.D
Registration Product Manager
Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Subject: EPA Reg. No.: 264-789
Poncho 600
Label Amendment to Add a New Rate
Submission Dated July 10, 2003
Revised Confidential Statements of Formula
Submission Dated July 8, 2003

Dear Dr. Huang:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records. Please submit one (1) final printed copy for the above mentioned label before releasing the product for shipment.

The Agency has also reviewed your submission for the revised Confidential Statements of Formula dated July 8, 2003 for the Basic and Alternate formulations. It has been determined that the Confidential Statements of Formula agree with the label claim in compliance with PR Notice 91-2 and are acceptable. The Confidential Statements of Formula have been added to your file as part of the record.

A detailed review of the product chemistry is also enclosed for your records. If you have any questions or comments about this letter, please contact Stephanie Nguyen at 703-605-0702.

Sincerely yours,

Daniel C. Kenny
Product Manager (01)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

Poncho™ 600

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insect pests.
All seed treated with this product must be conspicuously coloured at the time of treatment.

ACTIVE INGREDIENT:
Clothianidin 48.0%
INERT INGREDIENTS: 52.0%
Contains 5 lbs. active ingredient per gallon. **TOTAL** 100.0%

E.P.A. Reg. No. 264-789 **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:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • 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.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.
Have the 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 symptometically.

PRECAUTIONARY STATEMENTS

CAUTION
HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ACCEPTED
OCT 20 2003
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 264-789

USER SAFETY RECOMMENDATIONS

Users should: Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment 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. Contain any product spills or equipment leaks and dispose of wastes according to disposal instructions on this label. Do not contaminate water when disposing of equipment washwaters.

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 by commercial treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting. This product is to be used in commercial liquid or slurry treaters. Mix thoroughly before use or use entire container at one time.

All seed treated with this product must be conspicuously coloured at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by *40 CFR 153.155* must be strictly adhered to when using this product.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SEED QUALITY AND STORAGE OF TREATED SEED

Treatment of highly mechanically damaged seed, or seed of known low vigor or 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.

LABELLING OF TREATED SEED

Seed commercially treated with Poncho™ 600 must be labelled in compliance with the *Federal Seed Act*.

All bags containing treated seed must be labelled or tagged as follows:

- This seed has been treated with Poncho™ 600 seed protectant, which contains clothianidin.
- Do not use treated seed for feed, food or oil processing.
- Rapeseed greens and seed grown or harvested from Poncho™ 600-treated seed must not be used for feed or human consumption. Rapeseed grown and harvested from Poncho™ 600-treated seed is only for industrial uses and can not be used for edible oil or any other human/feed consumption.
- Store away from feeds and other foodstuffs.
- Wear long-sleeved shirt, long pants and waterproof gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be doublesown 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.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, and dried beans. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

GENERAL INFORMATION

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insects.

For use in commercially available equipment designed for seed treatment only. Not for use in hopper-box, slurry-box, or similar seed treatment applications used at planting. This product is to be used in liquid or slurry treaters. Mix thoroughly before use or use entire container at one time. All tank mixes should be pre-tested to determine physical compatibility between formulations. Observe all cautions and limitations on labeling of all products used in mixtures.

For Early Season Protection Against Certain Insects:

Poncho™ 600 will aid in the protection of seeds and seedlings against injury by certain early season insects.

RECOMMENDED APPLICATIONS

CROP	INSECT PESTS	RATE PONCHO™ 600	
		mg a.i./Kernel	80,000 Unit of Seed
Corn (including field, sweet and pop)	Corn rootworm (including Northern, Western, Southern and Mexican) Southern corn billbug[1]	1.25	5.64 fl. oz. or 166.7 mL
	Chinch bug Corn flea beetle Corn leaf aphid Cutworm, black Grape colaspis Seedcorn maggot Southern corn leaf beetle Southern green stinkbug White grub (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Thrips Wireworm	0.25	1.13 fl. oz or 33.3 mL
	Wireworm * White grub * Seedcorn maggot * Corn flea beetle (through first true seed leaf) * For seed protection only	0.125	0.57 fl. oz or 16.7 mL

CROP	INSECT PESTS	RATE PONCHO™ 600	REMARKS
Canola Rapeseed	Flea beetle Wireworm	3.84 fl. oz per 100 lbs. seed or 250 mL per 100 kg seed	Use this rate under low to moderate flea beetle pressure.
		5.12 fl. oz per 100 lbs. seed or 333 mL per 100 kg seed	Use this rate under moderate flea beetle pressure.
		10.23 fl. oz per 100 lbs. seed or 666 mL per 100 kg seed	Use this rate under high to extreme flea beetle pressure when extended control is required.*

[1] Follow-up foliar sprays of a locally registered insecticide may be needed under heavy pest pressure. Consult your local Extension office for recommendations.

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.

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 should 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: 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. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: 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 CROPSCIENCES ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS: 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™ 600 (PENDING) Submitted 7/10/03.

Jamin Huang
<jamin.huang@bayercropscience.com>
07/24/03 04:36 PM

To: Stephanie Nguyen/DC/USEPA/US@EPA
cc:
Subject: Poncho - protocol for a bee chronic toxicity study

Dear Stephanie,

I recalled that you had asked us to submit a protocol for a bee chronic toxicity field study by the end of July (2 months from approval). May I request for an extension? Dave Fischer is going to discuss this topic and protocol with several bee researchers in Canada and PMRA in August, he would like to incorporate their inputs into the protocol to be submitted to EPA.. Please let me know whether it is acceptable to you if we submit a protocol to EPA in September instead. Thank you for your consideration.

Best Regards,
Jamin

****

Jamin Huang, Ph.D.
Registration Product Manager
Bayer CropScience

tel: 919-549-2634
e-mail: jamin.huang@bayercropscience.com

Bayer CropScience

July 10, 2003

Ms. Stephanie Nguyen
Document Processing Desk
Office of Pesticide Programs (7504C)
Registration Division
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202-4501

Re: Poncho 600 (EPA Reg. No. 264-789)

Label Amendment to Add A New Rate (Lower Than Approved Rate) to Provide Seed Protection

Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709
Phone: 919 549-2000

Dear Ms. Nguyen,

Bayer Cropscience is herein submitting a label amendment to add a new rate (0.125 mg ai/kernel) to provide only seed protection from wireworm, white grub, seedcorn maggot and corn flea beetle. These four pests are already included in the currently approved Poncho 600 labeling. The proposed new rate is lower than the 0.25 and 1.25 mg ai/kernel rates that have been reviewed and approved by the Agency.

In support of the proposed amendment we are submitting the following:

1. Application for Pesticide Amendment (EPA Form 8570-1), dated July 10, 2003.

2. Five copies of the proposed labeling for Poncho 600, dated July 10, 2003.

3. One copy of the above proposed labeling with all changes highlighted in yellow.

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

Sincerely,

Jamin Huang

Jamin Huang, Ph.D.
Product Registration Manager

Attachments

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

July 18, 2003

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JAMIN HUANG, PH.D.
BAYER CROPSCIENCE LP
2 T.W. ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, NC 27709

PRODUCT NAME: PONCHO 600
COMPANY NAME: BAYER CROPSCIENCE LP
EPA FILE SYMBOL: 264-789
EPA RECEIPT DATE: 07/11/03

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 1, at (703) 305-7546.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Resources and Services Division

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[✓] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 264-789

2. EPA Product Manager: Daniel C. Kenny

3. Proposed Classification: [✓] None [ ] Restricted

4. Company/Product (Name): Poncho 600

PM#: 01

5. Name and Address of Applicant (Include ZIP Code)
Bayer Cropscience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709
[ ] Check if this is a new address

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

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

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

Label amendment to add a new rate (0.125 mg ai/kernel, lower than the approved 0.25 and 1.25 mg ai/kernel rates) to provide only seed protection from wireworm, white grub, seedcorn maggot and corn flea beetle. These 4 pests are already included in the currently approved Poncho 600 label.

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: [ ] Label [ ] Container

4. Size(s) Retail Container

5. Location of Label Directions: [ ] ON 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)
Jamin Huang, Ph.D.	Registration Product Manager	919-549-2634

Certification

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

6. Date Application Received (Stamped)

2. Signature: Jamin Huang

3. Title: Registration Product Manager

4. Typed Name: Jamin Huang, Ph.D.

5. Date: July 10, 2003

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Stephanie Nguyen
08/05/03 03:54 PM

To: Jamin Huang <jamin.huang@bayercropscience.com>
cc:
Subject: Re: Poncho - protocol for a bee chronic toxicity study

Jamin:

The bee chronic toxicity field study can be extended to September.
Best Regards,
Stephanie

Jamin Huang <jamin.huang@bayercropscience.com>

Jamin Huang <jamin.huang@bayercropscience.com>
07/24/03 04:36 PM

To: Stephanie Nguyen/DC/USEPA/US@EPA
cc:
Subject: Poncho - protocol for a bee chronic toxicity study

Dear Stephanie,

I recalled that you had asked us to submit a protocol for a bee chronic toxicity field study by the end of July (2 months from approval). May I request for an extension? Dave Fischer is going to discuss this topic and protocol with several bee researchers in Canada and PMRA in August, he would like to incorporate their inputs into the protocol to be submitted to EPA. Please let me know whether it is acceptable to you if we submit a protocol to EPA in September instead. Thank you for your consideration.

Best Regards,
Jamin

****

Jamin Huang, Ph.D.
Registration Product Manager
Bayer CropScience

tel: 919-549-2634
e-mail: jamin.huang@bayercropscience.com

Jamin Huang
<jamin.huang@bayercropscience.com>
08/04/03 09:03 AM

To: Stephanie Nguyen/DC/USEPA/US@EPA
cc:
Subject: DERs of some clothianidin study reports

Dear Stephanie,

Welcome back, how was your vacation? When you have a chance, could you please provide me the DERs for the following six study reports? Thank you.

Best Regards,
Jamin

45422324 Gilges, M.; Brumhard, B. (2000) Aerobic Degradation and Metabolism of TI-435 in the Water / Sediment System: Lab Project Number: M 1510842-1: 109870: MR 505/99.

45422329 Swales, S. (2000) (Carbon 14)TI-435: Aerobic Aquatic Biotransformation: Lab Project Number: COVANCE-1820/3: 1820/3: BAYER CORP-T5882401. Unpublished study prepared by Covance Laboratories Ltd. 55 p.

45422412 Noack, M.; Geffke, T. (1998) TI 435 Technical: Daphnia magna Reproduction Test (21 d): Lab Project Number: DRE54471/CDR54471: 110018. Unpublished study prepared by Dr. U. Noack Laboratory for Applied Biology. 59 p.

45422421 Gallagher, S.; Casey, C.; Beavers, J. et al. (2000) TI-435 Technical A Reproduction Study with the Northern Bobwhite (Colinus virginanus): Lab Project Number: 197-122: 110052. Unpublished study prepared by Wildlife International, Ltd. 183 p.

45422422 Gallagher, S.; Casey, C. ; Beavers, J. et al. (2000) TI-435 Technical A Reproduction Study with the Mallard (Ana platyrhynchos): Lab Project Number: 197-123: 110053. Unpublished study prepared by Wildlife International, Ltd. 182 p.

45422509 Heimbach, F. (1999) Influence of TI 435 Technical on Development and Emergence of Larvae of Chironomus riparius in a Water-Sedimenc System: Lab Project Number: E 416 1397-1: 110065. Unpublished study prepared by Bayer AG. 43 p.

****

Jamin Huang, Ph.D.
Registration Product Manager
Bayer CropScience

tel: 919-549-2634
e-mail: jamin.huang@bayercropscience.com

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 11, 2003

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

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

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

Bayer Cropscience Lp
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

EPA Registration Number: 264-789
Name of Product: PONCHO 600

Daniel C. Kenny
Product Manager
Insecticide/Rodenticide Branch
Registration Division (7505C)

Bayer CropScience

Fax

To:	From:
EPA	Meshea J. Brodie
Attn: Document Processing Desk: Betty Williams	Regulatory Affairs
Fax: 703-305-6596	Tel.: 919-549-2425
Total Pages: 1	Fax: 919-549-2545
Date: June 9, 2003	e-mail: Meshea.Brodie@bayercropscience.com

This is to request three (3) gold seal certificates of registration for the following:
EPA Reg. No. 264-789 PONCHO 600

I will need these certificates as quickly as possible. Please send them to me at the following address:

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

Thank you for your assistance. Please call me if you have any questions or concerns.

Regards,

Meshea J. Brodie
Sr. Registration Associate
Bayer CropScience

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 25, 2003

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

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

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

Bayer Cropscience Lp
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

EPA Registration Number: 264-789
Name of Product: PONCHO 600

Daniel C. Kenny
Product Manager
Insecticide/Rodenticide Branch
Registration Division (7505C)

Bayer CropScience

Fax

To:	From:
EPA	Meshea J. Brodie
Attn: Document Processing Desk: Betty Williams	Regulatory Affairs
Fax: 703-305-6596	Tel.: 919-549-2425
Total Pages: 1	Fax: 919-549-2545
Date: June 9, 2003	e-mail: Meshea.Brodie@bayercropscience.com

This is to request three (3) gold seal certificates of registration for the following:
EPA Reg. No. 264-789 PONCHO 600

I will need these certificates as quickly as possible. Please send them to me at the following address:

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

Thank you for your assistance. Please call me if you have any questions or concerns.

Regards,

Meshea J. Brodie
Sr. Registration Associate
Bayer CropScience

tel: 919-549-2634
e-mail: jamin.huang@bayercropscience.com

Nguyen.Stephanie@epamail.epa.gov
<jamin.huang@bayercropscience.com>
Kenny.Dan@epamail.epa.gov
06/23/2003 12:57 PM

To: Jamin Huang
cc:
Subject: Re: question - nominal concentration of clothianidin ai

Jamin:

It has been stated in the review dated 1/25/02 that nominal concentration for the AI is 97.8%. The product label must be changed to 97.8% in compliance with PR Notice 91-2.

PMRA's review dated 02-25-02 also concurred with EPA's review and had also asked Bayer to change the nominal concentration to 97.8%.

Bayer is required to correct the label claim to 97.8% which is the nominal concentration of clothianidin in the CSF for basic formulation.

If you have any questions regarding clothianidin, please let me know.
Stephanie

12-28-02 Clothianidin Tech Guarante

DATE OUT: 24/JUN/2003

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [ ] End-Use Product [X]
DP CODE #:D288402 EPA RECEIVED DATE:15/JAN/2003 FILE SYMBOL/REG: 3125-LTN
PRODUCT NAME: Poncho 600 FS: 48% Clothianidin FOOD USE [X]
COMPANY NAME: Bayer CropScience ACTION CODE:101
PPC NUMBER OF THE TGAIs IN THE PRODUCT: 044309

FROM: Sami Malak, Chemist
Technical Review Branch/RD (7505C)

TO: 04 Meredith laws/Stephanie Nguyen
Insecticide-Rodenticide Branch/RD (7505C)

INTRODUCTION:

The Insecticide-Rodenticide Branch requested TRB to review for acceptability product's alternate formulation, CSF dated 05/NOV/2002.

FINDINGS:

1a. Review an alternate formulation entails that the subject product must have a registered basic or an alternate formulation, for comparison. Since subject product is undergoing registration, this application can not be processed at this time. The product, Reg. No. 3125-LTN, was transferred to Reg.No. 264-TIO.

1b. The submitted alternate formulation is substantially similar in composition to the currently pending basic CSF dated 28/MAR/2001.

2. Product chemistry data requirements for Clothianidin Technical Insecticide, Reg. No. 74207-R, was previously submitted and reviewed in connection with DP #277701, S. Mathur, 25/JAN/2002.

3. The subject product is produced by an integrated formulation system, meaning that the technical source in the product is currently undergoing registration. The product contains 48% Clothianidin, Reg. No. 74207-R.

4a. The submitt ed product's alternate CSF 05/NOV/2002 was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed on the CSF are cleared for use in pesticide formulations intended for food uses (seed treatment of conola and corn).

4b. For future data submissions, the applicant should be advised to change the purpose, listed in column 15 of the CSF, from [redacted] for two ingredients [redacted] The term [redacted] implies that both ingredients are pesticidally active against the same pests as Clothianidin and must be listed on the label, each at the percentage nominal claimed in the CSF.

CONCLUSIONS:

TRB objects to this application because of Finding 1(a) & 4(b) above.

cc:S. Malak and Central File (Reg. No. 3125-LTN).
7505C:RD:TRB:CM-2:268:s.m.:24/JUN/2003:703-308-9365:<3125-LTN>.

WEST INGREDIENT INFORMATION IS NOT DISCLOSED

Bayer CropScience

June 2, 2003

Ms. Stephanie Nguyen
Document Processing Desk
Office of Pesticide Programs (7504C)
Registration Division
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202-4501

Re: Final Printed Label of Poncho 600 (EPA Reg. No. 264-789)

Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709
Phone: 919 549-2000

Dear Ms. Nguyen,

In compliance with the requirement # 6 in the May 30, 2003 Notice of Pesticide Registration for Poncho 600 (EPA Registration Number 264-789), we are herein submitting one copy of the revised final printed label dated May 30, 2003 for your record. This revision includes all of the requested changes listed in the requirements 2-a and 2-b.

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

Sincerely,

Jamin Huang, Ph.D.
Product Registration Manager

attachment

191

Poncho™ 600

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insect pests.
All seed treated with this product must be conspicuously coloured at the time of treatment.

ACTIVE INGREDIENT:
Clothianidin 48.0%
INERT INGREDIENTS: 52.0%
Contains 5 lbs. active ingredient per gallon. TOTAL 100.0%

E.P.A. Reg. No. 264-789 **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:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • 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.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.
Have the 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.

PRECAUTIONARY STATEMENTS

CAUTION
HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables, 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. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment 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. Contain any product spills or equipment leaks and dispose of wastes according to disposal instructions on this label. Do not contaminate water when disposing of equipment washwaters.

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 by commercial treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting. This product is to be used in commercial liquid or slurry treaters. Mix thoroughly before use or use entire container at one time.

All seed treated with this product must be conspicuously coloured at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by *40 CFR 153.155* must be strictly adhered to when using this product.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SEED QUALITY AND STORAGE OF TREATED SEED

Treatment of highly mechanically damaged seed, or seed of known low vigor or 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.

LABELLING OF TREATED SEED

Seed commercially treated with Poncho™ 600 must be labelled in compliance with the *Federal Seed Act.*

All bags containing treated seed must be labelled or tagged as follows:

- This seed has been treated with Poncho™ 600 seed protectant, which contains clothianidin.
- Do not use treated seed for feed, food or oil processing.
- Rapeseed greens and seed grown or harvested from Poncho™ 600-treated seed must not be used for feed or human consumption. Rapeseed grown and harvested from Poncho™ 600-treated seed is only for industrial uses and can not be used for edible oil or any other human/feed consumption.
- Store away from feeds and other foodstuffs.
- Wear long-sleeved shirt, long pants and waterproof gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be doublesown 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.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, and dried beans. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

GENERAL INFORMATION

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insects.

For use in commercially available equipment designed for seed treatment only. Not for use in hopper-box, slurry-box, or similar seed treatment applications used at planting. This product is to be used in liquid or slurry treaters. Mix thoroughly before use or use entire container at one time. All tank mixes should be pre-tested to determine physical compatibility between formulations. Observe all cautions and limitations on labeling of all products used in mixtures.

For Early Season Protection Against Certain Insects:

Poncho™ 600 will aid in the protection of seeds and seedlings against injury by certain early season insects.

RECOMMENDED APPLICATIONS

CROP	INSECT PESTS	RATE PONCHO™ 600	
		mg a.i./Kernel	80,000 Unit of Seed
Corn (including field, sweet and pop)	Corn rootworm (including Northern, Western, Southern and Mexican)	1.25	5.64 fl. oz. or 166.7 mL
	Chinch bug Corn flea beetle Cutworm, black Grape colaspis Seedcorn maggot Southern green stinkbug White grub (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Wireworm	0.25	1.13 fl. oz or 33.3 mL

CROP	INSECT PESTS	RATE PONCHO™ 600	REMARKS
Canola Rapeseed	Flea beetle Wireworm	3.64 fl. oz per 100 lbs. seed or 250 mL per 100 kg seed	Use this rate under low to moderate flea beetle pressure.
		5.12 fl. oz per 100 lbs. seed or 333 mL per 100 kg seed	Use this rate under moderate flea beetle pressure.
		10.23 fl. oz per 100 lbs. seed or 666 mL per 100 kg seed	Use this rate under high to extreme flea beetle pressure where extended control is required.

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.

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 should 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: 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. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: 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: 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™ 600 (MASTER) Approved 05/30/03

Jamin Huang
<jamin.huang@bayercropscience.com>
06/30/03 01:11 PM

To: Stephanie Nguyen/DC/USEPA/US@EPA
cc: Leslie Fontaine <leslie.fontaine@bayercropscience.com>
Subject: clothianidin

Dear Stephanie,

I am forwarding additional justifications of using 97.5% ai as nominal concentrations for clothianidin technical (summarized by Leslie) to you. If it is acceptable to you, we will begin to revise both CSF and final printed label of clothianidin technical based on 97.5% ai.

Best Regards,
Jamin

****

Jamin Huang, Ph.D.
Registration Product Manager
Bayer CropScience

tel: 919-549-2634
e-mail: jamin.huang@bayercropscience.com

---- Forwarded by Jamin Huang/MOVAJ/US/BCS/BAYER on 06/30/2003 01:05 PM ----

Leslie Fontaine
06/30/2003 12:17 PM

To: Jamin Huang/MOVAJ/US/BCS/BAYER@BAYER-US-NOTES
cc:
Subject: clothianidin

Jamin - here is the table to provide to Stephanie at EPA (I told her that I would route the table that she asked for through you)

Here is the data for the nominal value - it is based on the 5 batch material accountability study as well as one additional batch that was analyzed under a separte study. The information is as follows:

batch #	% AI value	Report #	mrid
30037120	95.3	Covance Report 6155-119 revised (Brochure 2210	mrid 456546-01
50071820	97.5	Covance Report 6155-119 revised (Brochure 2210	mrid 456546-01
50074309	99.1	Covance Report 6155-119 revised (Brochure 2210	mrid 456546-01
50074509	98.7	Covance Report 6155-119 revised (Brochure 2210	mrid 456546-01
50074909	98.4	Covance Report 6155-119 revised (Brochure 2210	mrid 456546-01
30034708	96.2	Covance Report 6155-127 (Brochure 2210)	mrid 456546-01
average value =	97.5		

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:
264-789	May 30, 2003
	Date of Expiration: May 30, 2006
	Term of Issuance: Conditional
	Name of Pesticide Product: Poncho ™ 600

Name and Address of Registrant (include ZIP Code):

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

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted in and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product please refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered 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 sec. 3(c)(7)(C) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product when the Agency requires all registrants of similar products to submit such data.

2. Make the following label changes before you release the product for shipment:

   a. Revise the EPA Registration Number to read, "EPA Reg. No. 264-789 ".

   b. Change the requirement for "...waterproof gloves..." in the list of required personal protective equipment for applicators and other handlers to a requirement for "...chemical-resistant gloves...".

3. Submit the following information to satisfy the data gaps in the data base for clothianidin. The following information is required within three (3) years of the date of this Notice:

   a. Submit an acceptable Developmental Immunotoxicity study.

Signature of Approving Official:

Daniel C. Kenny, Product Manager (01)
Insecticide-Rodenticide Branch, Registration Division (7505C)

Date: MAY 30 2003

EPA Form 8570-6

b. Submit acceptable rotational crop residue field trials with mature soybeans.

c. Submit additional analysis of test the materials used in the previously submitted mutagenicity studies. Please refer to the Human Health Risk Assessment for Clothianidin dated May 1, 2003 by EPA's OPP Health Effects Division for specific details regarding the information that should be included in this analysis.

d. Submit an acceptable Whole Sediment Acute Toxicity to Freshwater Invertebrates study.

e. Submit an acceptable Field Test for Pollinators. Please refer to the EFED Risk Assessment for the Seed Treatment of Clothianidin dated February 20, 2003 and addendum dated April 10, 2003 by EPA's OPP Environmental Fate and Effects Division for specific details regarding the information that should be included in this test.

f. Submit an acceptable Aerobic Aquatic Metabolism study.

g. Submit an acceptable Seed Leaching study. Please refer to the EFED Risk Assessment for the Seed Treatment of Clothianidin dated February 20, 2003 by EPA's OPP Environmental Fate and Effects Division for specific details regarding the information that should be included in this study.

4. This registration is time-limited and will termite on May 30, 2006 unless renewed by EPA.

5. Submit one copy of the revised final printed label for the record before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 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.

Daniel C. Kenny
Product Manager (01)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAY 30 2003
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 264-787

Poncho™ 600

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insect pests.

All seed treated with this product must be conspicuously coloured at the time of treatment.

ACTIVE INGREDIENT:

Clothianidin 48.0%

INERT INGREDIENTS: 52.0%

Contains 5 lbs. active ingredient per gallon. TOTAL 100.0%

E.P.A. Reg. No. 264-XXX **E.P.A. Est. No.**

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 1-888-99BAYER (1-888-992-2937)

FIRST AID

IF SWALLOWED:	▫ Immediately call a poison control center or doctor for treatment advice. ▫ Do not induce vomiting unless told to do so by a poison control center or doctor. ▫ Have person sip a glass of water if able to swallow. ▫ 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.
IF INHALED:	▫ Move person to fresh air. ▫ If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. ▫ Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	▫ Take off contaminated clothing. ▫ Rinse skin immediately with plenty of water for 15-20 minutes. ▫ Call a poison control center or doctor for treatment advice.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.

Have the 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.

PRECAUTIONARY STATEMENTS

CAUTION

HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, waterproof gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables, 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. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment 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. Contain any product spills or equipment leaks and dispose of wastes according to disposal instructions on this label. Do not contaminate water when disposing of equipment washwaters.

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 by commercial treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting. This product is to be used in commercial liquid or slurry treaters. Mix thoroughly before use or use entire container at one time.

All seed treated with this product must be conspicuously coloured at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertant use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by *40 CFR 153.155* must be strictly adhered to when using this product.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SEED QUALITY AND STORAGE OF TREATED SEED

Treatment of highly mechanically damaged seed, or seed of known low vigor or 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.

LABELLING OF TREATED SEED

Seed commercially treated with Poncho™ 600 must be labelled in compliance with the *Federal Seed Act*.

All bags containing treated seed must be labelled or tagged as follows:

- This seed has been treated with Poncho™ 600 seed protectant, which contains clothianidin.
- Do not use treated seed for feed, food or oil processing.
- Rapeseed greens and seed grown or harvested from Poncho™ 600-treated seed must not be used for feed or human consumption. Rapeseed grown and harvested from Poncho™ 600-treated seed is only for industrial uses and can not be used for edible oil or any other human/feed consumption.
- Store away from feeds and other foodstuffs.
- Wear long-sleeved shirt, long pants and waterproof gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be doublesown 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.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Areas planted with treated seed may be replanted immediately with corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, grasses, nongrass animal feeds, soybeans, and dried beans. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

GENERAL INFORMATION

Poncho™ 600 is a systemic insecticide seed treatment for use on canola, rapeseed and corn for the control of certain insects.

For use in commercially available equipment designed for seed treatment only. Not for use in hopper-box, slurry-box, or similar seed treatment applications used at planting. This product is to be used in liquid or slurry treaters. Mix thoroughly before use or use entire container at one time. All tank mixes should be pre-tested to determine physical compatibility between formulations. Observe all cautions and limitations on labeling of all products used in mixtures.

For Early Season Protection Against Certain Insects:

Poncho™ 600 will aid in the protection of seeds and seedlings against injury by certain early season insects.

RECOMMENDED APPLICATIONS

CROP	INSECT PESTS	RATE PONCHO™ 600	
		mg a.i./Kernel	80,000 Unit of Seed
Corn (including field, sweet and pop)	Corn rootworm (including Northern, Western, Southern and Mexican)	1.25	5.64 fl. oz. or 166.7 mL
	Chinch bug Corn flea beetle Cutworm, black Grape colaspis Seedcorn maggot Southern green stinkbug White grub (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Wireworm	0.25	1.13 fl. oz or 33.3 mL

CROP	INSECT PESTS	RATE PONCHO™ 600	REMARKS
Canola Rapeseed	Flea beetle Wireworm	3.84 fl. oz per 100 lbs. seed or 250 mL per 100 kg seed	Use this rate under low to moderate flea beetle pressure.
		5.12 fl. oz per 100 lbs. seed or 333 mL per 100 kg seed	Use this rate under moderate flea beetle pressure.
		10.23 fl. oz per 100 lbs. seed or 666 mL per 100 kg seed	Use this rate under high to extreme flea beetle pressure where extended control is required.

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.

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 should 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: 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. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: 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:

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™ 600 (PENDING) Submitted 5/4/01, Resubmitted 2/10/03, Resubmitted 3/24/03, Resubmitted 4/7/03, Resubmitted 5/15/03.

Bayer CropScience

May 30, 2003

Ms. Debbie Edwards
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Crystal Mall Building 2, Room 266A
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Dear Ms. Edwards:

Re: Clothianidin
PONCHO® 600, EPA Reg. No. 264-789

We would like to thank the Agency for the conditional approval of PONCHO® 600. The joint review between the US EPA and Canada PMRA was coordinated in a high quality manner by Terri Stowe. In addition, Meredith Laws and her team, particularly Dan Kenny and Stephanie Nguyen, managed the internal Agency's review in a prompt and professional manner.

Bayer CropScience
2 T.W. Alexander Drive
RTP, NC 27709
Phone: 919-549-2000

Bayer CropScience (BCS) is very pleased with the excellent communication between all parties (EPA, PMRA and BCS). All review timelines and milestones were met in an expedient and timely way. The entire process was participatory and transparent. We encourage the Agency to continue joint review and harmonization efforts with Canada.

We recognize and appreciate that your entire team exerted extra time and effort in the Agency's approval of clothianidin. Thank you for your personal involvement and support throughout this entire process. If you have any questions or would like to discuss future joint review projects involving Bayer CropScience compounds, please contact me either by telephone at 919-549-2828 or e-mail at wayne.carlson@bayercropscience.com.

Sincerely,

Wayne C. Carlson

Wayne C. Carlson
Vice President
Regulatory Affairs

cc: Jim Jones

Commodity	Parts per million
Pea, blackeyed, seed	4.0
Pea, southern, seed	4.0
* * * * *	
Turnip, greens	30
* * * * *	
Vegetable, cucurbit, group 9	0.3
* * * * *	

[FR Doc. 03–13563 Filed 5–29–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0133; FRL–7306–8]

Clothianidin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clothianidin in or on canola, corn, and milk. In addition, tolerances are established for indirect or inadvertent residues of clothianidin in or on nongrass animal feed; cereal grain forage, fodder and straw; grass forage, fodder and hay; and soybean forage and hay. Bayer Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective May 30, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0133, must be received on or before July 29, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Daniel Kenny, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7546; e-mail address: *kenny.dan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop Production (NAICS 111)
- Animal Production (NAICS 112)
- Food Manufacturing (NAICS 311)
- Pesticide Manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0133. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html,* a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the Federal Register of November 14, 2001 (66 FR 57079) (FRL–6809–7), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 1F6315) by Bayer Corporation, 8400 Hawthorn Road, Kansas City, MO 64120. That notice included a summary of the petition prepared by Bayer Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on canola, seed at 0.01 parts per million (ppm); corn, field, grain at 0.01 ppm; corn, pop, grain at 0.01 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; corn, field, forage at 0.10 ppm; corn, sweet, forage at 0.10 ppm; corn, field, stover at 0.10 ppm; corn, sweet, stover at 0.10 ppm; corn, pop, stover at 0.10 ppm; and milk at 0.01 ppm. Following the review of all the data, tolerances are also required on the following rotational crops, which are used only for livestock feeds. These tolerances do not impact the dietary risk

assessment since these residues are significantly lower than those in feed items from the crops which are treated directly with clothianidin and/or thiamethoxam. Tolerances are established on animal feed, nongrass at 0.02 ppm; grain, cereal, forage, fodder and straw at 0.02 ppm; grass, forage, fodder and hay at 0.02 ppm; soybean, forage at 0.02 ppm; and soybean, hay at 0.02 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. * * *"

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for residues of clothianidin on canola, seed at 0.01 ppm; corn, field, grain at 0.01 ppm; corn, pop, grain at 0.01 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; corn, field, forage at 0.10 ppm; corn, sweet, forage at 0.10 ppm; corn, field, stover at 0.10 ppm; corn, sweet, stover at 0.10 ppm; corn, pop, stover at 0.10 ppm; and milk at 0.01 ppm; animal feed, nongrass at 0.02 ppm; grain, cereal, forage, fodder and straw at 0.02 ppm; grass, forage, fodder and hay at 0.02 ppm; soybean, forage at 0.02 ppm; and soybean, hay at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by clothianidin are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents (rats)	NOAEL: 27.9/34.0 milligrams/kilogram/day (mg/kg/day) (male/female) LOAEL: 202.0/254.2 mg/kg/day (male/female: decreased body weight (bwt) and bwt gain)
870.3150	90-Day oral toxicity in nonrodents (dogs)	NOAEL: 19.3/42.1 mg/kg/day (male/female) LOAEL: 40.9/61.8 mg/kg/day (thinness, decreased bwt, bwt gain and anemia (one male); decreased white blood cells, albumin, and total protein (female)
870.3200	21/28-Day dermal toxicity (rats)	NOAEL: 1,000 mg/kg/day (highest dose tested) LOAEL: > 1,000 mg/kg/day
870.3700	Prenatal developmental in rodents (rats)	Maternal NOAEL: 10 mg/kg/day Maternal LOAEL: 40 mg/kg/day (decreased bwt gain and food consumption) Developmental NOAEL: 125 mg/kg/day Developmental LOAEL: cannot be established
870.3700	Prenatal developmental in nonrodents (rabbit)	Maternal NOAEL: 25 mg/kg/day Maternal LOAEL: 75 mg/kg/day (increased incidences of clinical signs (scant feces and orange urine), mortalities, decreased food consumption, early delivery, abortion, and decreased bwt gain) Developmental NOAEL: 25 mg/kg/day Developmental LOAEL: 75 mg/kg/day (premature deliveries, decreased gravid uterine weights, an increased litter incidence of a missing lobe of the lung and decreased litter average for ossified sternal centra per fetus)