

100-935

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 2, 2007

Fred J. Pearson
NAFTA Insecticide Team Leader
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

SUBJECT: Application for Pesticide Notification – Addition of Pest
Helix XTra™ Insecticide with Fungicides
EPA Reg. No. 100-935
Application Dated December 12, 2007

Dear Mr. Pearson:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above product. The Registration Division (RD) has conducted a preliminary screen of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please me directly at 703-305-6249 or Terri Stowe of my staff at 703-305-6117.

Sincerely,

A handwritten signature in cursive script that reads "Rachel C. Holloman".

for Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

STG



United States
Environmental Protection Agency
 Washington, DC 20460

| | |
|-------------------------------------|--------------|
| <input type="checkbox"/> | Registration |
| <input type="checkbox"/> | Amendment |
| <input checked="" type="checkbox"/> | Other |

OPP Identifier Number
NOTIFICATION

Application for Pesticide - Section I

| | | |
|---|--|--|
| 1. Company/Product Number 100-935 | 2. EPA Product Manager Daniel Kenny | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) HELIX XTRA™ INSECTICIDE WITH FUNGICIDES | PM# (01) IRB | |
| 5. Name and Address of Applicant (Include ZIP Code) Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419 <input type="checkbox"/> 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

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

NOTIFICATION

JAN 02 2007

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

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

Syngenta Crop Protection Inc., is submitting this Notification for Helix Xtra™ Insecticide with Fungicides (EPA Reg. No. 100-935) to add the pest "aphids" to the crop use directions for canola. Two copies of labeling (one with the change high lighted) are attached.

To complete this Notification, EPA form 8570-1 is enclosed as well as a self-addressed postcard to indicate your acceptance/rejection of this Notification.

The label code is SCP 935A-L (Notif aphid).

Section - III

| | | | | | |
|--|---|--|---|---|----------------------------------|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No | Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | | <input type="checkbox"/> Metal | <input type="checkbox"/> Plastic |
| | | | | <input type="checkbox"/> Glass | <input type="checkbox"/> Paper |
| *Certification must be submitted | | If "Yes" Unit Packaging wgt. No. per Container | If "Yes" Unit Packaging wgt. No. per container | <input type="checkbox"/> Other (Specify) _____ | |
| 3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container | | 5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product | | | <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | <input type="checkbox"/> Other _____ | |

Section - IV

| | | |
|---|---|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | |
| Name Fred J. Pearson | Title NAFTA Insecticide Team Leader | Telephone No. (Include Area Code) 336.632-2365 |
| 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 NAFTA Insecticide Team Leader | |
| 4. Typed Name Fred J. Pearson | 5. Date December 12, 2006 | |



NOTIFICATION

JAN 02 2007

December 12, 2006

Document Processing Desk (NOTIF)
Office of Pesticide Programs (H7504P)
Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATT: Ms. Joyce Edwards

SUBJECT: HELIX XTRA™ INSECTICIDE WITH FUNGICIDES
EPA REG. NO. 100-935
NOTIFICATION OF ADDITION OF APHIDS TO CANOLA CROP USE DIRECTIONS

Dear Ms. Edwards,

Syngenta Crop Protection Inc., is submitting this Notification for Helix Xtra™ Insecticide with Fungicides (EPA Reg. No. 100-935) to add the pest "aphids" to the crop use directions for canola. Two copies of labeling (one with the change high lighted) are attached.

To complete this Notification, EPA form 8570-1 is enclosed as well as a self-addressed postcard to indicate your acceptance/rejection of this Notification.

The label code is SCP 935A-L (Notif aphid).

Thank you in advance for approving this request. However, should you have any questions, please contact me at 336.632-2365 or via e-mail at fred.pearson@syngenta.com.

Sincerely,

Fred J. Pearson
NAFTA Insecticide Team Leader
Syngenta Regulatory Affairs

Enclosures: 2 copies of labeling (1 high lighted with changes)
EPA Form 8570-1
Return addressed postcard

cc: Daniel Kenny PM (01) IRB

| FIRST AID | |
|--|--|
| If in eyes | <ul style="list-style-type: none"> • 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 eye. • Call a poison control center or doctor for treatment advice. |
| If on skin or clothing | <ul style="list-style-type: none"> • 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. |
| If inhaled | <ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice. |
| If swallowed | <ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person. |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal) Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident), Call 1-800-888-8372 | |

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Harmful if inhaled or absorbed through the skin. Avoid contact with eyes, skin, or clothing. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling, and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash before reuse.

Personal Protective Equipment

Workers involved in treating, cleanup, or maintenance of seed treatment equipment must wear:

- Chemical-resistant coveralls over long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material – Category A (e.g., polyvinyl chloride [PVC], nitrile rubber or butyl rubber, barrier laminate, neoprene rubber, natural rubber, polyethylene, or viton)
- Head gear
- Respirator protection (i.e., half-mask respirator with suitable dust filter or fresh air hood)

Baggers, sewers, and stackers must wear:

- Regular coveralls over long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material – Category A (e.g., polyvinyl chloride [PVC], nitrile rubber or butyl rubber, barrier laminate, neoprene rubber, natural rubber, polyethylene, or viton)
- Head gear
- Respirator protection (i.e., single use dust masks, quarter or half-mask respirator, fresh air hood)

Forklift operators must wear regular coveralls over long-sleeved shirt and long pants and gloves.

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

Environmental Hazards

This pesticide is toxic to wildlife and highly toxic to aquatic invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Drift or runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash water.

- **Surface Water Advisory**

This product may contaminate water through drift of spray in wind. This product has a high potential for runoff for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water from rainfall runoff (See manual at the following internet address:

<http://www.wcc.nrcs.usda.gov/pestmgt/core4.html>). Runoff of this product will be reduced by avoiding applications when rainfall is forecast to occur within 48 hours.

- **Ground Water Advisory**

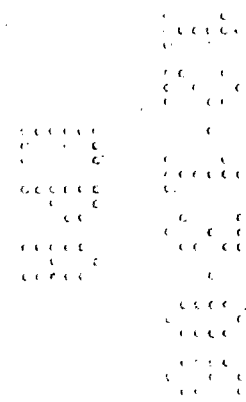
Thiamethoxam has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow may result in ground water contamination.

- **Spray Drift Advisory**

Do not allow this product to drift.

Physical and Chemical Hazards

Do not use, pour, spill, or store near heat or open flame.



CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and Buyer and User assume the risk of any such use. SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

IT IS SYNGENTA'S AND SELLER'S INTENTION THAT to the extent allowed by State law, that SYNGENTA or Seller not be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

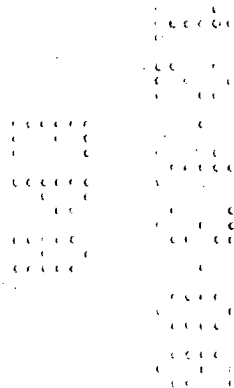
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Not for use on agricultural establishments in hopper-box, planter-box, slurry-box, or other seed-treatment applications at or immediately before planting.

FAILURE TO FOLLOW THE DIRECTIONS FOR USE AND PRECAUTIONS ON THIS LABEL MAY RESULT IN CROP INJURY, POOR INSECT AND/OR DISEASE CONTROL, AND/OR ILLEGAL RESIDUES.

Treatment of highly mechanically scarred or damaged seed, or seed known to be of low vigor and poor quality, except for the purpose of curative control of existing disease pests, may result in reduced germination and/or reduction of seed and seedling vigor. Treat a small quantity of seed using equipment similar to that planned for treating the total seed lot. Conduct germination tests on a small portion of seed before committing the total seed lot to a selected seed treatment. Due to seed quality and seed storage conditions beyond the control of Syngenta, no claims are made to guarantee the germination of carry-over seed or propagating material for all crop seed.



CROP USE DIRECTIONS

Canola

To provide early season protection against aphids, flea beetles, seedcorn maggot, white grubs, wireworm, seed-borne blackleg (*Leptosphaeria maculans*), seed-borne *Alternaria*, and the seedling disease complex (damping-off, seedling blight, seed rot, and root rot) caused by *Pythium* species, *Fusarium* species, and *Rhizoctonia* species, apply Helix Xtra at 23 fluid ounces of product per 100 pounds of seed.

Rotational Crops

Treated areas may be replanted immediately to canola or wheat following harvest. All other crops may be planted 30 days after canola seeding or the last application of Helix Xtra.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment.

Pesticide Storage

Store in a cool, dry place.

Pesticide Disposal

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be used according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA regional office for guidance in proper disposal methods.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes.

Container Disposal

Triple rinse (or equivalent), then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures allowed by state and local authorities.

Apron XL®, Cruiser®, Dividend®, Helix Xtra™, Maxim® and the Syngenta logo are trademarks of a Syngenta Group Company.

U.S. Patent Nos. 5,852,012 and 6,022,871

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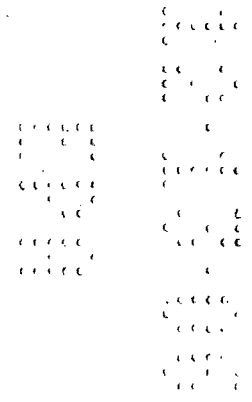
For non-emergency (e.g., current product information) call
Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:

Syngenta Crop Protection, Inc.
Greensboro, North Carolina 27409
www.syngenta-us.com

SCP 935A-L(notif aphid)

HEL XTR 935A-L(notif aphid)-lg-12-12-06



(Non-detachable Container Label)

Helix XTra™

Insecticide with Fungicides

A seed treatment product for control of certain insects and diseases of canola.

For use in commercial seed treatment facilities with closed transfer systems only. No open transfer.

Active Ingredients:

| | |
|--------------------|---------|
| Thiamethoxam:* | 20.70% |
| Difenoconazole:** | 1.25% |
| Mefenoxam*** | 0.40% |
| Fludioxonil:**** | 0.13% |
| <hr/> | |
| Other Ingredients: | 77.52% |
| Total: | 100.00% |

*CAS No. 153719-23-4

**CAS No. 119446-68-3

***CAS Nos. 70630-17-0 and 69516-34-3

****CAS No. 131341-86-1

Helix XTra contains the following amounts of active ingredient per gallon: 2.23 lbs. thiamethoxam; 0.13 lbs. difenoconazole; 0.04 lbs. mefenoxam; 0.01 lbs. fludioxonil.

KEEP OUT OF REACH OF CHILDREN.

CAUTION

See storage, disposal, additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-935

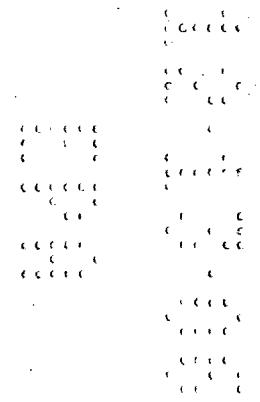
EPA Est. xxxxx

Product ID xxxxx

SCP 935A-L(notif aphid)

30 gallons

Net Contents



| FIRST AID | |
|--|---|
| If in eyes | <ul style="list-style-type: none">• 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 eye.• Call a poison control center or doctor for treatment advice. |
| If on skin or clothing | <ul style="list-style-type: none">• 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. |
| If inhaled | <ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice. |
| If swallowed | <ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person. |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal) Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident), Call 1-800-888-8372 | |

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

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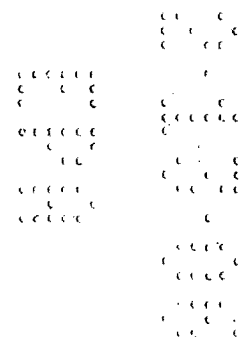
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Physical and Chemical Hazards

Do not use, pour, spill, or store near heat or open flame.



CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

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SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and Buyer and User assume the risk of any such use. SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

IT IS SYNGENTA'S AND SELLER'S INTENTION THAT to the extent allowed by State law, that SYNGENTA or Seller not be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Not for use on agricultural establishments in hopper-box, planter-box, slurry-box, or other seed-treatment applications at or immediately before planting.

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Pesticide Disposal

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For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes.

Container Disposal

Triple rinse (or equivalent), then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures allowed by state and local authorities.

Helix XTra™ and the Syngenta logo are trademarks of a Syngenta Group Company
U.S. Patent Nos. 5,852,012

©2006 Syngenta

Manufactured for:

Syngenta Crop Protection, Inc.
Greensboro, North Carolina 27409
www.syngenta-us.com

SCP 935A-L(notif aphid)

HEL XTR 935A-L(notif aphid)-lg-12-12-06

