

100-935

9/8/2009

1 of 18



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ms Pat Dinnen
Syngenta Crop Protection
P.O.BOX 18300
Greensboro, NC 27419

SEP 8 2009

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4

Dear Registrant:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated August 17, 2009 for:

EPA Registration 100-935 Helix XTRA™ Insecticide with Fungicides

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and finds that the label change(s) requested falls within the scope of PRN-2007-4. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Banza Djapao of my staff at 703-305-7269.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington", is located below the "Sincerely," text.

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

NOTIFICATION
SEP - 8 2009



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

SUBJECT: HELIX XTRA™ INSECTICIDE WITH FUNGICIDES
EPA REG. NO. 100-935
NOTIFICATION OF LABEL CHANGE PER PR NOTICE 2007-4

Attached are:

- One copy of the label with the changes clearly marked
- One unmarked copy of the label
- A CD of the unmarked copy of the label for “Electronic Comparison and Review”
- Certificate with Respect to Label Integrity Form
- Completed EPA Form 8570-1

Sincerely,

Pat Dixon

Pat Dinnen
Label Group Leader
Regulatory Affairs

Enclosures

[illegible]

4 of 18

(Booklet)

NOTIFICATION

SEP - 8 2009

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%
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 additional precautionary statements and directions for use in booklet.

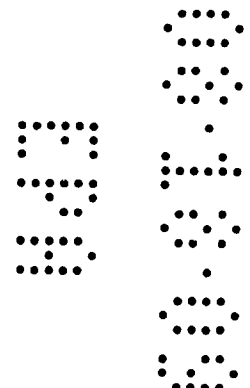
EPA Reg. No. 100-935

EPA Est. xxxxx

Product of xxxxx

SCP 935A-L(12-12-06)

30 gallons
Net Contents



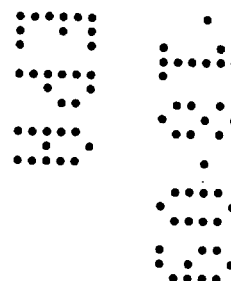
FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<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.	
<p align="center">HOT LINE NUMBER</p> <p align="center">For 24-Hour Medical Emergency Assistance (Human or Animal) Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident), Call 1-800-888-8372</p>	

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**

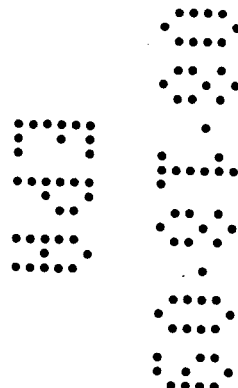
Thiamethoxam has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow may result in ground water contamination.

- **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

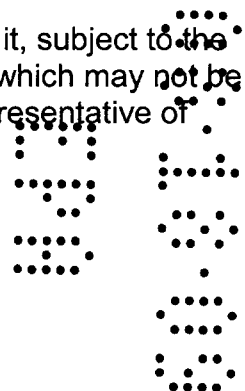
NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

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.



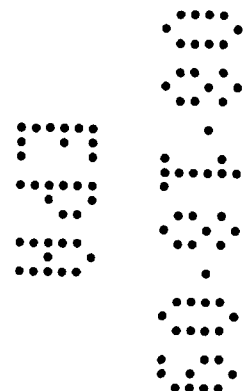
DIRECTIONS FOR USE

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.



GENERAL INFORMATION

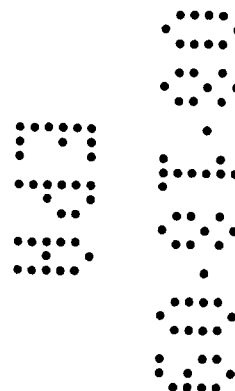
Helix XTra is a seed treatment product that contains both insecticide and fungicide components with activity against aphids, flea beetles, seedcorn maggot, white grubs, wireworm, and certain seed borne and damping off diseases of canola. Thiamethoxam, the insecticide component, provides activity against flea beetles and the remaining components are fungicides with activity against damping off diseases caused by *Pythium* species, *Fusarium* species, *Rhizoctonia* species, and seed-borne blackleg (*Leptosphaeria maculans*). Thiamethoxam, difenoconazole, mefenoxam, and fludioxonil are the active ingredients in Cruiser® 5FS, Dividend®, Apron XL® LS, and Maxim® 4FS, respectively.

Note: Mefenoxam is a systemic fungicide having a specific mode of action. Mefenoxam could be subject to development of insensitive strains of fungi. Development of insensitivity cannot be predicted. Therefore, Syngenta cannot assume liability for crop damage resulting from insensitive strains of fungi. Consult your State Agricultural Experiment Station or Extension Service Specialist for guidance and ways to control any possible insensitive strains of fungi that may occur.

MIXING PROCEDURES

Helix XTra is especially formulated as a ready to apply seed treatment. An EPA-approved coloring agent, C.I. Pigment Blue No. 15, has been added to the formulation. No additional colorant, dyes, binders, or water are needed. Helix XTra has a density of approximately 10.8 pounds per gallon. Apply utilizing standard slurry seed treatment equipment which provides uniform seed coverage. Uneven or incomplete seed coverage may not give the desired level of insect or disease control. Consult the manufacturer of the application equipment you plan to use for suitability for this application and for instructions on operation and calibration of the equipment. Allow seed to dry before bagging.

Federal law requires that bags containing treated seed shall be labeled with the following information: "This seed has been treated with thiamethoxam insecticide and fludioxonil, difenoconazole, and mefenoxam fungicides. Do not use for feed, food, or oil purposes. Store away from feed and foodstuffs."



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.

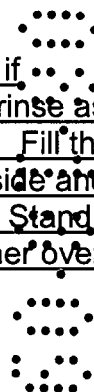
Pesticide Disposal

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/Handling

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into



application equipment or a mix tank or store rinsate for later use and disposal. Repeat this procedure two more times. ; Then offer for recycling if available or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or, if other procedures allowed by state and local authorities, by burning. If burned, stay out of smoke.

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

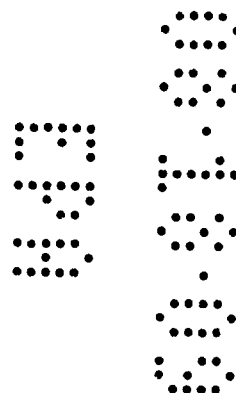
U.S. Patent Nos. 5,852,012 and 6,022,871

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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)



(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:

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Other Ingredients:	77.52%
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*CAS No. 153719-23-4

**CAS No. 119446-68-3

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

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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.

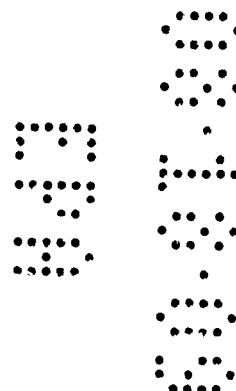
EPA Reg. No. 100-935

EPA Est. xxxxx

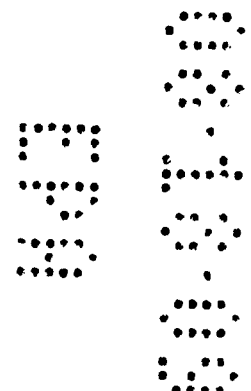
Product ID xxxxx

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.
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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.
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<p align="center">HOT LINE NUMBER</p> <p align="center">For 24-Hour Medical Emergency Assistance (Human or Animal) Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident), Call 1-800-888-8372</p>	



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.

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**

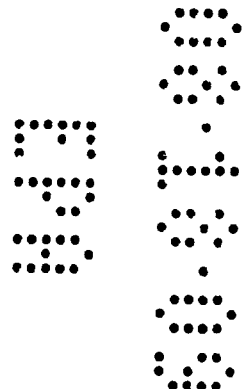
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- **Spray Drift Advisory**

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

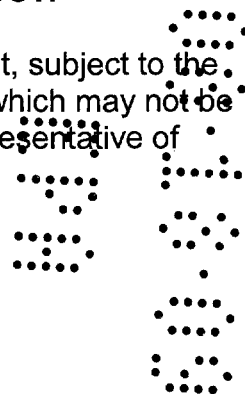
NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

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.

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 ~~Handling~~

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container(or equivalent) promptly after emptying. Triple rinse as

follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use and disposal. Repeat this procedure two more times. Then offer for recycling if available or ~~reconditioning~~ or puncture and dispose of in a sanitary landfill, or by incineration, or, if other procedures allowed by state and local authorities, by burning. If burned, stay out of smoke.

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(12-12-06)

HEL XTR 935A-L(12-12-06) PRN2007-4 NOTIF-AUG2009 – pl –8/17/09

