

100-973

12-4-2000

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (H7505C)  
401 "M" St., S.W.  
Washington, D.C. 20460

EPA Reg. Number:  
100-973

Date of Issuance:  
DEC 4 2000

Term of Issuance: Conditional

NOTICE OF PESTICIDE:

Registration  
 Reregistration

(under FIFRA, as amended)

Name of Pesticide Product:  
Helix™ Insecticide with  
Fungicides

Name and Address of Registrant (include ZIP Code):  
Syngenta Crop Protection, Inc.  
P. O. Box 18300  
Greensboro, NC 27419-8300  
Attn: Robert Wurz

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/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 submit the following data and label revisions:

1. Submit and/or cite all data required for registration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. Before you release the product for shipment revise the EPA Registration number to read "EPA Reg. No. 100-973.
3. Submit the following information to satisfy the data gaps in the data base for Thiamethoxam and its metabolite. The following information is required within 15 months of the date of this Notice:

**Residue Chemistry:**

- 860.1340: Modification of Method AG-675 to add microwave extraction of liver or a new enforcement method for liver; additional radiovalidation data for beef liver
- 860.1380: Storage stability data continued to cover the conditions and intervals that plant and animal commodity samples were stored (up to 30 months)
- 860.1480: Reanalysis of the cow liver samples from the feeding study using a microwave extraction step
- 860.1900: Reanalysis of field rotational crop samples for metabolite CGA-265307 and description of storage conditions for future uses
- 860.1300: Plant metabolism study on a leafy vegetable (Crop Group 4 or 5)
- 860.1300: Poultry metabolism study

Signature of Approving Official:

Date:

DEC 4 2000

EPA form 8570-6 (EPA reg. No. 100-973) continued from page 1...

- Submit the following information to satisfy the data gaps in the data base for Thiamethoxam and its metabolite. The following information is required within two years of the date of this Notice:

**Toxicology Data:**

870.6300: Developmental neurotoxicity study.

**Ecological Effects**

72-4b: Daphnia chronic study repeated to fulfill guideline requirements

5. Submit two (2) copies of your **final printed label** for before your release the product for shipment. Please refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

A stamped copy of the label is enclosed for your records. If you have any questions regarding this action, please contact Dani Daniel at 703 305-5409.

Sincerely,

Kerry Leifer, Acting Chief  
Insecticide-Rodenticide Branch  
Registration Division (7505C)

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(11/30/00 harmonized w/Canada)

HELIX®

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: (CAS No. 153719-23-4).....	10.30%
Difenoconazole: (CAS No: 119446-68-3).....	1.28%
(R)-[(2,6-dimethylphenyl)- methoxyacetyl-amino]- propionic acid methyl ester (CAS No: 70630-17-0).....	0.40%
Related Compounds .....	0.01%
Fludioxonil: (CAS No. 131341-86-1).....	0.13%
<b>Other Ingredients:</b>	<b>87.88%</b>
<b>Total:</b>	<b>100.00%</b>

Helix contains the following amounts of active ingredient per gallon: 1.12 lbs. thiamethoxam; 0.14 lbs. difenoconazole; 0.04 lbs. (R)-[(2,6-dimethylphenyl)-methoxyacetyl-amino]-propionic acid methyl ester; 0.01 lbs. fludioxonil.

EPA Reg. No. 100-

EPA Est.

**KEEP OUT OF REACH OF CHILDREN.**

**CAUTION**

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

Made in Canada

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated:**

DEC 4 2000

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

100-973

**DIRECTIONS FOR USE AND 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 Novartis Crop Protection, Inc. or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold Novartis and Seller harmless for any claims relating to such factors.

Novartis 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 Novartis, and Buyer and User assume the risk of any such use. Novartis **MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

In no event shall Novartis or Seller 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 NOVARTIS 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 NOVARTIS OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

Novartis and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of Novartis.

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**DIRECTIONS FOR USE**

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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 Novartis, no claims are made to guarantee the germination of carry-over seed or propagating material for all crop seed.



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## GENERAL INFORMATION

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Helix is a seed treatment product that contains both insecticide and fungicide components with activity against flea beetles 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 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* spp., *Fusarium* spp. and *Rhizoctonia* spp." Thiamethoxam, difenoconazole, (R)-[(2,6-dimethylphenyl)-methoxyacetyl-amino]-propionic acid methyl ester, and fludioxonil are the active ingredients in Adage 5FS, Dividend®, Apron XL™ LS, and Maxim® 4FS, respectively.

**Note:** (R)-[(2,6-dimethylphenyl)-methoxyacetyl-amino]-propionic acid methyl ester is a systemic fungicide having a specific mode of action. (R)-[(2,6-dimethylphenyl)-methoxyacetyl-amino]-propionic acid methyl ester could be subject to development of insensitive strains of fungi. Development of insensitivity cannot be predicted. Therefore, Novartis 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 which may occur.

### Mixing Procedures

Helix is especially formulated as a ready to apply seed treatment. An EPA-approved coloring agent has been added to the formulation. No additional colorant, dyes, binders, or water are needed. 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 (R)-[(2,6-dimethylphenyl)-methoxyacetyl-amino]-propionic acid methyl ester fungicides." Do not use for feed, food, or oil purposes. Store away from feed and foodstuffs.

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## CANOLA

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To provide early season protection against flea beetles, 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* spp., *Fusarium* spp. and *Rhizoctonia* spp., apply Helix XTra at 23 fluid ounces of product per 100 lbs. of seed.

**Rotational Crops:** Treated areas may be replanted immediately following harvest or as soon as practical following the last application with canola. All other crops may be planted 30 days after the last application of Helix.

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## STORAGE AND DISPOSAL

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### Pesticide Storage and Disposal

Store in a cool, dry place. Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment. 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.

### Container Disposal

Triple rinse (or equivalent), then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or by open burning, if allowed by state and local authorities. If burned, keep out of smoke.

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. In the event of a major spill, fire, or other emergency, call 1-800-888-8372, day or night.

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## PRECAUTIONARY STATEMENTS

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### Hazards to Humans and Domestic Animals

#### CAUTION

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

**First Aid**

<b>If inhaled</b>	<ul style="list-style-type: none"> <li>• Move the person to fresh air.</li> <li>• If person is not breathing, call an ambulance, then give artificial respiration, preferably mouth to mouth, if possible.</li> <li>• Call a poison control center, doctor, or 1-800-888-8372 immediately for treatment advice.</li> </ul>
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, and after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center, doctor, or 1-800-888-8372 immediately for treatment advice.</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center, doctor or 1-800-888-8372 immediately for treatment advice.</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center, doctor, or 1-800-888-8372 immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor</li> </ul>

**Note to Physician:** There is no specific antidote if Helix is ingested. Induce emesis or lavage stomach. Treat symptomatically.

**Personal Protective Equipment**

Workers involved in treating, clean-up, or maintenance of seed treatment equipment must wear:

- Chemical-resistant coveralls over long sleeve shirt and long pants
- Chemical-resistant gloves
- 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 sleeve shirt and long pants
- Chemical resistant gloves
- 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 sleeve 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.



### **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 features such as ponds, streams, and streams, and springs will reduce the potential for contamination of water from rainfall runoff (See manual at the following internet address:

<http://www.nrcs.usda.gov/water/quality/common/pestmgmt/files/core4.html>).

Runoff of this product will be reduced by avoiding applications when rainfall is forecasted 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.

### **Environmental Hazards**

This pesticide is toxic to fish and 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 washwaters.

### **Spray Drift Advisory**

Do not allow this product to drift.

Helix®, Apron XL™, Maxim®, and Dividend® are trademarks of Novartis  
U.S. Patent Nos. 5,852,012 and 6,022,871

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Novartis Crop Protection, Inc.  
Seed Treatment Products  
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