

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

MAR 16 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Mr. Pat Dinnen Syngenta Crop Protection, LLC P.O. Box 18300 Greensboro, NC 27419

Subject: Removal of Expired Patent Numbers

Dear Mr. Dinnen:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated March 3, 2011 for:

EPA Reg. No 100-941 EPA Reg. No. 100-973

Cruiser Insecticide
Helix Insecticide with Fungicides

The Registration Division (RD) has conducted a review of this request for applicability under PRN 98-10 and finds that the label change(s) requested falls within the scope of PRN-98-10. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, call me at 703 305-5409 or electronically at daniel.dani@epa.gov.

Sincerely,

Dani Daniel

Registration Division (7504P)

Insecticide/Rodenticide Branch

Please read instructions on reverse	before completi <sup>ca</sup> form.					
	ار عاد المارك	es	Re tration	OPP Identifier Number		
Environmental Protection Age Washington, DC 20460		ction Agenoy IEIC A.	Amendment	Notification		
_	Washington, DC	20460 WOIIIUA	ther ther			
Application for Pesticitie (Section I						
Company/Product Number     100-973		2. EPA Produc Venus Eagle	t Manager	Proposed Classification		
4. Company/Product (Name)		PM#		x None Restricted		
Helix Insecticide with Fung  5. Name and Address of Applic		6. Expedited	Review. In accordance	with FIFRA Section 3(c)(3) (b)(i), my		
Syngenta Crop Prot			or identical in composition			
P. O. Box 18300 Greensboro, NC 27419		EPA Reg. No.	EPA Reg. No.			
Check if this is a new address		Product Name	Product Name			
		Section - II				
Amendment - Explain be	low.		Final printed labels in re	sponse to		
Resubmission in response to Agency letter dated			Agency letter dated  "Me Too" Application.			
X Notification - Explain belo			Other - Explain below.			
Explanation: Use additiona	page(s) if necessary. (F	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.						
Remove expired patent numbers	S					
Material This Product Will	Re Packaged In:	Section – III				
Child-Resistant Packaging Yes* No	Unit Packaging Yes No	Water Soluble Packa Yes No		pe of Container  Metal  Plastic  Glass		
*Certification must	If "Yes" No. Unit Packaging wgt. Cor	·	No. per	Paper		
be submitted			container	Other (Specify)		
3. Location of Net Contents Info	ormation 4. 30 ga ntainer	Size(s) Retail Container al.	×	on of Label Directions On Label On Labeling accompanying product		
6. Manner in Which Label is Af						
Paper glued CCCCC Stenciled CCCCC						
	<del>-</del>	Section - IV		C t C C C		
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)						
Name Pat Dinnen		Title Staff Label Group Leade	er	Telephone No. (Include Area Code) 333-632-2494		
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 (Stamped) both under applicable law.						
2. Signature		Title     Staff Label Group Leader				
Pat Alianen				( ( ( ( (		

5. Date March 3, 2011

4. Typed Name Pat Dinnen

## Certification with Respect to Label Integrity Version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL				
EPA Registration #	Date Submitted to EPA	Electronic file name		
100-973	3/3/11	000100-00973.20110303.PATENT_NOTIF_MAR2011.pdf		

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

Pat alinnen	March 3, 2011
Signature	Date
Pat Dinnen Name (typed)	-
Label Group Leader Title	-



# NOTIFICATION JAN 1 \$\phi\$ 2011

#### **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*	
Difenoconazole**	
Mefenoxam***	
Fludioxonil****	0.13%
Other Ingredients:	87.94%
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 contains the following amounts of active ingredient per gallon: 1.12 lbs. thiamethoxam; 0.13 lb. difenoconazole; 0.04 lb. mefenoxam; 0.01 lb. fludioxonil.

#### KEEP OUT OF REACH OF CHILDREN.

#### **CAUTION**

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

EPA Reg. No. 100-973

EPA Est. xxxxx

**Product of Canada** 

SCP 973A-M (8-27-09)

**Net Contents** 



FIRST AID		
If inhaled	<ul> <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>	
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, 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>	
If on skin or clothing	<ul> <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>	
If swallowed	<ul> <li>Call a poison control center, doctor, or 1-800-888-8372 immediately for treatment advice.</li> <li>Have a person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a 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.

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. 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., barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, natural rubber, polyethylene, polyvinylchloride [PVC] 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., barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, natural rubber, polyethylene, polyvinylchloride [PVC] 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 product 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 features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall runoff (See manual at the following internet address: <a href="http://www.wcc.nrcs.usda.gov/pestmgt/core4.html">http://www.wcc.nrcs.usda.gov/pestmgt/core4.html</a>). Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.

#### Ground Water Advisory

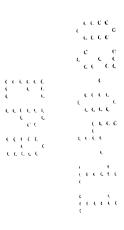
Thiamethoxam has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow may result in ground water contamination.

#### 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, LLC 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 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* species, *Fusarium* species, and *Rhizoctonia* species. Thiamethoxam, difenoconazole, mefenoxam, and fludioxonil are the active ingredients in Cruiser® 5FS, Dívidend®, 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 fungicial 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 which may occur.

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#### **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 mefenoxam fungicides. Do not use for feed, food, or oil purposes. Store away from feed and foodstuffs."

#### **CANOLA**

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* species, *Fusarium* species, and *Rhizoctonia* species, apply Helix at 23 fluid ounces of product per 100 pounds of seed.

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

#### 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 of at an expansion 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 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 or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Apron XL®, Cruiser®, Dividend®, Helix®, Maxim®, the Syngenta logo, and the CP FRAME are trademarks of a Syngenta Group Company

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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, LLC P.O. Box 18300 Greensboro, North Carolina 27419-8300

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