

100-973  
EPA

United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number  
NOTIFICATION

Application for Pesticide - Section I

1. Company/Product Number 100-973	2. EPA Product Manager Dani Daniel	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Helix®	PM# 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 Agency letter dated _____	<b>NOTIFICATION</b>  DEC 18 2001
<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.	

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)  
 Notification per PR-Notice 98-10, Alternate brand name: Helix Lite, Submission of final printed labels.  
 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. The following changes are being made via this notification: 1) Company name and address have been updated to reflect Syngenta Crop Protection, Inc. 2) The Conditions of Sale and Warranty statement has been changed to reflect the name change. Because Syngenta has been formed by the merger of Novartis Crop Protection, Inc. and Zeneca Ag Products, we have chosen to use the former Zeneca warranty statement as the Syngenta warranty statement. No other changes occur in the statement other than the name change. 3) The copyright date reflects Syngenta. 4) Trademark statements have been updated to reflect Syngenta for those products for which Syngenta holds the trademark. 5) The Internet address has been changed to reflect Syngenta. 6) Other places in the label which referring to the company name have been updated.

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	Metal <input type="checkbox"/>		Plastic <input type="checkbox"/>
*Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Unit Packaging wgt. No. per container		Glass <input type="checkbox"/>
					Paper <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) 336-632-2305
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 10, 2001	

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PULL HERE TO OPEN ▶



### **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) . . . . .	1.24%
(R)-[2,6-dimethylphenyl]-methoxyacetylamino]-propionic acid methyl ester (CAS No. 70630-17-0) . . . . .	0.39%
Related Compounds . . . . .	0.01%
Fludioxonil (CAS No. 131341-86-1) . . . . .	0.13%
<b>Other Ingredients:</b> . . . . .	<b>87.93%</b>

**Total:** 100.00%

*Helix Lite contains the following amounts of active ingredient per gallon: 1.12 lbs. thiamethoxam; 0.13 lb. difenoconazole; 0.04 lb. (R)-[2,6-dimethylphenyl]-methoxyacetylamino]-propionic acid methyl ester; 0.01 lb. fludioxonil.*

**KEEP OUT OF REACH OF CHILDREN.  
CAUTION**

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

EPA Reg. No. 100-973  
EPA Est. 71478-CAN-001

Product of Canada  
**SCP 973A-L4 1201**

**30 gallons**  
U.S. Standard  
Measure



**NOTIFICATION**

DEC 18 2001

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## Helix™ Lite

<b>FIRST AID</b>	
<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, 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 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>
<b>Note to Physician</b>	
There is no specific antidote if Helix Lite 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.	
<b>HOT LINE NUMBER</b>	
For 24 Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call <b>1-800-888-8372</b>	

### 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. 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
- 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
- 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.

**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: <http://www.nrcs.usda.gov/water/quality/common/pestmgt/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 product 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 wash water.

**Spray Drift Advisory**

Do not allow this product to drift.

**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.

In no event shall SYNGENTA 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 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 Limitations of Warranty and of 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.**

**STORAGE AND DISPOSAL****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.

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**GENERAL INFORMATION**

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.

Helix(Lite) 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 Cruiser® 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, 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.

**MIXING PROCEDURES**

Helix(Lite) 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."

**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* spp., *Fusarium* spp., and *Rhizoctonia* spp., apply Helix(Lite) at 23 fl. ozs. 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 Lite.

Helix™(Lite) Cruiser®, Apron XL®, Dividend®, 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.

Product of Canada

Syngenta Crop Protection, Inc.  
Greensboro, North Carolina 27409  
www.syngenta-us.com  
SCP 973A-L4 1201

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December 7, 2001

**FEDERAL EXPRESS**

Ms. Dani Daniel:  
Registration Division (H7505C)  
Insecticide-Rodenticide Branch  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington VA 22202-4501

Dear Ms. Daniel:

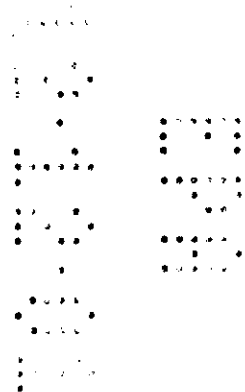
**Subject: Helix®  
EPA Reg. No. 100-973  
NOTIFICATION per PR Notice 98-10**  
**1. Alternate Brand Name: Helix Lite.**  
**2. Submission of Final Printed Labels**

Syngenta Crop Protection Inc. hereby notifies EPA under the provisions of PR Notice 98-10 of an alternate brand name: Helix Lite. The primary brand name remains Helix. All future label amendments will be submitted under the primary brand name.

Future final printed label submissions may reflect either Helix or Helix Lite.

The final printed label submitted herein reflects the alternate brand name: Helix Lite. In addition to the alternate brand name, the label also reflects the changes in the active ingredient percentages approved by EPA in a letter dated October 26, 2001.

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.



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We trust that you will find this submission in order, however, should you have any questions, please do not hesitate to contact me.

Sincerely,



Frederick J. Pearson  
NAFTA Insecticide Team Leader  
Regulatory Affairs  
Syngenta Crop Protection  
Phone: 336.632.2365  
Fax: 336.292.6374  
e-mail: [fred.pearson@syngenta.com](mailto:fred.pearson@syngenta.com)

