



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 26, 2020

Odette Alexander-Watkins
Regulatory Product Manager
Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, NC 27419

Subject: Registration Review Label Mitigation for Fludioxonil and Mefenoxam
Product Name: Helix Insecticide with Fungicides
EPA Registration Number: 100-973
Application Dates: 7/31/2018; 2/1/2019
Decision Numbers: 555251; 555252

Dear Ms. Alexander-Watkins:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with Fludioxonil and Mefenoxam Interim Decisions, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

A copy of your label stamped "Accepted" is enclosed. Products shipped after 12 months from the date of this amendment must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

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Decision No. 555251; 555252

If you have any questions about this letter, please contact Darius Stanton by phone at 703-347-0433, or via email at Stanton.Darius@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to be "Linda Arrington", written in a cursive style.

Linda Arrington, Branch Chief
Risk Management and Implementation Branch 4
Pesticide Re-Evaluation Division
Office of Pesticide Programs

Enclosure

(MASTER)

THIAMETHOXAM	GROUP	4A	INSECTICIDE
DIFENOCONAZOLE	GROUP	3	FUNGICIDE
MEFENOXAM	GROUP	4	FUNGICIDE
FLUDIOXONIL	GROUP	12	FUNGICIDE

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*	10.30%
Difenoconazole**	1.24%
Mefenoxam***	0.39%
Fludioxonil****	0.13%
<hr/>	
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 lb 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.

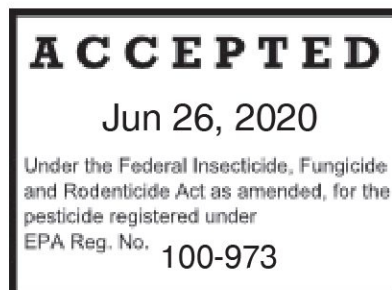
EPA Reg. No. 100-973

EPA Est. xxxx

Product of Canada

SCP 973A

Net Contents



FIRST AID	
If inhaled	<ul style="list-style-type: none">• Move the person to fresh air.• If person is not breathing, call an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a poison control center, doctor, or 1-800-888-8372 immediately for treatment advice.
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, doctor, or 1-800-888-8372 immediately 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, doctor, or 1-800-888-8372 immediately for treatment advice.
If swallowed	<ul style="list-style-type: none">• Call a poison control center, doctor, or 1-800-888-8372 immediately for treatment advice.• Have a person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.
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 barrier laminate, butyl rubber \geq 14 mils, nitrile rubber \geq 14 mils, neoprene rubber \geq 14 mils, natural rubber \geq 14 mils, polyethylene, polyvinylchloride (PVC) \geq 14 mils or Viton® \geq 14 mils
- Head gear
- Wear a minimum of an elastomeric half-face NIOSH-approved respirator with any N, R or P filter (TC-84A); OR a full-face NIOSH-approved particulate respirator with any N, R or P filter (TC-84A); OR a NIOSH-approved powered air purifying respirator with an HE filter (TC-21C).

Baggers, sewers, and stackers must wear:

- Regular coveralls over long-sleeved shirt and long pants
- Chemical-resistant gloves made of barrier laminate, butyl rubber \geq 14 mils, nitrile rubber \geq 14 mils, neoprene rubber \geq 14 mils, natural rubber \geq 14 mils, polyethylene, polyvinylchloride (PVC) \geq 14 mils or Viton® \geq 14 mils
- Head gear
- Wear a minimum of an elastomeric half-face NIOSH-approved respirator with any N, R or P filter (TC-84A); OR a full-face NIOSH-approved particulate respirator with any N, R or P filter (TC-84A); OR a NIOSH-approved powered air purifying respirator with an HE filter (TC-21C).

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:

<http://www.wcc.nrcs.usda.gov/pestmgmt/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.

- **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.

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.

Maximum usage when applying metalaxyl- and mefenoxam- containing products to the same crop within the same season: Do not apply more than the maximum yearly total application rate for the active ingredient as stated on the label of the product containing the lowest yearly total on that crop.

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.

PRODUCT 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, Dividend®, Apron XL LS®, and Maxim® 4FS, respectively.

RESISTANCE MANAGEMENT

DIFENOCONAZOLE	GROUP	3	FUNGICIDE
MEFENOXAM	GROUP	4	FUNGICIDE
FLUDIOXONIL	GROUP	12	FUNGICIDE

For resistance management, please note that Helix contains Group 3/difenoconazole, Group 4/mefenoxam, and Group 12/fludioxonil fungicides. Any fungal populations may contain individuals naturally resistant to Helix and other Group 3, Group 4 or Group 12 fungicides. A gradual or total loss of pest control may occur over time if these fungicides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.

Difenoconazole belongs to the triazole class of chemistry and is a demethylation inhibitor of sterol biosynthesis (DMI) which disrupts membrane synthesis of the fungal cell. Mefenoxam belongs to the phenylamide class of chemistry which interferes with fungal RNA synthesis. Fludioxonil belongs to the phenylpyrrole class of chemistry which interferes with osmotic signal transduction.

To delay fungicide resistance, take one or more of the following steps:

- Rotate the use of Helix or other Group 3, Group 4 or Group 12 fungicide within a growing season sequence with different groups that control the same pathogens.
- Use tank mixtures with fungicide from a different group that are equally effective on the target pest when such use is permitted. Use at least the minimum application rate as labeled by the manufacturer.
- Adopt an integrated disease management program for fungicide use that includes scouting, uses historical information related to pesticide use, and crop rotation, and which considers host plant resistance, impact of environmental conditions on disease development, disease thresholds, as well as cultural, biological and other chemical control practices.
- Where possible, make use of predictive disease models to effectively time fungicide applications. Note that using predictive models alone is not sufficient to manage resistance.
- Monitor treated fungal populations for resistance development.
- Contact your local extension specialist or certified crop advisor for any additional pesticide resistance-management and/or IPM recommendations for specific crop and pathogens.
- For further information or to report suspected resistance contact Syngenta at 1-866-Syngent(a) (866-796-4368). You can also contact your pesticide distributor or university extension specialist to report resistance.

THIAMETHOXAM	GROUP	4A	INSECTICIDE
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For resistance management, Helix contains a Group 4A/thiamethoxam insecticide. Any insect population may contain individuals naturally resistant to Helix and other Group 4A insecticides. The resistant individuals may dominate the insect population if this group of insecticides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.

Thiamethoxam is a systemic insecticide belonging to the neonicotinoid class of chemistry which includes nicotinic acetylcholine receptor (nAChR) agonists.

In order to maintain susceptibility to this class of chemistry:

- Avoid using Group 4A insecticides exclusively for season long control of insect species with more than one generation per crop season.
- For insect species with successive or overlapping generations, apply Helix or other Group 4A insecticides using a “treatment window” approach. A treatment window is a period of time as defined by the stage of crop development and/or the biology of the pests of concern. Within the treatment window, depending on the length of residual activity, there may either be single or consecutive applications (seed treatment, soil, foliar, unless otherwise stated) of the Group 4A insecticides. Do not exceed the maximum Helix allowed per growing season.
- Following a treatment window of Group 4A insecticides, rotate to a treatment window of effective products with a different mode of action before making additional applications of Group 4A insecticides.
- A treatment window rotation, along with other IPM practices for the crop and use area, is considered an effective strategy for preventing or delaying a pest’s ability to develop resistance to this class of chemistry.
- If resistance is suspected, do not reapply Helix or any other Group 4A insecticides.

Other Insect Resistance Management (IRM) practices include:

- Incorporating IPM techniques into your insect control program.
- Monitoring treated insect populations for loss of field efficacy.
- Using tank-mixtures or premixes with insecticides from a different target site of action group as long as the involved products are all registered for the same crop outlet and effective rates are applied.

For additional information on Insect Resistance Management:

- Contact your local extension specialist, certified crop advisor and/or product manufacturer for additional insect resistance management recommendations.
- Visit the Insecticide Resistance Action Committee (IRAC) on the web at: <http://www.irac-online.org/>.

Syngenta encourages responsible product stewardship to ensure effective long term control of the fungal diseases and insect pests on this label.

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.

DO NOT apply more than 0.0013 lb ai/Acre (0.58 g ai/Acre) per calendar year of mefenoxam- or metalaxyl-containing products as a seed treatment on Canola.

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 Handling

Non-refillable container. Do not reuse or refill this container. 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 $\frac{1}{4}$ 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 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 by other procedures approved by state and local authorities.

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For non-emergency (e.g. current product information) call Syngenta Crop Protection at 1-800-334-9481.
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Manufactured for:
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Greensboro, North Carolina 27419-8300

SCP 973A

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