



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 20, 2019

Ricky Kyaw
Regulatory Product Manager
Syngenta Crop Protection, LLC
PO Box 18300
Greensboro, NC 27419

Subject: Registration Review Label Mitigation for Fludioxonil and Mefenoxam
Product Name: Helix Vibrance
EPA Registration Number: 100-1528
Application Date: 2/1/2019
Decision Number: 554973; 554974

Dear Mr. Kyaw:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the Registration Review of the above referenced product in connection with the 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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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 read "Linda Arrington".

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

Enclosure

(Master Label)

| | | | |
|-----------------------|--------------|-----------|--------------------|
| THIAMETHOXAM | GROUP | 4A | INSECTICIDE |
| DIFENOCONAZOLE | GROUP | 3 | FUNGICIDE |
| MEFENOXAM | GROUP | 4 | FUNGICIDE |
| SEDAXANE | GROUP | 7 | FUNGICIDE |
| FLUDIOXONIL | GROUP | 12 | FUNGICIDE |

Helix® Vibrance®

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.

Active Ingredients:

| | |
|-------------------------------------|---------|
| Thiamethoxam ¹ | 20.7% |
| Difenoconazole ² : | 1.25% |
| Mefenoxam ³ : | 0.40% |
| Fludioxonil ⁴ : | 0.13% |
| Sedaxane ⁵ | 0.26% |
| <hr/> | |
| Other Ingredients: | 77.26% |
| Total: | 100.00% |

¹CAS No. 153719-23-4²CAS No. 119446-68-3³CAS Nos. 70630-17-0 and 69516-34-3⁴CAS No. 131341-86-1⁵CAS No. 874967-67-6

Helix® Vibrance® contains the following amounts of active ingredient per gallon:
 2.25 lb thiamethoxam; 0.14 lb difenoconazole; 0.04 lb mefenoxam; 0.01 lb fludioxonil,
 0.03 lb sedaxane.

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

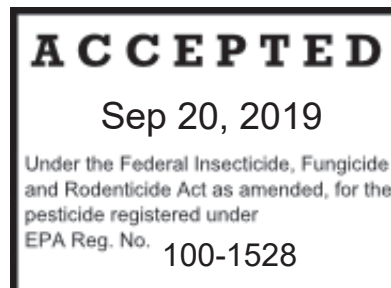
See additional precautionary statements and directions for use in booklet [on label].

EPA Reg. No. 100-1528

EPA Est. xxxxx

SCP 1528-MAS 0614

_____ Net Contents



| FIRST AID | |
|---|--|
| 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. |
| 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 swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Personal Protective Equipment

Workers involved in treating, cleanup, or maintenance of seed treatment equipment must wear:

- Coveralls worn over long-sleeved shirt and long pants
- Socks and shoes
- Chemical-resistant gloves made of barrier laminate, butyl rubber ≥ 14 mils, nitrile rubber ≥ 14 mils, neoprene rubber ≥ 14 mils, natural rubber ≥ 14 mils, polyethylene, polyvinylchloride (PVC) or Viton® ≥ 14 mils

Baggers, sewers, and stackers must wear:

- Coveralls worn over long-sleeved shirt and long pants
- Socks and shoes
- Chemical-resistant gloves made of barrier laminate, butyl rubber ≥ 14 mils, nitrile rubber ≥ 14 mils, neoprene rubber ≥ 14 mils, natural rubber ≥ 14 mils, polyethylene, polyvinylchloride (PVC) or Viton® ≥ 14 mils

Forklift operators

- Coveralls worn over long-sleeved shirt and long pants.
- Socks and shoes

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.

User Safety Recommendations**Users should:**

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards

This pesticide is toxic to wildlife, freshwater and estuarine/marine fish and highly toxic to aquatic invertebrates. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Exposed treated seed may be hazardous to wildlife. Do not contaminate water when disposing of equipment wash water or rinsate.

Pollinator Precautions:

Thiamethoxam is highly toxic to bees, and effects are possible as a result of exposure to translocated residues in blooming crops.

If treated seed is spilled outdoors or in areas accessible to birds, promptly clean up or bury to prevent ingestion.

Ground Water Advisory

Thiamethoxam has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into the ground water if used in areas where soils are permeable, particularly where the water table is shallow.

Mefenoxam is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

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 must 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. To the extent permitted by applicable law, 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. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. To the extent permitted by applicable law, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, 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.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

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 Vibrance is a seed treatment product that contains both insecticide and fungicide components with activity against certain early season insects, and seed borne and damping off diseases of canola. Thiamethoxam, the insecticide component, provides activity against aphids, flea beetles, seedcorn maggot, white grubs, and wireworms. The remaining components are fungicides with activity against diseases caused by *Alternaria* species, *Pythium* species, *Fusarium* species, *Rhizoctonia* species, and seed-borne blackleg (*Leptosphaeria maculans*).

MIXING PROCEDURES

Important: Always re-circulate Helix Vibrance thoroughly before using.

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.

Helix Vibrance contains an EPA approved dye/colorant that imparts an unnatural color to the seed as required by the Federal Seed Act.

Helix Vibrance has a density of approximately 10.85 pounds per gallon.

SEED BAG LABEL REQUIREMENTS

The Federal Seed Act requires that bags containing treated seeds shall be labeled with the following statements:

- This seed has been treated with thiamethoxam insecticide and fludioxonil, difenoconazole, mefenoxam, and sedaxane fungicides.
- Do not use for feed, food, or oil purposes.
- User is responsible for ensuring that the seed bag meets all requirements under the Federal Seed Act.

In addition, the U.S. Environmental Protection Agency requires the following statements on bags containing seeds treated with Helix Vibrance:

- Ground Water Advisory:
Thiamethoxam has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into the ground water if used in areas where soils are permeable, particularly where the water table is shallow.
Mefenoxam is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.
- Pollinator Precautions:
Thiamethoxam is highly toxic to bees, and effects are possible as a result of exposure to translocated residues in blooming crops.
- Excess treated seed may be used for ethanol production only if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in the ethanol by-products that are used in agronomic practice.
- Do not allow children, pets, or livestock to have access to treated seed.

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- Store away from feeds and foodstuffs.
- Wear long-sleeved shirt, long pants and chemical resistant gloves when handling treated seed.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Treated seed must be planted into the soil at a depth greater than 1/2 inch.
- Dispose of all excess treated seed. Leftover treated seed may be doublesown around the headland or buried away from water sources in accordance with local requirements.
- Do not contaminate water bodies when disposing of planting equipment wash waters.
- Dispose of seed packaging in accordance with local requirements.
- For seed treated with Helix Vibrance, do not graze or feed livestock on treated areas for 45 days after planting.
- In the event of a crop failure or harvest of a crop grown from Helix Vibrance treated seed, the field may be replanted immediately to canola, soybean, barley, oat, rye, triticale and wheat, sweet corn, and chickpea.
- Alfalfa, *Brassica* (cole) leafy vegetables, buckwheat, corn, pearl millet, proso millet, popcorn, rice (dry-seeded), sorghum, teosinte, wild rice, cotton, cucurbit vegetables, dry bulb onions, fruiting vegetables, leafy vegetables, legume vegetables, mint (peppermint and spearmint), oil seed crops (black mustard seed, borage seed, crambe seed, field mustard seed, flax seed, Indian mustard seed, Indian rapeseed seed, peanuts, rapeseed seed, and safflower seed), root vegetables, strawberry, sunflowers, tobacco, and tuberous and corm vegetables may be planted 30 days from the date the Helix Vibrance treated seed was planted.
- For any other crop, the minimum plant back interval is 120 days from the date the Helix Vibrance treated seed was planted. A cover crop other than the crops listed above that is planted for erosion control or soil improvement may be planted sooner than the 120 day interval; however, the crop may not be grazed or harvested for food or feed.
- Do not use at a rate that will result in more than 0.05 lb thiamethoxam per acre (22.7 grams ai/A) per year as a seed treatment application.
- This seed has been treated with 0.01 mg ai thiamethoxam per seed.
- Do not make any soil or foliar applications containing thiamethoxam to crops grown from seed treated with Helix Vibrance.

Resistance Management

| | | | |
|-----------------------|--------------|-----------|------------------|
| DIFENOCONAZOLE | GROUP | 3 | FUNGICIDE |
| MEFENOXAM | GROUP | 4 | FUNGICIDE |
| SEDAXANE | GROUP | 7 | FUNGICIDE |
| FLUDIOXONIL | GROUP | 12 | FUNGICIDE |

For resistance management, please note that Helix Vibrance contains Group 3/difenoconazole, Group 4/mefenoxam Group 7/sedaxane and Group 12/fludioxonil fungicides. Any fungal populations may contain individuals naturally resistant to Helix Vibrance and other Group 3, Group 4, Group 7 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. Sedaxane is a succinate dehydrogenase inhibitor (SDHI) and belongs to the carboxamide class of chemistry which disrupts cellular respiration and energy generation. 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 Vibrance or other Group 3, Group 4, Group 7 or Group 12 fungicides 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 |
|---------------------|--------------|-----------|--------------------|

For resistance management, Helix Vibrance contains a Group 4A/thiamethoxam insecticide. Any insect population may contain individuals naturally resistant to Helix Vibrance 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 [brand name] 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 in the Directions for Use) of the Group 4A insecticides. When using Helix Vibrance seed treatment in the first treatment window rotate to effective products with a different mode of action in the subsequent treatment window 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 apply Helix Vibrance 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 and insect pests on this label.

CROP USE DIRECTIONS

Canola

To provide early season protection against aphids, flea beetles, seedcorn maggot, white grubs, wireworms, 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 Vibrance at 23 fluid ounces of product per 100 pounds of seed.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage

Store in original containers only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, mop and remove to chemical waste storage area until proper disposal can be made if product cannot be used according to the label.

Pesticide Disposal

Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative of the nearest EPA Regional Office for guidance.

Container Handling [less than 5 gallons]

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 and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use and disposal. Drain for 10 seconds after the flow begins to drip. 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 allowed by state and local authorities.

Container Handling [greater than 5 gallons]

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 by other procedures allowed by state and local authorities.

Container Handling [greater than 5 gallons]

Refillable container. Refill this container with pesticide only. Do not use this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing 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 allowed by state and local authorities.

CONTAINER IS NOT SAFE FOR FOOD, FEED OR DRINKING WATER.

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

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