

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 23, 2019

Ian Murphy Federal Registrations Manager Bayer Crop Science 2 T.W. Alexander Drive P. O. Box 12014 RTP, NC 27709

Subject: Registration Review Label Mitigation for Metalaxyl and Trifloxystrobin Product Name: Pentrime EPA Registration Number: 264-1182 Application Dates: 06/28/2018 and 09/10/2019 Decision Numbers: 555264 and 555165

Dear Mr. Murphy:

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 Metalaxyl and Trifloxystrobin 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 Srijana Shrestha by phone at 703-305-6471, or via email at Shrestha.srijana@epa.gov.

Sincerely,

2.

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

Enclosure

PENFLUFEN	GROUP	7	FUNGICIDE
TRIFLOXYSTROBIN	GROUP	11	FUNGICIDE
METALAXYL	GROUP	4	FUNGICIDE

PENTRIME ABN: EverGol[®] Activ

For: Use as a fungicide treatment for protection against listed soilborne, seedborne, and post-emergence diseases of listed crop plants. ACTIVE INCREDIENTS

ACTIVE INGREDIENTS. Penflufen Trifloxystrobin Metalaxyl	0.77%
OTHER INGREDIENTS:	

Contains 0.126 pound penflufen per U.S. gallon (15.1 grams Al/liter) Contains 0.0834 pound trifloxystrobin per U.S. gallon (10.0 grams Al/liter) Contains 0.0834 pound metalaxyl per U.S. gallon (10.0 grams Al/liter)

EPA Reg. No. 264-1182

EPA Est.

KEEP OUT OF REACH OF CHILDREN CAUTION

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577 For PRODUCT USE Information Call 1-800-331-2867

Please refer to [back panel] [booklet] for additional precautionary statements and directions for use. [Note to reviewer: Location of additional precautionary statements and directions for use will vary between those listed, depending on container type/size.]

Net Contents:

PRODUCED FOR



Bayer CropScience LP 800 N. Lindbergh Blvd. St. Louis, MO 63167 1-866-99BAYER (1-866-992-2937)

ACCEPTED

Sep 23, 2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 264-1182

FIRST AID		
If Swallowed:	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 by a poison control center or doctor. 	
	Do not give anything by mouth to an unconscious person.	
lf on Skin:	Take off contaminated clothing.	
	Rinse skin immediately with plenty of water for 15-20 minutes.	
	Call a poison control center or doctor for treatment advice.	
If in Eyes:	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.	
	Call a poison control center or doctor for treatment advice.	
	emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577. duct container or label with you when calling a poison control center or doctor, or going for treatment.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

- Harmful if swallowed.
- Harmful if absorbed through skin.
- Causes moderate eye irritation.
- Avoid contact with skin, eyes, or clothing.
- · Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are barrier laminate, butyl rubber ≥14 mils, nitrile rubber ≥14 mills, neoprene rubber ≥14 mills, polyvinyl chloride (PVC) ≥14 mils, and viton ≥14 mills.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Applicators and other handlers must wear:

- Protective eye wear.
- Long sleeved shirt and long pants.
- Socks plus shoe.
- Chemical resistant gloves such as barrier laminate, butyl rubber ≥14 mils, nitrile rubber ≥14 mills, neoprene rubber ≥14 mills, polyvinyl chloride (PVC) ≥14 mils, or viton ≥14 mills.

USER SAFETY RECOMMENDATIONS

- Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product.
- Users should wash the outside of gloves before removing.
- · Users should as soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Applying this product when rain is not predicted for the next 24 hours will help reduce potential risk to aquatic invertebrates by reducing pesticide runoff from the treatment area into water bodies.Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate. Drift or run-off from treated areas is hazardous to fish and aquatic organisms in water adjacent to treated areas. Treated seed exposed on the soil surface may be hazardous to wildlife. Treated seed exposed on soil surface may be hazardous to wildlife.

This product has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow. Therefore contain any product spills or equipment leaks and dispose of wastes according to the disposal instructions on this label.

CONDITIONS OF SALE AND LIMITATIONS OF WARRANTY AND LIABILITY

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience, no claims are made to guarantee germination of carry-over seed.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label before using this product. Formulation Type: Flowable Suspension

PRODUCT INFORMATION AND INSTRUCTIONS

PENTRIME:

- Is a fungicide seed treatment for use on canola (including Brassica napus and Brassica rapa), mustard and rapeseed.
- Is used for the control of seed rot, damping off, seedling blight and early season root rot caused by *Pythium*, *Rhizoctonia*, *Fusarium*, *Alternaria* and seedborne Blackleg.

USE RESTRICTIONS

- For protection of seeds and emerging seedlings only.
- For use only in commercial seed treatment equipment.
- Do not use in hopper box, planter box, slurry box, or other on-farm seed treatment applications.
- Maximum usage when applying both 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.

Refer to the specific use directions and restrictions in each Crop Use Direction table.

COMPATIBILITY

It is essential that before using PENTRIME seed treatment in any tank mixture the compatibility of the mixture be established. Add PENTRIME at the labeled rate to a clean quart jar containing approximately one-half the amount of water intended for a final slurry application rate. Next, follow with all other tank mix components that will be used in the total slurry application. Add last the remaining balance of water. The total amount of volume is determined by the seed size and how much is necessary to ensure complete and uniform coverage and distribution on the seed, as well as the type of commercial seed treating application equipment that will be used. DO NOT USE MIXTURES THAT CURDLE, PRECIPITATE, OR GEL. USE TANK MIXTURES IMMEDIATELY AFTER MIXING WITH ADEQUATE AGITATION.

RESISTANCE MANAGEMENT RECOMMENDATION

For resistance management, please note that PENTRIME contains a Group 7 [Succinate- dehydrogenase inhibitors], a Group 11 [Qolfungicides] and a Group 4 [Phenylamides class] fungicide. Any fungal population may contain individuals naturally resistant to PENTRIME and other Group 7, 11, or 4 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.

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

- 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.
- 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 crops and pathogens.
- For further information or to report suspected resistance contact Bayer CropScience at 1-866-99BAYER (1-866-992-2937). You can also contact your pesticide distributor or university extension specialist to report resistance

SPECIFIC CROP DIRECTIONS

CROP USE DIRECTIONS

COMMERCIAL SEED TREATMENT

CANOLA Including Brassica napus and Brassica rapa, Rapeseed and Mustard Disease(s) Product Rate (Per 100 lbs Seed) Seed Rot 15.34 fl oz Damping Off (1.0 liters of product per 100 kgs of seed) Seedling Blight (15.92 g ais per 100 lb seed, based on an average of 100,000 Early season root rot caused by Pythium, Rhizoctonia, Fusarium seeds per lb) and Alternaria Seedborne Blackleg **Crop Specific Directions and Restrictions:** Apply using commercial slurry or mist-type seed treatment equipment. Mix thoroughly before use. Use high quality, properly cleaned seed. • Pre-test all tank mixes to determine the physical compatibility between formulations. Follow all cautions and most restrictive . limitations on labeling for all products used in mixtures.

Prior to and during application, PENTRIME must be thoroughly agitated to ensure uniform mixing.

For protection of seeds and emerging seedlings only.

SEED TAG LABELING

The Federal Seed Act requires that the container of seed treated with PENTRIME must be labeled with the following statements:

- This seed has been treated with:
 - o PENTRIME, which contains 0.77% Metalaxyl, 0.77% Trifloxystrobin, and 1.16 % Penflufen.
- Do not use treated seed for food, feed, or oil production. User is responsible for ensuring that the seed bag meets all the requirements under the Federal Seed Act.

In addition, the following statements must be on containers of seed treated with **PENTRIME**:

- Store treated seeds away from food and feedstuffs.
- Do not allow children, pets, or livestock to have access to treated seed.
- Wear long-sleeved shirt, long pants and chemical-resistant gloves when handling treated seed.
- 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 ethanol by-products that are used in agronomic practice.
 - Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Dispose of all excess treated seed. Leftover treated seed may be buried away from water sources in accordance with local requirements.
- Do not contaminate water bodies when disposing of planting equipment wash waters.
- Use planting equipment that will plant treated seed into the soil to a minimum depth of 0.5 inch.
- Dispose of seed packaging or containers in accordance with local requirements. Do not use empty seed bags for any other purpose.
- To reduce seed dust which can drift onto blooming crops or weeds, ensure that planting equipment is functioning properly in accordance with manufacturer's recommendations. Surplus seed or empty seed containers should be stored or disposed according to local regulations.
- This pesticide is toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.
- Runoff may be hazardous to aquatic organisms in water adjacent to treated areas.
- This compound is toxic to birds. Treated seed exposed on soil surface may be hazardous to birds. Cover or collect seeds spilled during loading.
- This seed treatment contains metalaxyl that is known to leach through soil into ground water under certain conditions as result
 of agricultural use. Use of this product in areas where soils are permeable, particularly where the water table is shallow, may
 result in ground water contamination.
- Crops for which tolerances exist for trifloxystrobin and penflufen may be replanted at any time. All other crops may be planted after 30 days.
- For Canola (including *Brassica napus* and *Brassica rapa*), rapeseed and Mustard (based on canola, rapeseed or mustard seeding rate): Do not exceed 0.00123 lb. penflufen/A (0.6 g ai/A) per crop season.

For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

For MEDICAL, TRANSPORTATION or OTHER Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment.

Pesticide storage

Store in original container away from feed and food. Store in cool, dry area. Do not store in direct sunlight. Do not allow prolonged storage in temperatures that exceed 105° F (40° C) or in temperatures that fall below 14° F (-10° C).

Pesticide disposal

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Container handling

[Dilutable Seed Treatment Products in Non-Refillable Plastic Containers]

Rigid Non-refillable containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs) Non-refillable container. Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

Bottom Discharge IBC (e.g. - Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g.- Snyder 120 Next Gen, Bonar B120, Drums, and Kegs)

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

[Dilutable Seed Treatment Products in Non-Refillable Metal Containers]

Nonrefillable container. Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

Liquid dilutables in containers small enough to shake (5 gallons or less)

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 or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Solid dilutables in containers small enough to shake (5 gallons or 50 pounds or less)

Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. 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 or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times

Any dilutable pesticides in containers too large to shake (larger than 5 gallons or 50 pounds)

Triple Rinse as follows: Empty 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.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

[Non-Dilutable Seed-Treatment Products in Non-Refillable Containers]

Seed-Treatment Products in Non-Refillable Fiber Drums with Liners

Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment, then offer for recycling if available or dispose of in a sanitary landfill or by incineration. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

Seed-Treatment Products in Non-rigid, Non-Refillable Containers

Nonrefillable container. Do not reuse or refill this container. Completely empty container into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

[Seed Treatment Products in Refillable Containers]

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781) or rinse and either recycle or dispose of the container as follows:

Bottom Discharge IBC (e.g. - Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing 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 pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g. - Snyder 120 Next Gen, Bonar B120, Drums, and Kegs)

Triple rinsing 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 triple rinse the containers before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

End users are authorized to remove tamper evident cables as required to remove the product from the container unless the container is equipped with one way valves and refilling or returning is planned. If this is the case, end users are not authorized to remove tamper evident cables, one way valves or clean container.

PENTRIME (Pending) 06/01/2018, 06/26/2018, 07/15/2019, 08/22/2019