



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: Trilex AI Concentrate
EPA Registration Number: 264-1068
Application Dates: 06/28/2018 and 09/11/2019
Decision Numbers: 555287 and 555169

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,

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

ACCEPTED

Sep 23, 2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 264-1068

TRIFLOXYSTROBIN	GROUP	11	FUNGICIDE
METALAXYL	GROUP	4	FUNGICIDE

TRILEX[®] AL Concentrate

ACTIVE INGREDIENTS (% by weight):

Trifloxystrobin.....	7.12%
Metalaxyl.....	5.69%
OTHER INGREDIENTS:	87.19%
TOTAL:	100.00%

Contains 0.64 lbs. trifloxystrobin per gallon and 0.51 lbs. metalaxyl per gallon.

EPA Reg. No. 264-1068

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 1-866-99BAYER (1-866-992-2937)

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.]

FIRST AID

IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.
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 or doctor 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 or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.

In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577. Have the product 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, absorbed through skin, or inhaled. Causes moderate eye irritation. 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 and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear: Long-sleeved shirt and long pants, socks plus shoes, chemical-resistant gloves made of any waterproof material and protective eyewear. Chemical resistant materials include Barrier laminate, nitrile rubber ≥14 mills, Neoprene Rubber ≥14 mills and viton ≥14 mills.

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

Engineering Controls: When handlers use closed systems in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should: Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on 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 washwaters 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. Cover or collect seeds spilled during loading.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Groundwater Advisory: Metalaxyl is known to leach through soil into groundwater 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 groundwater contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours. PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: coveralls, chemical resistant materials include Barrier laminate, nitrile rubber ≥ 14 mills, Neoprene Rubber ≥ 14 mils and viton ≥ 14 mills, shoes plus socks and protective eyewear.

PRODUCT INFORMATION

Trilex AL Concentrate provides seed and seedling protection against seedborne fungi, *Alternaria* spp., *Aspergillus* spp, *Cladosporium* spp., and *Penicillium* spp. causing seed decay and soilborne pathogens, *Rhizoctonia solani*, *Fusarium* spp., and *Pythium* spp. that cause seed and seedling damping-off. Trilex AL Concentrate can be used for suppression of early season *Phytophthora* seed and root rot. Trilex AL Concentrate is a concentrated formulation especially formulated for application using standard slurry or mist-type seed treatment equipment. Consult a seed treatment specialist for proper guidelines in using Trilex AL Concentrate to insure uniform coverage of seed, thus ensuring seed safety and best disease protection. For commercial and on-farm use.

USE PRECAUTIONS

- When using formulations that do not contain dye, to comply with 40 CFR 153.155, all seed treated with an economic poison must be colored to distinguish it and prevent subsequent inadvertent use as a food for man or feed for animals.

USE RESTRICTION

- Do not use treated seed for food, feed, or oil processing.
- 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.

RESISTANCE MANAGEMENT RECOMMENDATION

For resistance management, please note that Trilex AL Concentrate contains a Group 4 [Phenylamides class] and a Group 11 [Quinone outside Inhibitors] fungicide. Any fungal population may contain individuals naturally resistant to Trilex AL Concentrate and other Group 4 or 11 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.

ROTATIONAL CROP RESTRICTION

Areas planted with treated seed may be replanted immediately with any crop for which a tolerance exists for trifloxystrobin. Do not plant any crop without trifloxystrobin tolerances until 30 days after planting trifloxystrobin treated seed.

SPECIFIC CROP USE DIRECTIONS

Corn

Apply at a product rate of 0.5 fl. oz. of product per 100 lbs. of seed.

Cotton

Apply at a product rate of 2.0 fl. oz. of product per 100 lbs. of seed.

Soybean, Adzuki Bean, Asparagus Bean, Broad Bean (Succulent or Dry), Catjang Bean, Chinese Longbean, Field Bean, Guar Bean, Jackbean, Kidney Bean, Lablab Bean, Lima Bean (Succulent or Dry), Moth Bean, (Succulent or Dry), Mung Bean, Navy Bean, Pinto Bean, Rice Bean, Runner Bean, Snap Bean, Sword Bean, Tepary Bean, Urd Bean, Wax Bean, Yardlong Bean, Blackeyed Pea (Succulent or Dry), Chickpea, Cowpea (Succulent or Dry), Crowder Pea, Dwarf Pea, Edible-Pod Pea, English Pea, Field Pea, Garden Pea, Green Pea, Pigeon Pea (Succulent or Dry), Snow Pea, Southern Pea (Succulent or Dry), Sugar Snap Pea, Grain Lupin, Sweet Lupin, White Lupin, White Sweet Lupin, Lentil

Apply at a product rate of 1.0 fl. oz. of product per 100 lbs. of seed.

Rice

Apply at a product rate of 1.0 – 2.0 fl. oz. of product per 100 lbs. of seed.

LABELING OF TREATED SEED

Federal Seed Act requires that containers containing treated seeds shall be labeled with the following information.

- This seed has been treated with Trilex AL Concentrate, a fungicide containing 7.12% Trifloxystrobin and 5.69% Metalaxyl.
- Do not use for feed, food or oil purposes.

The U.S. Environmental Protection Agency requires the following statements on containers containing seed treated with Trilex AL Concentrate:

- Store away from feeds and foodstuffs.
- Do not allow children, pets, or livestock to have access to treated seeds.
- Wear long pants, long-sleeved shirt and protective gloves when handling treated seed.
- Treated seeds exposed on the soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting (such as in row ends).
- Dispose of all excess treated seed by burying seed away from bodies of water.
- Do not contaminate bodies of water when disposing of planting equipment wash water.
- Dispose of seed packaging or containers in accordance with local requirements.
- Excess treated seed may be used for ethanol production 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.
- Trilex AL Concentrate provides seed and seedling protection against seedborne fungi, *Alternaria* spp., *Aspergillus* spp., *Cladosporium* spp., and *Penicillium* spp. causing seed decay and soilborne pathogens, *Rhizoctonia solani*, *Fusarium* spp., and *Pythium* spp. that cause seed and seedling damping-off. Trilex AL Concentrate can be used for suppression of early season *Phytophthora* seed and root rot. Trilex AL Concentrate is a concentrated formulation especially formulated for application using standard slurry or mist-type seed treatment equipment. Consult a seed treatment specialist for proper guidelines in using Trilex AL Concentrate to insure uniform coverage of seed, thus ensuring seed safety and best disease protection. For commercial and on-farm use.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store in a cool dry location.

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 at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Non-refillable container. Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying.

Rigid Non-refillable containers small enough to shake (capacities equal to or less than 5 gallons).

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.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Rigid non-refillable containers that are too large to shake (capacities greater than 5 gallons).

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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Offer for recycling, if available. If not recycled, then puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

IMPORTANT: READ BEFORE USE

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 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.

NET CONTENTS:

Trilex is a registered trademark of Bayer

Produced for



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

TRILEX AL CONCENTRATE (PENDING) 06/13/2018, 06/14/2018, 08/29/2019, 09/10/2019