

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 14, 2020

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 Product Name: Imidacloprid Metalaxyl Seed Treatment EPA Registration Number: 264-1044 Application Dates: 06/28/2018 Decision Numbers: 559477

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 the Metalaxyl Interim Decision, 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 <u>Shrestha.srijana@epa.gov</u>.

Sincerely,

2.

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

Enclosure

IMIDACLOPRID	GROUP	4A	INSECTICIDE
METALAXYL	GROUP	4	FUNGICIDE

IMIDACLOPRID-METALAXYL Seed Treatment

For the protection of Seeds and Seedlings of Field Corn, Sweet Corn and Popcorn against Damping-Off, Seed Decay caused by *Pythium;* also for protection against Seed Corn Beetle, Seed Corn Maggots, Wireworm, White Grub, Flea Beetle (up to first true leaf), and Imported Fire Ants. For the protection of Seeds and Seedlings of Sorghum against Damping-Off, Seed Decay caused by *Pythium;* also for suppression against Wireworm, Seed Corn Maggot, true White Grub, and protection of seed against Imported Fire Ants.

For the protection of Seeds and Seedlings of Soybeans against Damping-Off, Seed Decay caused by Pythium; also suppression of Seed Corn Maggots and early season control of over-wintering Bean Leaf Beetles.

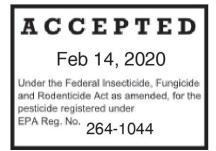
ACTIVE INGREDIENTS:	
Imidacloprid	
Metalaxyl	
OTHER INGREDIENTS	
TOTAL	
EPA Reg. No. 264-1044	EPA Est.

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.]

KEEP OUT OF REACH OF CHILDREN CAUTION

For <u>MEDICAL</u> And <u>TRANSPORTATION</u> Emergencies <u>ONLY</u> Call 24 Hours A Day 1-800-334-7577 For <u>PRODUCT USE</u> Information Call 1-866-99BAYER (1-866-992-2937)

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 do so by a poison control center or doctor.				
	Do not give anything by mouth to an unconscious person.				
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 eye.				
	Call a poison control center or doctor for treatment advice.				
In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577. Have a 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. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear: long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material (such as barrier laminate, butyl rubber ≥14 mils, nitrile rubber ≥14 mills, polyvinyl chloride (PVC) ≥14 mils, and viton ≥14 mills), and shoes plus socks.

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.

USER SAFETY RECOMMENDATIONS

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS

This product is highly toxic to birds and aquatic invertebrates and toxic to fish. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Exposed treated seeds may be hazardous to birds. In the event that treated seeds are spilled and cannot be salvaged, completely cover them with soil. Do not contaminate water when disposing of equipment washwaters or rinsate.

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.

Exception: If the seed is treated with the product and the treated seed is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated. 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 gloves made of any waterproof material (such as barrier laminate, butyl rubber ≥14 mils, nitrile rubber ≥14 mills, polyvinyl chloride (PVC) ≥14 mils, and viton ≥14 mills),

• Shoes plus socks, protective eyewear

PRODUCT INFORMATION

Imidacloprid-Metalaxyl may be used on seed previously treated with a full dosage of protective fungicide to give added protection against *Pythium* damping-off or seed decay.

Note: Adjust the seed drill or planter to give the required rate of seed delivery with treated seed. Regularly inspect planter plates and clean as required. At the end of each day, clean the electric-eye monitors as directed by the manufacturer.

Important: Treated seed must not be used for or mixed with food or animal feed, or processed for oil. Treat only those seeds needed for immediate use, minimizing the interval between treatment and planting. Do not store excess treated seed beyond planting time.

RESTRICTIONS

The maximum application rate for metalaxyl and mefenoxam-containing products (including seed treatments, foliar applications, soil application) is 12.3 lb per acre per calendar year. DO NOT apply more than 12.3 lb of active ingredient, metalaxyl per acre per calendar year.

RESISTANCE MANAGEMENT RECOMMENDATIONS

For resistance management, please note that Imidacloprid-Metalaxyl Seed Treatment contains a Group 4 [Phenylamides class] fungicide. Any fungal population may contain individuals naturally resistant to Imidacloprid-Metalaxyl Seed Treatment and other Group 4 [Phenylamides class] 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.

Imidacloprid-Metalaxyl Seed Treatment contains a Group 4A [Neonicotinoids class] insecticide. Any insect population may contain individuals naturally resistant to Imidacloprid-Metalaxyl Seed Treatment and other Group 4A insecticides. The resistant individuals may dominate the insect population if this group of insecticides is used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.

SPECIFIC CROP USE DIRECTIONS

Field Corn, Sweet Corn, Popcorn: Use at a rate of 1.5 ounces per 42 pounds of seed.

Sorghum: Use at a rate of 5.0 ounces per 100 pounds of seed.

Soybeans: Use at a rate of 4.0 oz. per 100 pounds of seed.

Mixing Instructions (1.5 oz canister)

Use as a dry mixture in the planter box as a seed treatment prior to planting. Apply Imidacloprid- Metalaxyl to seed at planting time with the canister applicator tube system.

Field corn, Sweet Corn, Popcorn: Apply at a rate of 1.5 oz. canister per 42 pounds of seed.

Sorghum: Apply at a rate of 1.5 oz. canister per 30 pounds of seed.

Soybeans: Apply at a rate of 1.5 oz. canister per 37 pounds of seed.

For best results, fill planter box with seed, add Imidacloprid- Metalaxyl through applicator tube and mix so that all seeds are covered. DO NOT MIX WITH BARE HANDS. Use only at the recommended rate. Lower amounts may not give desired control.

Mixing Instructions (4-pound pail)

Use as a dry mixture in the planter box as a seed treatment prior to planting.

Field Corn, Sweet Corn, Popcorn: Use two scoops full (1.5 oz.) per 42 pounds of seed.

Sorghum: Use two scoops full (1.5oz.) per 30 pounds of seed.

Soybeans: Use two scoops full (1.5 oz.) per 37 pounds of seed.

For best results, fill planter box half full of seed, add half the required amount of Imidacloprid- Metalaxyl and mix thoroughly with a stick or paddle. Add remainder of the seed and Imidacloprid- Metalaxyl and mix again so that all seeds are covered. DO NOT MIX WITH BARE HANDS. Use only at the recommended rate. Lower amounts may not give desired control.

NOTE: Do not graze or feed livestock on treated areas for 45 days.

ROTATIONAL CROPS

Treated areas may be replanted with any crop specified on the Imidacloprid-Metalaxyl label, or for any crop for which a tolerance exists for imidacloprid, as soon as practical following the last application. The following plant-back intervals should be observed for listed crops:

ROTATIONAL PLANT-BACK INTERVALS*							
	30-DAY PLANT-BACK						
Artichoke Barley Rrassica (cole) leafy veg. Canola Cilantro Corn, Field Corn, Sweet Cotton	Cranberry Cucurbits Eggplant Ground cherry Leaf petiole veg. Leafy veg. Legume veg. (succulent or dried, including soybean)	Mustard seed Okra Pepinos Pepper Popcorn Potato Rapeseed Sorghum Soybean Strawberry	Sugar beet Tomatillo Tomato Triticale Veg. Root and Tuber Watercress Wheat	Cereals (Including buckwheat, millet, oats, popcorn, rice and rye) Safflower			

* Cover crops for soil building or erosion control may be planted any time, but do not graze or harvest for food or feed.

* All other crops not listed on an Imidacloprid label, or for crops for which no tolerance for the active ingredient have been established, a 12-month plant-back interval should be observed.

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. Open dumping is prohibited. Do not reuse empty containers.

STORAGE: Keep pesticide in original container. Do not put concentrate or dilute into food or drink containers. Store in a cool dry location. Protect from excessive heat.

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 Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Completely empty container into application equipment. Then dispose of empty container in a sanitary landfill, or by incineration.

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. 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. 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:

PRODUCED FOR



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

IMIDACLOPRID-METALAXYL Seed Treatment (PENDING) 05/31/2018, 06/14/2018, 06/22/2018, 06/26/2018, 08/29/2019