

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 19, 2019

Ricky Kyaw Regulatory Product Manager Syngenta CropScience, LLC. P.O. Box 18300 Greensboro, NC 27419

Subject: Registration Review Label Mitigation for Fludioxonil

Product Name: Maxim® MZ

EPA Registration Number: 100-1158

Application Date: 2/1/2019 Decision Number: 552869

Dear Ricky 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 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.

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

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Sincerely,

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

Enclosure

MANCOZEB	GROUP	М3	FUNGICIDE
FLUDIOXONIL	GROUP	12	FUNGICIDE

Maxim® MZ

Fungicide

A seed treatment product for suppression of certain diseases of potatoes.

Active Ingredients:

Fludioxonil ¹ :	
Mancozeb ² :	5.70%
Other Ingredients:	93.80%
Total:	100 00%

¹CAS No. 131341-86-1 ²CAS No. 8018-01-7

Maxim® MZ is a powder for dry seed treatment containing 0.005 lb fludioxonil and 0.057 Ib mancozeb per pound.

KEEP OUT OF REACH OF CHILDREN.

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

[See additional precautionary statements and directions for use [on label] [printed on bag.]

EPA Reg. No. 100-1158

EPA Est.

50 pounds _ pounds Net Weight

ACCEPTED

Jul 19, 2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 100-1158

FIRST AID					
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.				
If on skin or	Take off contaminated clothing.				
clothing	Rinse skin immediately with plenty of water for 15-20 minutes.				
	Call a poison control center or doctor for treatment advice.				
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 inhaled	Move person to fresh air.				
	If person is not breathing, call 911 or an ambulance, then give				
	artificial respiration, preferably mouth-to-mouth if possible.				
	Call a poison control center or doctor for further treatment advice.				
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

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, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE)

Loaders, Applicators, and other handlers must wear:

• Long-sleeved shirt and long pants

- Shoes plus socks
- Chemical-resistant gloves made of barrier laminate, butyl rubber ≥14 mils, natural rubber ≥14 mils, neoprene rubber ≥14 mils, nitrile rubber ≥14 mils, polyethylene, polyvinyl chloride (PVC) ≥14 mils, or Viton® ≥14 mils
- Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter; <u>OR</u> a NIOSH-approved elastomeric particulate respirator with any N, R or P filter; <u>OR</u> a NIOSH-approved powered air purifying respirator with HE filters

In addition to the above PPE requirements, Mixers and Loaders must also wear:

- Protective eyewear: face shield, goggles, or safety glasses
- Chemical-resistant apron

User Safety Requirements

Follow the 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. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

Engineering Controls

Large scale seed piece treatment facilities that, on any given week in the current year or in the past year, treated \geq 50,000 cwt (\geq 2,500 tons) must use a dust collection system during the treatment of the seed pieces that prevents dust from contacting handlers or other persons.

Handlers using the dust collection system must wear:

- Long-sleeved shirt and long pants
- Shoes and socks
- Chemical-resistant gloves made of barrier laminate, butyl rubber ≥14 mils, natural rubber ≥14 mils, neoprene rubber ≥14 mils, nitrile rubber ≥14 mils, polyethylene, polyvinyl chloride (PVC) ≥14 mils, or Viton® ≥14 mils
- Must be provided with, have immediately available, and wear in an emergency, such as a broken package, spill, or equipment breakdown: Wear a minimum of a NIOSHapproved particulate filtering facepiece respirator with any N, R or P filter; <u>OR</u> a NIOSH-approved elastomeric particulate respirator with any N, R or P filter; <u>OR</u> a NIOSH-approved powered air purifying respirator with HE filters.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticide gets 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 fish, aquatic invertebrates, oysters and shrimp. Do not contaminate water when disposing of equipment wash water or rinsate.

Groundwater Advisory

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

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.

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
- Shoes plus socks
- Chemical-resistant gloves made of barrier laminate, butyl rubber ≥14 mils, neoprene rubber ≥14 mils, nitrile rubber ≥14 mils, polyvinyl chloride (PVC) ≥14 mils, or Viton ≥14 mils

FAILURE TO FOLLOW THE DIRECTIONS FOR USE AND PRECAUTIONS ON THIS LABEL MAY RESULT IN CROP INJURY, POOR DISEASE CONTROL, AND/OR ILLEGAL RESIDUES.

Treatment of highly bruised or damaged seed pieces, or seed pieces 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. Conduct germination tests on a small portion of seed before committing the total seed lot to a selected seed treatment. Treat test samples using equipment similar to that planned for treating the total seed lot.

PRODUCT INFORMATION

Maxim MZ is a dry seed protectant fungicide designed to suppress certain fungal diseases of seed potatoes. Maxim MZ effectively suppresses *Fusarium* dry rot seed decay, seed-borne *Rhizoctonia solani* that causes stem canker and tuber black scurf, and seed-borne *Helminthosporium solani*, the causal agent of silver scurf disease on potato tubers. It does not control bacterial disease nor diseases present within the seed. Maxim MZ also provides protection against seed to seed transmission of the potato late blight pathogen caused by *Phytophthora infestans*.

Maxim MZ is to be used as an integral part of a potato disease management strategy. This strategy includes the use of high quality certified seed and the incorporation of cultural practices such as: crop rotation, optimal harvest time for tubers to minimize disease development, and proper handling of tubers without bruising, etc. The practices should also include management and sanitation of equipment and storage areas to reduce disease inoculum. In addition, storage management practices that maintain appropriate temperature, ventilation, and relative humidity to avoid free moisture or condensation must be carried out. Consult your local agricultural extension agent for more detailed information on disease management practices.

RESISTANCE MANAGEMENT

MANCOZEB	GROUP	М3	FUNGICIDE
FLUDIOXONIL	GROUP	12	FUNGICIDE

For resistance management, please note that Maxim MZ contains Group M3/mancozeb and Group 12/fludioxonil fungicides. Any fungal population may contain individuals naturally resistant to Maxim MZ and other Group M3 and 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.

Mancozeb belongs to the dithiocarbamate class of chemistry and has multi-site contact activity. 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 Maxim MZ or other Group M3 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.

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

SEED CONTAINER LABEL REQUIREMENTS

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

- This seed has been treated with fludioxonil and mancozeb fungicides.
- Do not use treated seed for feed, food or oil purposes.

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

- Store treated seed away from food and feedstuffs.
- When opening this bag or loading/pouring the treated seed/seed-pieces, wear long-sleeved shirt, long pants, shoes, socks, chemical-resistant gloves, and a NIOSH approved particulate respirator with any N, R or P filter with NIOSH approval number prefix TC-84A; or a NIOSH approved powered air purifying respirator with HE filter with NIOSH approval number prefix TC-21C.
- **Do not** allow children, pets or livestock to have access to treated seeds.

- Dispose of all excess treated seed by burying seed away from bodies of water.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting.
- **Do not** contaminate bodies of water when disposing of planting equipment wash water.
- Dispose of seed packaging or containers in accordance with local requirements.
- After the seeds/seed pieces have been planted, do not enter or allow worker entry
 into treated areas during the restricted-entry interval (REI) of 24 hours. Exception:
 Once the seed/seed pieces are planted in the soil or other planting media, the
 Worker Protection Standard allows workers to enter the treated area without
 restriction if there will be no worker contact with the soil/media subsurface.
- Forage must not be grazed until 30 days after planting.
- 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.

SEED TREATMENT

Use Maxim MZ at the rate of 0.5 lb of product per 100 lb of seed pieces. Apply using equipment that ensures uniform and thorough coverage of each seed piece. Periodically clean and sanitize all surfaces of cutting (e.g., cutting machines, knives, tables, etc.), as well as planting equipment and planters thoroughly, before cutting and planting seed pieces. After cutting, treated seed pieces should be planted in soil above 45°F with adequate soil moisture required for planting. If cut seed pieces need to be stored or held for a few days, make sure that there is adequate cool air (60°F) movement through the pile of seed pieces at relative humidity of 85-90%. Cut seed pieces and treated seed should not be piled above 6 ft in height. When transporting seed pieces and Maxim MZ-treated seed, make sure the seed is covered.

Restrictions

- Apply only in areas with adequate ventilation and/or dust collection and control equipment.
- Do not exceed the maximum rate of 0.5 lb of product per 100 lb of seed pieces.
- 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 and prevent subsequent inadvertent use as a food for man or feed for animals.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in the original container and only in a cool, dry, secure place.

Pesticide Disposal

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. 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 Handling

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

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

Maxim®, the ALLIANCE FRAME the SYNGENTA Logo and the PURPOSE ICON are Trademarks of a Syngenta Group Company

Viton® is a trademark of E. I. du Pont de Nemours and Company.

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

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