



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 30, 2020

Marian Bleeke
Senior Regulatory Affairs Manager
Bayer U.S. – Crop Science
Monsanto Company
Building FF
Chesterfield, MO 63303

Subject: PRIA Label Amendment – Changes to Precautionary Label Statements
Product Name: Tioxazafen Technical (Wetcake)
EPA Registration Number: 524-623
Application Date: December 19, 2019
Decision Number: 558767

Dear Ms. Bleeke:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

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Your release for shipment of the product 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, please contact Briana Hanlon by phone at (703) 347-8337, or via email at hanlon.briana@epa.gov.

Sincerely,

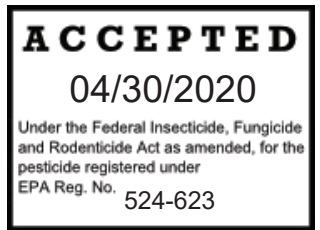
A handwritten signature in black ink, appearing to read "Michael Walsh", written in a cursive style.

Michael Walsh
Product Manager 11
Invertebrate & Vertebrate Branch 2
Registration Division
Office of Pesticide Programs

Attachment

Primary Brand Name:
Tioxazafen Technical (Wetcake)

Alternate Brand Name:
MON 102100 Technical (Wetcake)



ACTIVE INGREDIENT:	
tioxazafen, 3-phenyl-5-(2-thienyl)-1,2,4-oxadiazole	82.5%
OTHER INGREDIENTS:.....	17.5%
	100.0%

EPA Reg. No. 524-623

EPA Est. [Enter appropriate EPA establishment no.]

HOTLINE NUMBER

In case of an emergency involving this product, or for medical assistance,
call collect, day or night, (314) 694-4000.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children

CAUTION

MAY CAUSE ALLERGIC SKIN REACTION. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals.

Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Personal Protective Equipment (PPE)

All handlers must wear coveralls over long-sleeved shirt, long pants, shoes plus socks, and chemical-resistant gloves made of barrier laminate, butyl rubber ≥ 14 mils, nitrile rubber ≥ 14 mils, neoprene rubber ≥ 14 mils, natural rubber ≥ 14 mils, polyethylene polyvinyl chloride (PVC) ≥ 14 mils, or viton ≥ 14 mils.

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

Environmental Hazards

This product is toxic to birds, mammals, fish and aquatic invertebrates. 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 Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

Read entire label before using this product.

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

For use only in the formulation of end-use seed treatment products for corn, soybean, and cotton.

STORAGE AND DISPOSAL

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

PESTICIDE STORAGE: Store in original container. Do not store near heat or open flame. Keep container closed to prevent spills and contamination.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product that cannot be used or chemically reprocessed must be disposed of in a landfill approved for pesticide disposal or in accordance with applicable federal, state and local regulations and procedures. In case of spill or leak, sweep up and dispose of waste properly.

CONTAINER HANDLING AND DISPOSAL: Non-refillable container. Do not reuse or refill this container. Completely empty the contents of this bag into formulation equipment by shaking and tapping the sides and bottom to loosen clinging material. Then dispose of empty bag in accordance with applicable federal, state and local regulations and procedures, which may include disposing in a sanitary landfill.

LIMIT OF WARRANTY AND LIABILITY

To the extent consistent with applicable law, Monsanto Company does not warrant any product reformulated or repackaged from this product except in accordance with this Company's stewardship requirements and with express written permission from Monsanto Company.

EPA Reg. No. 524-623

© [YEAR]

Produced for:

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167 USA

EPA Est. [Enter appropriate EPA establishment no.]

NET [Allow blank space for fill in] LBS [Alternative text: KG or other appropriate unit of measure]

LOT NO. [Allow blank space for fill in]

[Print Plate Number]