



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 5, 2020

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

Subject: PRIA Label Amendment – Change to Precautionary Label Statements, Container Handling, and Other Minor Revisions
Product Name: MON 102133 SC Nematicide Seed Treatment
EPA Registration Number: 524-624
Application Date: December 19, 2019
Decision Number: 558916

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.

SEE NEXT PAGE

Page 2 of 2
EPA Reg. No. 524-624
Decision No. 558916

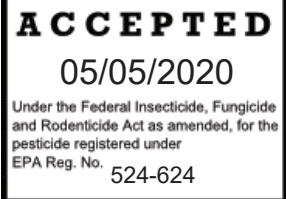
Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Briana Hanlon by phone at (703) 347-8337, or via email at hanlon.briana@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Walsh", written over a light blue horizontal line.

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

Attachment



Product Brand Name:
MON 102133 SC Nematicide Seed Treatment

Alternate Names:
Acceleron® N-364 Nematicide Seed Treatment
Acceleron® NemaStrike™ ST
Acceleron® NemaStrike™ ST Soybeans

Seed treatment for nematode control on corn, cotton and soybean.

[Optional marketing text or logo: With NemaStrike™ Technology]

ACTIVE INGREDIENT:	
tioxazafen*, 3-phenyl-5-(2-thienyl)-1,2,4-oxadiazole	45.9%
OTHER INGREDIENTS:	54.1%
	100.0%

*This product is a suspension concentrate containing 4.51 pounds of tioxazafen per gallon.

EPA Reg. No. 524-624

EPA Est. No. [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.

For product use information regarding Acceleron® Seed Applied Solutions call: 1-877-775-8787

[Optional referral statement for containers with label booklet: See label booklet for complete
Precautionary Statements, Directions for use, and Limits of Liability and Warranty.]

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 mixers, loaders, applicators, and other handlers must wear 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.

Workers performing cleaning, maintenance, and repair of equipment 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 contaminate water when disposing of equipment washwater or rinsate.

Do not plant treated seeds by broadcasting to the soil surface. Ensure that all seeds are thoroughly covered with soil. Treated seed exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.

DIRECTIONS FOR USE

Read the entire label before using this product.

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

For use only in commercial seed treatment facilities using fully-automated closed transfer and application equipment. Not for use in hopper box, planter box, slurry box, or other on-farm seed treatment applications.

Restrictions

- Do not treat seeds on farm or in field.
- To be used in commercial seed treatment facilities using fully-automated closed transfer and application equipment ONLY.
- Do not plant treated seeds by broadcasting to the soil surface.

Application Information

USE INFORMATION

Apply MON 102133 SC Nematicide Seed Treatment as a water-based slurry either alone or with registered seed treatments using fully-automated and closed standard slurry or mist-type seed treatment application equipment and closed transfer equipment.

MON 102133 SC Nematicide Seed Treatment may be used in combination with other registered Acceleron® Seed Applied Solutions. Pre-test for compatibility with other seed treatment products. Users must follow the most restrictive directions for use and precautionary statements of each product that is co-applied.

Uniform application of seed is necessary to ensure seed safety and performance. Dilute with a sufficient amount of water to achieve uniform application to seed. Use high quality, properly cleaned seed.

All seed treated with this product must be adequately dyed with a suitable color to prevent accidental use as food for humans or feed for animals. Use an EPA-approved dye or colorant that imparts an unnatural color to the seed. Any dye or colorant added to treated seed must be cleared for use pursuant to 40 CFR, Part 153.155.

MIXING INSTRUCTIONS

Mix well before use. Add approximately 1/2 to 2/3 of the required water to the treatment slurry tank followed by the accompanying seed treatment products and MON 102133 SC Nematicide Seed Treatment. The order of product addition is dependent on the accompanying seed treatment products and application equipment used. Allow each slurry component to disperse completely prior to the next addition

until a uniform suspension is obtained. After all slurry components have been added and dispersed completely add the remaining 1/2 to 1/3 of required water for proper slurry volume and mix until uniform. Maintain adequate agitation until treatment slurry is applied.

APPLICATION RATES TO CONTROL NEMATODES

Crop	Use Rates	Maximum Annual Rates
Corn, field	0.5 – 1.0 mg a.i./seed or 2.5 – 5.0 fl oz product/80,000 seeds	Do not apply more than 0.089 lb a.i./acre/year. This is based on a maximum seeding rate of 40,250 seeds/acre or 33.2 lbs seed/acre
Soybean (<i>Glycine</i> spp.)	0.25 – 0.5 mg a.i./seed or 2.2 – 4.4 fl oz product/140,000 seeds	Do not apply more than 0.28 lb a.i./acre/year. This is based on a maximum seeding rate of 250,000 seeds/acre or 166.7 lbs seed/acre
Cotton	0.5 – 1.0 mg a.i./seed or 7.2 – 14.4 fl oz product/230,000 seeds	Do not apply more than 0.19 lb a.i./acre/year. This is based on a maximum seeding rate of 85,000 seeds/acre or 18.9 lbs seed/acre

SEED LABELING

The user is responsible for ensuring that the seed container meets all of the requirements under the Federal Seed Act. The Federal Seed Act requires that the container of seed treated with MON 102133 SC Nematicide Seed Treatment must be labeled with the following statements:

- This seed has been treated with tioxazafen.
- Do not use treated seed for food, feed or oil production.

In addition, the US Environmental Protection Agency requires the following statements on the container of seed treated with MON 102133 SC Nematicide Seed Treatment:

- Wear long-sleeved shirt, long pants, shoes, 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 when handling treated seed.
- Store treated seed away from food and feed, and do not allow access by children, pets, or livestock. Do not reuse empty seed bags.
- Surplus treated seed or empty seed containers should be stored or disposed according to local requirements.
- Do not contaminate bodies of water when disposing of excess treated seed or wash waters of planting equipment.
- Treated seed is toxic to birds and mammals. Exposed seed is hazardous to birds and mammals that come in contact with treated seed. Cover or collect treated seeds that are spilled during loading and planting.
- Do not plant seeds by broadcasting to the soil surface.
 - For corn and soybeans: Treated seeds must be planted at a minimum depth of 1 inch.
 - For cotton: Treated seeds must be planted at a minimum depth of 0.5 inches.
- Do not use at a rate that will result in more than 0.28 lb tioxazafen per acre per year.
- In case of early season crop failure, seeds (treated or untreated) may be immediately replanted as long as the maximum yearly application rate per acre is not exceeded.
- Plant-back Restrictions: Corn, cotton, and soybeans may be replanted immediately. All other crops may be planted after 30 days.

CROP ROTATION

Crops listed on this label may be replanted at any time as long as yearly maximum application rate per acre is not exceeded. All other crops may be planted after 30 days.

In case of early season crop failure, seeds (treated or untreated) may be replanted immediately as long as yearly maximum application rate per acre is not exceeded.

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 a cool, dry place. Do not store in direct sunlight.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be used 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 in proper disposal methods.

CONTAINER HANDLING AND DISPOSAL: Non-refillable container (5 gallons or less). Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. 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 $\frac{1}{4}$ 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.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, by incineration, or by other procedures allowed by state and local authorities.

{Note to reviewer: Appropriate language for the container label type and size will be selected from the options below:}

Non-refillable container (greater than 5 gallons). Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. 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 $\frac{1}{4}$ 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 side and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use and 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.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, by incineration, or by other procedures allowed by state and local authorities.

Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square Stackable): Do not reuse or refill this container. 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 approximately 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.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, by incineration, or by other procedures allowed by state and local authorities.

Refillable container. Refill this container with pesticide only. Do not use this container for any other purpose. Cleaning 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 clean container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, by incineration, or by other procedures allowed by state and local authorities.

LIMITS OF LIABILITY AND WARRANTY

Monsanto Company warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes set forth in the Directions for Use ("Directions") when used in accordance with those Directions under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this Company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

To the extent consistent with applicable law, buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this Company, including, but not limited to, crop injury, ineffectiveness or other unintended consequences that may result because of such factors such as weather conditions at planting, environmental conditions during seed storage, presence of other materials, seed of low quality or low vigor or low germination, or the manner of use or application inconsistent with that set forth in the Directions.

This 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 this Company.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES.

Upon opening and using this product, buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement. If terms are not acceptable, return at once unopened.

EPA Reg. No. 524-624

© [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] GAL [*Alternative text: L or other appropriate unit of measure*]

LOT NO. [*Allow blank space for fill in*]

[*Print Plate Number*]

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