

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 21, 2023

Christina M. Dubas Manager Regulatory and Scientific Affairs Nichino America, Inc. 4550 Linden Hill Rd. Wilmington, DE 19808

Subject: Registration Review Label Mitigation for Flutolanil Product Name: MONCOAT MZ FUNGICIDE EPA Registration Number: 71711-8 Application Date: January 31, 2022 Decision Number: 591967

Dear Christina Dubas:

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 Flutolanil 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 Assurance.

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 12 months from the date of this letter. After 12 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently

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approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

If you have any questions about this letter, please contact Caleb Carr by phone at (202) 566-0636, or via email at carr.caleb@epa.gov.

Sincerely,

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

Enclosure



FLUTOLANIL	GROUP	7	FUNGICIDE
MANCOZEB	GROUP	M3	FUNGICIDE

# **MONCOAT<sup>®</sup> MZ Fungicide**

## **ACTIVE INGREDIENTS:**

Flutolanil: Benzamide, N-[3-(1-methylethoxy)phenyl]-2-(trifluoromethyl) <b>1.5%</b> Mancozeb: <b>6.0%</b>	
a coordination product of zinc ion and manganese ethylene Bisdithiocarbamate, in which the ingredients are:	е
Manganese <sup>++</sup>	
Zinc <sup>++</sup> 0.15%	
Ethylene bisdithiocarbamate ion (C4H6N2S4)4.65%	
OTHER INGREDIENTS:	
TOTAL 100.0%	

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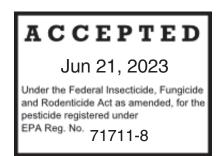
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# KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID				
If swallowed:	Call a poison control center or doctor immediately for treatment advice.			
	<ul> <li>Have person sip a glass of water if able to swallow.</li> </ul>			
	<ul> <li>Do not induce vomiting unless told to by a poison control center or</li> </ul>			
	doctor.			
	<ul> <li>Do not give anything to an unconscious person.</li> </ul>			
If on skin:	<ul> <li>Take off contaminated clothing.</li> </ul>			
	<ul> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>			
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>			
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.			
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>			
HOTLINE NUMBER				
Have the product of	container or label with you when calling a poison control center or doctor or			
	t. You may also contact 1-800-348-5832 for emergency medical treatment			
information. In cas	se of fire or spills, information may be obtained by calling 1-800-424-9300.			

#### NET CONTENTS: \_\_\_\_\_

See [attached, inside] booklet for First Aid, Precautionary Statements, and Directions for Use



Formulated and Packaged in U.S.A. for Nichino America Inc. 4550 Linden Hill Road, Suite 501 Wilmington, DE 19808 888-740-7700

# PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals CAUTION

Harmful if swallowed or absorbed through skin. 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)**

Some materials that are chemical resistant to this product are listed below.

#### Loaders, applicators, and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves, (barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, natural rubber, polyethylene, polyvinyl chloride, or Viton<sup>®</sup>)
- 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 a HE filter.

See Engineering Controls for additional requirements.

#### **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.

#### **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.

#### **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 plus socks
- Chemical-resistant gloves, (barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, natural rubber, polyethylene, polyvinyl chloride, or Viton) (except pilots, groundboom applicators, and airblast applicators)
- 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 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 a HE filter.

# **ENVIRONMENTAL HAZARDS**

This product is toxic to aquatic organisms. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or 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 State or Tribal 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 product 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. For early entry into 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, wear:

- Coveralls
- Shoes plus socks
- Chemical resistant gloves (barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, natural rubber, polyethylene, polyvinyl chloride, or Viton)

# **USE INFORMATION**

MONCOAT MZ fungicide is a coformulation containing two fungicides effective for the suppression of Black scurf and Rhizoctonia stem canker (*Rhizoctonia solani*), Fusarium dry rot (*Fusarium sambucinum; F. coeruleum*), and Silver scurf (*Helminthosporium solani*) on potato seed-pieces. MONCOAT MZ fungicide will help reduce the spread of *Phytophthora infestans* (late blight) that may occur from surface infestation resulting from seed-piece to seed-piece contact during the handling, cutting, and planting process. [MONCOAT MZ fungicide is <u>not</u> effective against systemic seed-piece infections or airborne (secondary) inoculum of *P. infestans*.] MONCOAT MZ fungicide contains 1.5% flutolanil and 6.0% mancozeb in a tree bark based formulation. This pesticide will not control bacterial diseases or other diseases not claimed on this label for varieties known to be susceptible to bacterial soft rot. Companion

fungicides known to be effective against this organism should be used. Consult your extension potato pathologist for variety and treatment information.

MONCOAT MZ fungicide 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 to minimize disease development, and proper handling of tubers to minimize bruising and improve storage quality. Sound strategy should also include sanitation of equipment and storage areas to reduce disease inoculum and control of storage area temperature, humidity, and ventilation. Consult your local agricultural extension agent for more information on disease management practice.

**ATTENTION:** This product contains mancozeb and ETU, chemicals known to the state of California to cause cancer. ETU is also known to the state of California to cause birth defects or other reproductive harm.

Crop/Crop Group	Plantback Timing	
Cotton	0 days	
Soybean	0 days	
Wheat	30 days	
Leafy vegetables (lettuce, spinach, celery)	150 days	
Small grains other than wheat (barley, oats, rye)	150 days	
Corn (field, sweet, popcorn)	240 dava	
Sorghum	240 days	
All other crops	365 days	

# **CROP ROTATION RESTRICTIONS**

# **RESISTANCE MANAGEMENT**

For resistance management, please note, the Flutolanil component of MONCOAT MZ Fungicide belongs to the succinate dehydrogenase inhibitor class (FRAC Group 7). The Mancozeb component of MONCOAT MZ Fungicide belongs to the dithiocarbamates and relatives (electrophiles) class (FRAC Group M3). Any fungal population may contain individuals naturally resistant to MONCOAT MZ Fungicide and other Group 7 or Group M3 fungicides. A gradual or total loss of pest control may occur over time if these fungicides are used repeatedly in the same fields. Nichino America, Inc. encourages responsible product stewardship to ensure effective long-term control of the fungal diseases on this label. Appropriate resistance-management strategies should be followed.

To delay fungicide/bactericide resistance, take one or more of the following steps:

- Rotate the use of Moncoat MZ Fungicide or other Group (FRAC groups 7 or M3) fungicides within a growing season sequence with different groups that control the same pathogens.
- Use tank mixtures with fungicides 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 crops and pathogens.

# **APPLICATION RESTRICTIONS**

Seeds/seed-pieces that have been treated with this product that are then packaged or bagged for future use must contain the following labeling on the outside of the seed/seed-piece package or bag:

- When opening this bag or loading/pouring the treated seed/seed pieces, wear a long-sleeved shirt, long pants, shoes, socks, chemical resistant gloves and 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 a HE filter.
- Treated Seed/Seed Pieces Do Not Use for Food, Feed, or Oil Purposes. Treat only those seeds needed for immediate use, minimizing the interval between treatment and planting.
- 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 seeds/seed-pieces are planted in 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.

Potato (seed-piece treatment only)					
Disease	Rate/Acre	Directions for Use			
Seed borne Black scurf*	0.75 to 1.0 lb./100	<ul> <li>Apply to the seed-pieces immediately after cutting. Use dispensing equipment that</li> </ul>			
Seed borne Fusarium dry rot	lbs. of cut	will give thorough coverage of the dust to			
(Fusarium sambucinum;	seed-	the cut seed-piece surfaces.			
Fusarium coeruleum)*	pieces	<ul> <li>Thoroughly clean and sanitize cutting</li> </ul>			
Seed borne Rhizoctonia stem canker ( <i>Rhizoctonia solani</i> )*		equipment including knives, belts, rollers, tables, trucks, and planting equipment before planting seed-pieces.			
Seed borne Silver scurf ( <i>Helminthosporium solani</i> )*					
*Suppression					

# MONCOAT MZ FUNGICIDE APPLICATION RATE CHART

# SEED BAG LABEL REQUIREMENTS

- This seed has been treated with MONCOAT MZ, a fungicide containing Flutolanil and Mancozeb.
- 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 MONCOAT MZ:

- Store treated seed away from food and feedstuffs.
- 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.

Note: This product does not contain dye and is not covered by an appropriate tolerance, tolerance exemption, or other clearance under the Federal Food, Drug and Cosmetic Act. To comply with 40 CFR 153.155, therefore, all seed treated commercially with this product must be colored with an EPA-approved dye or colorant of a suitable color to prevent accidental use as 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 original container, and keep tightly closed when not in use. Store in a cool, dry place.

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

#### **CONTAINER HANDLING:**

#### Nonrefillable plastic container (Less than 50 pounds)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 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. Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

#### Nonrefillable plastic container (Greater than 50 pounds)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

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. Turn the container over onto its other 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. Hold container upside down over application equipment or a 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.

Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

#### Nonrefillable metal container (Greater than 50 pounds)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

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. Turn the container over onto its other 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. Hold container upside down over application equipment or a 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.

Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

#### Nonrefillable paper and plastic bag

Nonrefillable 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.

#### Nonrefillable fiber drum with liner

Nonrefillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment then offer for recycling if available or dispose of in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

#### Refillable plastic container

Refillable container. Refill this container with pesticide only. Do not reuse 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

the container before final disposal, empty the remaining contents from this container into application equipment or a 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. Return to point of sale or offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration or by other procedures approved by state and local authorities.

## Refillable metal container

Refillable container. Refill this container with pesticide only. Do not reuse 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 the container before final disposal, empty the remaining contents from this container into application equipment or a 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. Return to point of sale or offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

#### Refillable fiber drum with liner

Refillable container. Refill this container with pesticide only. Do not reuse 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 the container before final disposal, completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment or a mix tank. Return to point of sale or offer for recycling if available or reconditioning if appropriate or dispose of in a sanitary landfill or by incineration, or, if allowed by local and state authorities, by burning. If burned, stay out of smoke. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

# IMPORTANT: READ BEFORE USE

By using this product, user or buyer accepts the following conditions, warranty, disclaimer of warranties, and limitations of liability.

**CONDITIONS:** The directions for use of this product are believed to be accurate and must be followed carefully. However, because of extreme weather and soil conditions, use methods and other factors beyond the control of Nichino America, Inc. (NAI), it is impossible for NAI to eliminate all risks associated with the use of this product. As a result, crop injury or ineffectiveness is always possible. To the extent consistent with applicable law, all such risks are assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, WHICH EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of NAI is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, NAI disclaims any liability whatsoever for incidental or consequential damages, including, but not limited to, liability arising out of breach of contract, express or implied warranty (including warranties of merchantability and fitness for a particular purpose), tort, negligence, strict liability or otherwise.

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 THE ELECTION OF NICHINO AMERICA, THE REPLACEMENT OF PRODUCT.

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# Appendix

Text that may be included on the container label or promotional information supporting this product:

• Potato Seed-Piece Treatment for Suppression of Seedling Diseases