



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 5, 2021

Carolyn Miter
Registrations Specialist
Albaugh, LLC
P.O. Box 2127
Valdosta, GA 31604

Subject: Registration Review Label Mitigation for Metalaxyl
Product Name: Difenoconazole 16.5% + Metalaxyl 3.8% ST
EPA Registration Number: 42750-298
Application Dates: 06/21/2018
Decision Numbers: 568467

Dear Ms. Miter:

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 Quinn Gavin by phone at 703-347-0325, or via email at gavin.quinn@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Linda Arrington".

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

Enclosure

METALAXYL	GROUP	4	FUNGICIDE
DIFENOCONAZOLE	GROUP	3	FUNGICIDE

DIFENOCONAZOLE 16.5% + METALAXYL 3.8% ST

Fungicide

A seed treatment for control of diseases of wheat by commercial seed treaters.

Active Ingredients:

Difenoconazole*	16.50%
Metalaxyl**	3.85%
Other Ingredients:	79.65%
Total:	100.00%

Contains 1.46 lbs. per gallon of difenoconazole and 0.34 lbs. per gallon of metalaxyl

*CAS No. 119446-68-3

**CAS No. 57837-19-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

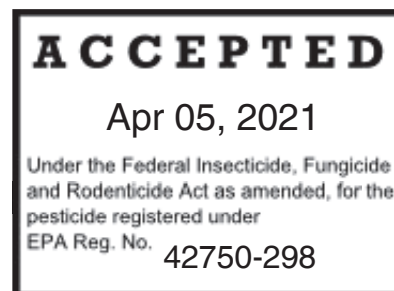
FIRST AID	
IF SWALLOWED	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person.
IF INHALED	<ul style="list-style-type: none"> 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.
NOTE TO PHYSICIAN: If ingested, induce emesis and treat symptomatically.	
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 Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), call CHEMTREC at 1-800-424-9300	

EPA Reg. No. 42750-298

EPA Est. No. xxxxxx-xx-xxx

NET CONTENTS:

Manufactured By:
ALBAUGH, LLC
1525 NE 36th Street
ANKENY, IA 50021



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. 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)

Applicators and other handlers must wear:

1. Long-sleeved shirt and long pants
2. Shoes plus socks
3. Chemical-resistant gloves (made of nitrile rubber >14 mils, butyl rubber >14 mils, neoprene rubber >14 mils, barrier laminate >14 mils, polyvinyl chloride (PVC) >14 mils and Viton >14 mils)

Follow 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.

ENGINEERING CONTROL STATEMENTS

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users Should:

- Wash hands thoroughly with soap and water after handling and 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 clothes.
- 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 product is toxic to fish and aquatic invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Do not contaminate water when disposing of equipment wash water or rinsate.

If treated seed is spilled outdoors or in areas accessible to birds, promptly clean up or bury to prevent ingestion.

Groundwater Advisory Statement: This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination

PHYSICAL-CHEMICAL HAZARDS

Do not mix or allow to come in contact with oxidizing agents. Hazardous chemical reaction may occur.

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.

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

PRODUCT INFORMATION

DIFENOCONAZOLE 16.5% + METALAXYL 3.8% ST is a systemic seed dressing that controls or suppresses certain seed-borne, soil-borne, and fall foliar diseases of wheat.

Metalaxyl provides Pythium damping-off activity and Difenoconazole provides activity on the remaining diseases claimed on this label.

RESISTANCE MANAGEMENT RECOMMENDATIONS

DIFENOCONAZOLE 16.5% + METALAXYL 3.8% ST is a systemic fungicide that contains:

- Difenoconazole, a Group 3 mode of action fungicide that belongs to the triazole class of chemistry and is a demethylation inhibitor of sterol biosynthesis (DMI) which disrupts membrane synthesis of the fungal cell.
- Metalaxyl, a Group 4 mode of action fungicide that belongs to the phenylamide class of chemistry which interferes with fungal RNA synthesis.

Any fungal population may contain individuals naturally resistant to Group 3 and Group 4 mode of action fungicides. A gradual or total loss of pest control may occur over time if these fungicides are used repeatedly in the same fields. Because resistance development cannot be predicted, the use of this product should follow appropriate resistance-management strategies. To delay fungicide resistance, use should be based on an IPM program that includes the following steps:

- Rotate the use of DIFENOCONAZOLE 16.5% + METALAXYL 3.8% ST or other Group 3 and Group 4 fungicides within a growing season sequence with different groups that control the same pathogens. Avoid application of more than 3 and consecutive applications of DIFENOCONAZOLE 16.5% + METALAXYL 3.8% ST or other fungicides in the same group in a season.
- 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 crops and pathogens.
- For further information or to report suspected resistance contact Albaugh, LLC at 1-800-247-8013. You can also contact your pesticide distributor or university extension specialist to report resistance.
- Scout after herbicide application to monitor weed populations for early signs of resistance development. Indicators of possible herbicide resistance include: (1) failure to control a weed species normally controlled by the herbicide at the dose applied, especially if control is achieved on adjacent weeds; (2) a spreading patch of non-controlled plants of a particular weed species; (3) surviving plants mixed with controlled individuals of the same species. If resistance is suspected, prevent weed seed production in the affected area by an alternative herbicide from a different group or by a mechanical method such as hoeing or tillage. Prevent movement of resistant weed seeds to other fields by cleaning harvesting and tillage equipment when moving between fields and planting clean seed.
- If a weed pest population continues to progress after treatment with this product, discontinue use of this product, and switch to another management strategy or herbicide with a different mode of action, if available.

MIXING PROCEDURES

Apply DIFENOCONAZOLE 16.5% + METALAXYL 3.8% ST as a water-based slurry through standard slurry or mist-type commercial seed treaters. Prepare a slurry by mixing DIFENOCONAZOLE 16.5% + METALAXYL 3.8% ST in up to 16 fl. oz. of water per 100 lbs. of seed. Mix the slurry thoroughly with the seed to provide uniform coverage. Do not use for at-plant applications involving hopper boxes, seed boxes, etc.

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.

CEREALS

Apply DIFENOCONAZOLE 16.5% + METALAXYL 3.8% ST to cereal (barley, oats, rye, triticale & wheat) seed at the rates given in the following tables:

WINTER WHEAT, TRITICALE, OATS & RYE

Fl. oz. of product per 100 lbs of seed*	Diseases Controlled	Fall Season Foliar Diseases Controlled ¹	Diseases Partially Controlled ¹
2 fl. oz.	Common Bunt ³ Dwarf Bunt Loose Smut Flag Smut Seed-borne Septoria General Seed Rots ⁴ Fusarium Seed Scab Pythium Damping-Off	Fall Season Powdery Mildew Fall Season Leaf Rust Fall Season Septoria Leaf Blotch	Common Root Rot (Cochliobolus spp.) Fusarium Root Rot Fusarium Crown Rot Take-All Rhizoctonia Root Rot
1 fl. oz.	Common Bunt ³ Dwarf Bunt Flag Smut		Common Root Rot (Cochliobolus spp.)

	Seed-borne Septoria Loose Smut General Seed Rots ⁴ Fusarium Seed Scab Pythium Damping-Off		Rhizoctonia Root Rot
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*1.0 fluid ounce of DIFENOCONAZOLE 16.5% + METALAXYL 3.8% ST contains 0.0115 lbs of difenoconazole active and 0.0026 lbs of metalaxyl active.

¹ DIFENOCONAZOLE 16.5% + METALAXYL 3.8% ST provides control of fall season powdery mildew, fall season leaf rust, and fall season Septoria leaf blotch in winter wheat for the first 6 weeks after planting. For full season control of these foliar diseases, use a propiconazole fungicide labeled for cereal seed treatment.

² Partial control can either mean erratic control from good to poor or consistent control at a level below that generally considered acceptable for commercial disease control

³DIFENOCONAZOLE 16.5% + METALAXYL 3.8% ST controls both seed-borne and soil-borne common bunt.

⁴General seed rots controlled include those caused by saprophytic organisms, such as Penicillium and Aspergillus.

SPRING WHEAT, TRITICALE, OATS & RYE

Fl. oz. of product per 100 lbs of seed*	Diseases Controlled	Diseases Partially Controlled
2 fl. oz.	Common Bunt ¹ Loose Smut Flag Smut Seed-borne Septoria General Seed Rots ² Fusarium Seed Scab Pythium Damping-Off	Take-All Common Root Rot (Cochliobolus spp.) Rhizoctonia Root Rot
1 fl. oz.	Common Bunt ¹ Dwarf Bunt Flag Smut Seed-borne Septoria Loose Smut General Seed Rots ² Fusarium Seed Scab Pythium Damping-Off	Common Root Rot (Cochliobolus spp.) Rhizoctonia Root Rot

*1.0 fluid ounce of DIFENOCONAZOLE 16.5% + METALAXYL 3.8% ST contains 0.0115 lbs of difenoconazole active and 0.0026 lbs of metalaxyl active.

¹ DIFENOCONAZOLE 16.5% + METALAXYL 3.8% ST controls both seed-borne and soil-borne common bunt.

²General seed rots controlled include those caused by saprophytic organisms such as Penicillium and Aspergillus.

³Partial control can either mean erratic control from good to poor or consistent control at a level below that generally considered acceptable for commercial disease control.

BARLEY

Fl. oz. of product per 100 lbs of seed*	Diseases Controlled	Diseases Partially Controlled ¹
2 fl. oz.	Barley Stripe General Seed Rots ² Covered Smut Early-Season Pythium Damping-Off	Take All Common Root Rot (Cochliobolus spp.) Fusarium Root Rot and Crown Rot Rhizoctonia Root Rot
1 fl. oz.	Barley Stripe General Seed Rots ² Covered Smut Early-Season Pythium Damping-Off	Common Root Rot (Cochliobolus spp.) Fusarium Root Rot and Crown Rot Rhizoctonia Root Rot

*1.0 fluid ounce of DIFENOCONAZOLE 16.5% + METALAXYL 3.8% ST contains 0.0115 lbs of difenoconazole active and 0.0026 lbs of metalaxyl active.

¹Partial control can either mean erratic control from good to poor or consistent control at a level below that generally considered acceptable for commercial disease control.

²General seed rots controlled include those caused by saprophytic organisms such as *Penicillium* and *Aspergillus*.

CEREAL USE RESTRICTIONS:

1. Do not use treated seed for feed, food, or oil.
2. Green wheat, oats, rye or triticale forage may not be grazed until 55 days after planting. Green barley forage may not be grazed until 30 days after planting.
3. Do not plant any crop other than listed cereal crops within 30 days to fields in which treated seeds were planted.
4. When applying both metalaxyl-containing and mefenoxam-containing products to the same crop within the same season. Do not apply more than the maximum yearly total application rate for the active ingredient as stated on the label of the product containing the lowest yearly total on that crop.

NOTE: The following statements are required on containers containing seed treated with this product:

- This seed has been treated with difenoconazole and mefenoxam fungicides.
- Do not use for feed, food, or oil purposes.
- 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 soil surface may be hazardous to wildlife.
- Cover or collect treated seeds spilled during loading and planting.
- 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.
- Green wheat, oats, rye or triticale forage may not be grazed until 55 days after planting.
- Green barley forage may not be grazed until 30 days after planting.
- Do not plant any crop other than those on this label within 30 days to fields in which treated seeds were planted.
- 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.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in a tightly closed container out of reach of children.

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

CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

Triple rinse as follows: *For containers with capacity equal to or less than 5 gallons:* Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Add water - at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of 1/4 of the container volume - and recap. Shake for 30 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. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water.

For containers with capacities greater than 5 gallons: Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Add water - at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of 1/4 of the container volume. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 60 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. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water.

CONTAINER HANDLING [Bulk]

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.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

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 ALBAUGH or Seller. To the extent consistent with applicable law. Buyer and User agree to hold ALBAUGH and Seller harmless for any claims relating to such factors.

ALBAUGH 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 consistent with 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 ALBAUGH, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ALBAUGH 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 consistent with applicable law, in no event shall ALBAUGH be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF ALBAUGH 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 ALBAUGH OR SELLER, THE REPLACEMENT OF THE PRODUCT.

ALBAUGH 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 ALBAUGH.

031821

LABEL HISTORY

Not Part of Final printed Label

File Name	Version Mark	Comment
042750-00298.20180621.DRAFT	062118	Registration Review
042750-00298.20201203.DRAFT	120320	EPA Comment Revisions
042750-00298.20210318.DRAFT	031821	EPA Comment Revisions