



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 13, 2020

Ricky Kyaw
Regulatory Product Manager
Syngenta Crop Protection, LLC
PO Box 18300
Greensboro, NC 27419

Subject: Registration Review Label Mitigation for Fludioxonil and Mefenoxam
Product Name: A21458B
EPA Registration Number: 100-1588
Application Date: 2/1/2019
Decision Number: 554981; 554982

Dear Mr. 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 and Mefenoxam Interim Decisions, 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 Darius Stanton by phone at 703-347-0433, or via email at Stanton.Darius@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to be "Linda Arrington", with a stylized flourish at the end.

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

Enclosure

(Master label)

DIFENOCONAZOLE	GROUP	3	FUNGICIDE
MEFENOXAM	GROUP	4	FUNGICIDE
SEDAXANE	GROUP	7	FUNGICIDE
FLUDIOXONIL	GROUP	12	FUNGICIDE

A21458B

Fungicide

A seed treatment product for protection against damage from listed diseases on canola and cereals.

Active Ingredients:

Difenoconazole ¹	3.53%
Fludioxonil ²	0.37%
Mefenoxam ³	1.10%
Sedaxane ⁴	0.74%
Other Ingredients:	94.26%
Total:	100.00%

¹CAS No. 119446-68-3

²CAS No. 131341-86-1

³CAS No. 70630-17-0 and 69516-34-3

⁴CAS No. 874967-67-6

A21458B is a flowable concentrate for seed treatment containing 0.33 lb Difenoconazole, 0.03 lb Fludioxonil, 0.10 lb Mefenoxam, and 0.07 lb Sedaxane per gallon.

KEEP OUT OF REACH OF CHILDREN

CAUTION

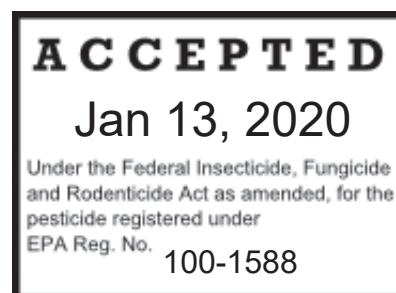
See inside booklet for additional precautionary statements and complete directions for use.

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EPA Est. No.

SCP

Net Contents



FIRST AID

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****PERSONAL PROTECTIVE EQUIPMENT (PPE)****Applicators and other handlers must wear:**

- Long-sleeved shirt and long pants
- 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
- Shoes plus socks

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 CONTROLS

When handlers use closed systems 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 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. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish, aquatic invertebrates, oysters and shrimp. Do not contaminate bodies of water when disposing of equipment rinsate or washwaters.

Groundwater Advisory

Mefenoxam is known to leach through soil into groundwater under certain conditions as a result of label use. Fludioxonil has properties and characteristics associated with chemicals detected in groundwater. These chemicals 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.

Use is permitted on-farm and in commercial seed treatment facilities. Do not use for at-plant applications (e.g. hopper box, planter box, etc.). This product is to be applied as a water-based slurry through standard slurry- or mist-type commercial seed treatment equipment.

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.

Treatment of highly mechanically scarred or damaged seed or seed known to be of low vigor and poor quality may result in reduced germination and/or reduction of seed and seedling vigor. Treat a quantity of seed using equipment similar to that planned for treating the total seed lot. Prior to treatment, conduct germination tests on a portion of seed before committing the total seed lot to a selected seed treatment.

Due to seed quality, crop or variety sensitivity, and seed storage conditions beyond the control of Syngenta, no claims are made to guarantee the germination of carry-over seed or propagating material for all crop seed when treated with A21458B.

Maximum usage when applying metalaxyl- 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.

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

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), notification to workers, 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 48 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
- 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
- Shoes plus socks

PRODUCT INFORMATION

A21458B is a broad-spectrum seed treatment fungicide containing four active ingredients: Difenoconazole, Fludioxonil, Mefenoxam and Sedaxane. A21458B protects against damage from listed seed-borne and seedling diseases of Canola and Cereals. All these active ingredients have a different mode of action against fungal pathogens.

Difenoconazole is active against Seed-borne Blackleg (*Leptosphaeria maculans*) on Canola and several seed, seedling and certain foliar diseases including bunts and smuts on Cereals.

Fludioxonil is active against Fusarium species and Rhizoctonia species in Canola as well as weakly pathogenic fungi such as Aspergillus and Penicillium species in Cereals.

Mefenoxam is active against Pythium species causing damping-off and seed rot in Canola and Cereals.

Sedaxane is active against seed decay, seedling blight and damping-off caused by Rhizoctonia species in Canola and loose smuts caused by Ustilago species in Cereals.

RESISTANCE MANAGEMENT

DIFENOCONAZOLE	GROUP	3	FUNGICIDE
MEFENOXAM	GROUP	4	FUNGICIDE
SEDAXANE	GROUP	7	FUNGICIDE
FLUDIOXONIL	GROUP	12	FUNGICIDE

For resistance management, please note that A21458B contains Group 3/ difenoconazole, Group 4/mefenoxam, Group 7/sedaxane and Group 12/fludioxonil fungicides. Any fungal population may contain individuals naturally resistant to A21458B and other Group 3, Group 4, Group 7 or 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.

Difenoconazole belongs to the triazole class of chemistry and is a demethylation inhibitor of sterol biosynthesis (DMI) which disrupts membrane synthesis of the fungal cell. Mefenoxam belongs to the phenylamide class of chemistry which interferes with fungal RNA synthesis. Sedaxane is a succinate dehydrogenase inhibitor (SDHI) and belongs to the carboxamide class of chemistry which disrupts cellular respiration and energy generation. 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 A21458B or other Group 3, Group 4, Group 7 or Group 12 fungicide 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.

For additional information on Fungicide Resistance Management:

- Contact Syngenta representatives at 1-800-334-9481.
- Contact your local extension specialist or certified crop advisor.
- Visit the Fungicide Resistance Action Committee (FRAC) on the web at: <http://www.frac.info>.

MIXING PROCEDURES

Important: Always re-circulate A21458B thoroughly before using.

Follow the manufacturer's application instructions for the seed treatment equipment being used.

Apply A21458B as a water-based slurry utilizing standard slurry seed treatment equipment which provides uniform seed coverage. Uneven or incomplete seed coverage may not give the desired level of disease control. Thoroughly mix the specified amount of A21458B into the required amount of water or liquid inoculant for the slurry treater and dilution rate to be used.

Certain crops require addition of inoculants when the seed is treated or planted. A21458B is compatible with several liquid inoculant products. Consult the maker of the inoculant product and a Syngenta representative for directions before applying A21458B with inoculants.

The total application volume must be sufficient to provide desired level of coverage. Dilution is typically done with water or liquid inoculants.

Continuous agitation or mixing of the slurry mixture is necessary to prevent settling out of the solution. Clean out any unused product from the treater after treating or maintain constant agitation if the leftover slurry will be maintained overnight.

- Use an EPA-approved dye or colorant that imparts an unnatural color to the seed as required in 40 CFR 153.155(c).
- Allow seed to dry before bagging.

SEED CONTAINER LABEL REQUIREMENTS

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

- This seed has been treated with Difenoconazole, Fludioxonil, Mefenoxam and Sedaxane fungicides.
- Do not use for feed, food, or oil purposes.

In addition, the following statements are required on containers of seeds treated with A21458B:

- Ground Water Advisory: Mefenoxam is known to leach through soil into groundwater under certain conditions as a result of label use. Fludioxonil has properties and characteristics associated with chemicals detected in groundwater. These chemicals may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow.
- Store away from feeds and foodstuffs.
- Do not allow children, pets, or livestock to have access to treated seed.
- Wear long-sleeved shirt, long pants and chemical-resistant gloves when handling treated seed.
- Treated seed must be planted into the soil at a depth greater than ½ inch.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Dispose of all excess treated seed. Leftover treated seed may be double-sown around the headland or buried away from water sources in accordance with local requirements.
- Do not contaminate water bodies when disposing of planting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements.
- 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 the ethanol by-products that are used in agronomic practice.
- In the event of crop failure or harvest of a crop grown from seed treated with A21458B, the field may be replanted immediately to the following crops:

Plantback Interval Table

Immediate Plantback
Cereals: Barley, Oats, Rye, Triticale, and Wheat
Cotton
Dried Shelled Pea and Bean Crop Subgroup 6C
Potato
Rapeseed (Including Canola) Crop Subgroup 20A

Soybean
Sugarbeet
Sweet Corn

- For any other crops the minimum plantback interval is 30 days from the date the seeds treated with A21458B were planted.
- Cereal forage must not be grazed until 30 days after planting.

SEED TREATMENT

When applied according to the **A21458B Rate Table for Canola and Cereals**, A21458B provides early season protection against the diseases listed in the table below.

A21458B Rate Table for Canola

Crop	For Protection Against the Following Diseases	Use Rate (fl oz/100 lb)	Use Rate (g ai/100 kg)
Canola	Seed-borne <i>Alternaria</i> species Seed-borne Blackleg (<i>Leptosphaeria maculans</i>) Seedling Disease Complex: Damping-off, Seedling Blight, Seed Rot, and Root Rot caused by <i>Fusarium</i> species, <i>Pythium</i> species, and <i>Rhizoctonia</i> species	9.2	Difenoconazole: 24 Fludioxonil: 2.5 Mefenoxam: 7.5 Sedaxane: 5

A21458B Rate Table for Cereals

Crop	For Protection Against the Following Diseases	Use Rate (fl oz/100 lb)	Use Rate (g ai/100 kg)
CEREALS: Barley Oats Rye Triticale Wheat, Spring Wheat, Winter	Diseases Controlled: General Seed Rots ¹ : Seedling Disease Complex: Damping-off, Seedling Blight, Seed Rot, and Root Rot caused by <i>Fusarium</i> species, <i>Pythium</i> species, and <i>Rhizoctonia</i> species Bunts ² : Common, Dwarf, and Karnal Seed-borne <i>Septoria</i> species Septoria Blotch ³ Smuts: Covered, False Loose, Flag, and Loose Diseases Suppressed⁴: Common Root Rot (<i>Cochliobolus</i> species) Crown and Foot Rot (<i>Fusarium</i> species) Take-All	4.6 – 9.2	Difenoconazole: 12 – 24 Fludioxonil: 1.25 – 2.5 Mefenoxam: 3.75 – 7.5 Sedaxane: 2.5 - 5

¹Active on pathogens that cause general seed rots. These seed rots include those caused by saprophytic organisms such as *Penicillium* and *Aspergillus* species.

²Provides protection against both seed- and soil-borne bunts (common, dwarf).

³Provides early-season foliar disease protection for up to 6 weeks after planting at the 9.2 fl oz/100 lb rate. For full-season protection, apply a foliar fungicide according to label directions.

⁴Suppression means consistent protection at a level which is not optimal but is still of commercial benefit.

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 [less than or equal to 5 gallons]

Non-refillable container. 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 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 puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

Container Handling [greater than 5 gallons – mini-bulk]

Non-refillable container. 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. 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 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. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

Container Handling [greater than 5 gallons – bulk]

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 person refilling. 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, 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.

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the SYNGENTA Logo and the PURPOSE ICON
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For non-emergency (e.g., current product information), call
Syngenta Crop Protection at 1-800-334-9481

Manufactured for:
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Greensboro, North Carolina 27419-8300

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