

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 5, 2019

Nakia Smith, M.S. Regulatory Product Manager Syngenta Crop Protection, LLC P.O. Box 18300 Greensboro, NC 27419-8300

Subject: Registration Review Label Mitigation for Acibenzolar

Product Name: Bion 375FS

EPA Registration Number: 100-1634 Application Date: February 1, 2019

Decision Number: 552356

Dear Ms. Smith:

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 Acibenzolar 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.

If you have any questions about this letter, please contact Jaclyn Pyne by phone at 703-347-0445, or via email at pyne.jaclyn@epa.gov

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Sincerely,

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

Enclosure

[Master]

ACIBENZOLAR-S-METHYL GROUP P01 FUNGICIDE

Bion® 375FS

Fungicide

For early-season protection against downy mildew in sunflower and sorghum as well as protection against certain early-season seed and seed-borne diseases, and nematodes in cotton.

Active Ingredient:	
Acibenzolar-S-methyl*	32.6%
Other Ingredients:	67.4%
Total:	

*CAS No. 135158-54-2

Bion® 375FS is a flowable concentrate for seed treatment containing 3.13 lb acibenzolar-Smethyl per gallon.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautionary statements and directions for use in booklet [on label].

EPA Reg. No. 100-1634

EPA Est.

Net Contents	
[Batch Code: _] (For nonrefillables only.)

ACCEPTED

Jul 05, 2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 100-1634

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1.0 FIRST AID

FIRST AID		
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. Call a poison control center or doctor for treatment advice. 	
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		

2.0 PRECAUTIONARY STATEMENTS

2.1 Hazards to Humans and Domestic Animals

CAUTION

Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. 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.

2.2 Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Protective eyewear
- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of: barrier laminate, butyl rubber ≥14 mils, neoprene rubber ≥14 mils, nitrile rubber ≥14 mils, polyvinyl chloride (PVC) ≥14 mils, or Viton® ≥14 mils
- Shoes and socks

2.2.1 User Safety Requirements

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.

2.2.2 User Safety Recommendations

Users should:

- Wash hands 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 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.

2.3 Environmental Hazards

This pesticide is toxic to fish and aquatic invertebrates. Do not contaminate water when disposing of equipment washwater or rinsate. If treated seed is spilled outdoors or in areas accessible to birds or mammals, promptly clean up and dispose of properly to prevent ingestion.

2.4 Physical or Chemical Hazards

Do not mix or allow contact with reducing agents. Hazardous chemical reaction may occur.

DIRECTIONS FOR USE

3.0 PRODUCT INFORMATION

3.1 Resistance Management

ACIBENZOLAR-S-METHYL GROUP P01 FUNGICIDE

For resistance management, Bion 375FS contains a Group P01 fungicide. Any fungal populations may contain individuals naturally resistant to Bion 375FS and other Group P01 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. Acibenzolar-S-methyl is a selective, non-pesticidal, systemic compound which induces host plant defense.

Since Bion 375FS has no direct activity on plant pathogens, the likelihood that resistance will develop is low. However, plant pathogens are known to develop resistance to induced host plant defense and to products used repeatedly for control. Because resistance development cannot be predicted, the use of this product should conform to sound resistance management strategies such as alternation with fungicides with a different mode of action and/or tank mixes established for the crop and use area.

Syngenta encourages responsible product stewardship to ensure effective long term control of the fungal diseases on this label.

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

- Rotate the use of Bion 375FS or other Group 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.
- 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.

3.2 Integrated Pest Management (IPM)

Use should be based on an IPM program that includes field sanitation, scouting, historical information related to pesticide use, and crop rotation. The IPM program should also consider cultural, biological, and other chemical control practices.

4.0 APPLICATION DIRECTIONS

Important: Recirculate Bion 375FS thoroughly before using.

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

Apply Bion 375FS 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 Bion 375FS into the required amount of water for the slurry treater and dilution rate to be used.

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.

Allow seed to dry before bagging.

Follow planter manufacturer's specifications for use of talc, graphite or other hopper box additives at planting. Seed must be completely dry before adding to planter.

5.0 SEED CONTAINER LABEL REQUIREMENTS

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

- This seed has been treated with Acibenzolar-S-Methyl fungicide.
- Do not use for feed, food, or oil purposes.

In addition, the following statements are required on containers of seeds treated with Bion® 375FS:

- Do not allow children, pets, or livestock to have access to treated seed.
- Store away from feeds and foodstuffs.
- 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 1 inch.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting.
- Dispose of excess treated seed by burying seed away from bodies of water.
- 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.

6.0 SEED TREATMENT DIRECTIONS

6.1 Cotton

	Use Rate		
Target Disease	Amount of Acibenzolar-S-Methyl (mg ai/seed)	Maximum Total Annual Application Rate (Ib ai/A)	Remarks
Protection from: Black Root Rot caused by <i>Thielaviopsis basicola</i>	0.0003 to 0.0009*	0.0002	*mg per seed rates based on 5,000 seeds per pound.
Suppression of: Fusarium oxysporum f. sp. vasinfectum that incites Fusarium wilt and early-season damping- off symptoms.			
Suppression of: Early-season nematodes.			Reduction in nematode fecundity.
For early season protection of pre- and postemergence damping-off caused by <i>Rhizoctonia solani</i> , <i>Pythium</i> and <i>Fusarium</i> sp. Apply Bion 500FS with azoxystrobin-based fungicide packages.			
For early-season protection against <i>T. basicola</i> and <i>Meloidogyne incognita</i> interactions (disease/nematode interaction), apply Bion 500FS with Avicta® Duo Cotton and Dynasty® CST.			

6.2 Sunflower

	Use R	late	
Target Disease	Amount of Acibenzolar-S-Methyl (mg ai/seed)	Maximum Total Annual Application Rate (Ib ai/A)	Remarks
For early-season protection from Downy Mildew caused by Plasmopara halstedii	0.021 – 0.029	0.005	Target Rate is 0.025 mg ai/seed.

6.3 Sorghum

	Use Rate		
Target Disease	Amount of Acibenzolar-S-Methyl (mg ai/seed)	Maximum Total Annual Application Rate (Ib ai/A)	Remarks
Suppression of: Downy Mildew (Peronosclerospora sorghi)*	0.0031-0.0062**	0.002	*For suppression of downy mildew, use in combination with the high rate of Dynasty. **mg per seed rates based on 14,500 seeds per pound.

7.0 STORAGE AND DISPOSAL

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.

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.

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 ¼ 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)

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 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. 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)

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.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER

8.0 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.

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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.

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For non-emergency (e.g., current product information), call Syngenta Crop Protection at 1-800-334-9481

Manufactured for: Syngenta Crop Protection, LLC P.O. Box 18300 Greensboro, North Carolina 27419-8300

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