



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 500FS
EPA Registration Number: 100-1363
Application Date: February 1, 2019
Decision Number: 552357

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,

A handwritten signature in blue ink, appearing to read "Linda Arrington", with a long horizontal flourish extending to the right.

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

Enclosure

Bion® 500FS

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 Ingredients:

Acibenzolar-S-methyl*	42.0%
Other Ingredients:	58.0%
Total:	100.0%

*CAS No. 135158-54-2

Contains 4.17 pounds of Acibenzolar-S-methyl per gallon.

KEEP OUT OF REACH OF CHILDREN.

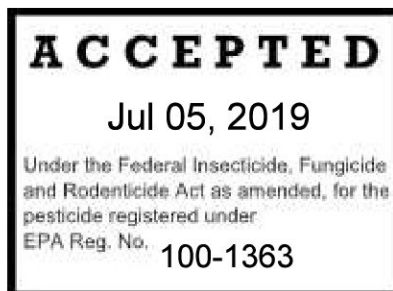
CAUTION

See additional precautionary statements and directions for use inside booklet.

EPA Reg. No. 100-1363

EPA Est.

Net Contents



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.
If in eyes	<ul style="list-style-type: none"> • 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 eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • 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	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Harmful if swallowed. Harmful if inhaled. Harmful if absorbed through skin. Avoid breathing vapor or spray mist. 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)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical resistant gloves made of any waterproof material such as barrier laminate, butyl rubber ≥ 14 mils, nitrile rubber ≥ 14 mils, neoprene rubber ≥ 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.

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.

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 endangered species, promptly clean up and dispose of properly to prevent ingestion.

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 this 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.

For use in commercial seed treatment operations only. Not for use in planter or hopper box applications.

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.

Seed treated with this product must be visually identifiable from untreated seed by the use of an approved colorant or dye to prevent accidental use of treated seed as food for humans or feed for animals. Refer to 21 CFR, Part 2.25. Any colorant or dye added to treated seed must be cleared for use in accordance with 40 CFR, Part 180.1001.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination test on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Syngenta Crop Protection, no claims are made to guarantee germination of carry-over seed.

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 seed or propagating material for all crop seed when treated with Bion 500FS.

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

PRODUCT INFORMATION

Bion 500FS is a selective, systemic compound used for early-season protection against downy mildew in sunflower and sorghum as well as protection of cotton from certain early-season diseases, and nematodes. Bion 500FS induces host plant resistance; it has no direct activity against target pathogens. Bion 500FS exhibits a unique mode of action which mimics the natural systemic activated resistance (SAR) response found in most plant species. It is recommended that Bion 500FS be used in combination with azoxystrobin based fungicide packages for early season protection against pre- and postemergence damping-off. Bion 500FS may be applied in tank mixes or sequentially with other registered seed treatment products.

All applications should be made according to the use directions that follow.

RESISTANCE MANAGEMENT

ACIBENZOLAR-S-METHYL	GROUP	P01	FUNGICIDE
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For resistance management, Bion 500FS contains a Group P01 fungicide. Any fungal populations may contain individuals naturally resistant to Bion 500FS 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.

Since Bion 500FS has no direct activity on plant pathogens, the likelihood that resistance (insensitivity) will develop in the pathogens is low. However, plant pathogens are known to develop tolerance to host plant resistance and to products used repeatedly for control. Because insensitivity development cannot be fully predicted, the use of this product should conform to sensitivity management strategies established for the crop and use area.

Syngenta encourages responsible product stewardship to ensure effective long-term disease control.

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

- Rotate the use of Bion 500FS 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.

MIXING INSTRUCTIONS

Apply Bion 500FS as a water-based slurry using seed treatment application equipment that will provide uniform coverage on the seed surface. Consult the manufacturer of the application equipment being used for calibration and operation procedures.

Bion 500FS mixes easily with water and other water-based seed treatments manufactured by Syngenta. Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures. When mixing with products from other manufacturers, the compatibility should be tested prior to use by conducting a jar test. Mix all intended seed treatments with the appropriate amount of water in a clear glass container. Mix well and let sit for one hour. Remix and observe for incompatibility.

Mixing Bion 500FS with tank-mix partners: Add $\frac{1}{2}$ of the required water to the mix tank and turn on the agitation. Mechanical agitation is preferred. If using wettable powders and/or products in water-soluble pouches, add them first to clean water allowing them to completely disperse prior to adding Bion 500FS or other products. Allow each tank-mix partner to completely disperse before adding the next product. Add the remaining amount of water and agitate. Maintain agitation until the entire slurry mixture has been used. Allow seed to dry prior to bagging. Treated seed bagged for later use must contain an EPA-approved dye or colorant that imparts an unnatural color to the seed.

SEED BAG LABEL REQUIREMENTS

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

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

In addition, the following statements are required on bags containing seeds treated with Bion 500FS:

- Store away from food and feedstuffs.
- Wear long-sleeved shirt, long pants and chemical-resistant gloves when handling treated seed.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Dispose of seed packaging in accordance with local requirements.
- Do not allow children, pets, or livestock to have access to treated seed.
- Treated seed must be planted into the soil at a depth greater than 1 inch.
- Dispose of all excess treated seed. Leftover treated seed may be doublesown 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.

CROP USE DIRECTIONS

Crop	Target Disease	Amount of Active Ingredient (Acibenzolar-S-Methyl)	Maximum Total Seasonal Application Rates	Comments
Cotton	<p>Protection from: Black Root Rot caused by <i>Thielaviopsis basicola</i></p> <p>Suppression of: <i>Fusarium oxysporum</i> f. sp. <i>vasinfectum</i> that incites Fusarium wilt and early-season damping-off symptoms.</p> <p>Suppression of: Early-season nematodes.</p> <p>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.</p> <p>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.</p>	0.0003 to 0.0009 mg ai/seed*	0.0002 lb. ai/A	<p>* mg per seed rates based on 5,000 seeds per pound.</p> <p>Reduction in nematode fecundity.</p>

Crop	Target Disease	Amount of Active Ingredient (Acibenzolar-S-Methyl)	Maximum Total Seasonal Application Rates	Comments
Sunflower	For early-season Protection from Downy Mildew caused by <i>Plasmopara halstedii</i>	0.021-0.029 mg ai/seed*	0.005 lb ai/A	target rate = 0.025 mg ai/seed *mg ai per seed rates based on 4,500 seeds per pound.

- 1 fluid ounce of Bion 500FS contains 14.8 g Acibenzolar-S-Methyl.

Crop	Target Disease	Amount of Active Ingredient (Acibenzolar-S-Methyl)	Maximum Total Season Application Rates	Comments
Sorghum	Suppression of: Downy Mildew (<i>Peronosclerospora sorghi</i>)*	0.0031-0.0062 mg ai/seed**	0.002 lb ai/A	*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.

- 1 fluid ounce of Bion 500FS contains 14.8 g Acibenzolar-S-Methyl.

Follow planter manufacturer instructions for use of talc, graphite- or other hopper box additives at planting.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

Pesticide Storage

Store in original containers only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, mop and remove to chemical waste storage area until proper disposal can be made if product cannot be used according to the label.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of federal law. 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 of 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 and 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 $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least once 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 and 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.

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.

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Bion® is a registered trademark of Merck KGaA

Viton® trademark of E. I. duPont de Nemours and Company, Inc.

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

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