100 - 1363

7/14/2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

> OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

JUL 1 4 2014

Patrick McCain Syngenta Crop Protection, Inc. P.O. Box 18300 Greensboro, NC 27419-8300

SUBJECT: Label Amendment Bion 500FS EPA Reg. No. 100-1363; Decision No. 480377 Your Submission Dated June 25, 2013

Dear Mr. McCain:

The master and supplemental label amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended, to add sorghum seed treatment has been reviewed and found to be unconditionally acceptable under FIFRA 3(c)(5).

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) 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 18 months from the date of this letter. After 18 months, you may only distribute or sell this productif it ears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and it's implementing regulation at 40 CFR 152.3.

If you have any questions regarding this correspondence, contact Rose Kearns of my staff by phone at 703-305-5611 or via email at <u>kearns.rosemary@epa.gov</u> or myself at 703-308-9443 or via email at <u>kish.tony@epa.gov</u>.

Sincerely.

Tony Kish Product Manager 22 Fungicide Branch Registration Division (7504P)

GROUP 21 FUNGICIDE

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*	
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. No. XXXX

SCP

1 quart 1 gallon 2.5 gallons 15 gallons _____ gallons Net Contents

ACCEPTED
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pestacide registered under EPA Reg. No. 100-1303

FIRST AID				
If swallowed	 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. 			
lf inhaled	 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 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. 				
lf on skin or clothing	 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.				
doctor, or going in	HOT LINE NUMBER			
For 24-Hour Medical Emergency Assistance (Human or Animal) or				
	nical 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)

Some materials that are chemical-resistant to this product are listed below. If you want more options follow the instructions for Category C on an EPA chemical-resistance category selection chart.

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 <u>>14</u> mils, nitrile rubber <u>>14</u> mils, neoprene rubber <u>>14</u> mils, polyvinyl chloride (PVC) <u>>14</u> mils and Viton® <u>>14</u> 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.

5/

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.

6/15

RESISTANCE MANAGEMENT

Bion 500FS exhibits a mode of action unique from currently available fungicides and bactericides. 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. Such strategies may include rotating and/or tank mixing with products with different modes of action as well as the use of good cultural practices. Consult your local pest control advisor or extension office for details. If insensitivity to this product develops in your area, this product or other products with a similar mode of action may not provide adequate control. If you experience difficulty with control and insensitivity is a likely cause, consult your local Syngenta Crop Protection representative, local agricultural extension office, or pest control advisor for the best alternative method of control. Syngenta encourages responsible product stewardship to ensure effective long-term disease control.

Bion 500FS

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-mixpartners: Add ½ 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	Protection from: Black Root Rot caused by <i>Thielaviopsis basicola</i>	0.0003 to 0.0009 mg ai/seed*	0.0002 lb. ai/A	* mg per seed rates based on 5,000 seeds per pound
	Suppression of: <i>Fusarium oxysporum</i> f. sp. <i>vasinfectum</i> 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</i> <i>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.</i> basicola and Meloidogyne incognita interactions (disease/nematode interaction), apply Bion 500FS with Avicta® Duo Cotton and Dynasty® CST.	· ·		

9/

Сгор	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.

Сгор	Target Disease	Amount of Active Ingredient (Acibenzolar-S- Methyl)	Maximum Total Season Application Rates	Comments
Sorghum	Suppression of: Downy Mildew (Peronosclerospora sorghi)*	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.

||/ |15

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 5 gallons]

Non-refillable-container. -Do-not-reuse-or-refill-this-container. Triple rinse-container (orequivalent) 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 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.

Container Handling [more 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 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.

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

Avicta®, Dynasty®, the ALLIANCE FRAME the SYNGENTA Logo and the PURPOSE ICON are Trademarks of a Syngenta Group Company

Bion® is a registered trademark of Merck KGaA

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

©20__ Syngenta

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

BION 500FS 1363 MAS 0113 AMEND JUN2013 VERSION B CLEAN 07-09-14 000100-01363B.20130620.BION500FS_AMEND_JUN2013_VERB_CLEAN.PDF

SUPPLEMENTAL LABELING

Syngenta Crop Protection, LLC P. O. Box 18300

Greensboro, North Carolina 27419-8300 SCP 1363-S2 0714

Bion® 500FS

Fungicide

This supplemental label expires on 07-18-2017 and must not be used or distributed after that date.

Active Ingredients:

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

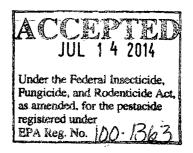
Contains 4.17 pounds of Acibenzolar-S-methyl per gallon.

KEEP OUT OF REACH OF CHILDREN.

CAUTION

EPA Reg. No. 100-1363

All applicable directions, restrictions and precautions on the EPAregistered label are to be followed. Before using Bion 500FS as permitted according to this supplemental label, read and follow all applicable directions, restrictions, and precautions on the EPA-registered label on or attached to the pesticide product container. This Supplemental Labeling contains revised use instructions and or restrictions that may be different from those that appear on the container label. This Supplemental Labeling must be in the possession of the user at the time of pesticide application. It is a violation of Federal law to use this product in a manner inconsistent with its labeling.





DIRECTIONS FOR USE

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

The Syngenta logo is a trademark of a Syngenta Group Company Bion® is a registered trademark of Merck KGaA

©2014 Syngenta

BION 500FS 1363 MAS 0113 AMEND JUN2013 SUPP-CLEAN - dt - 07/09/14 000100-01363B.20130620.BION500FS_AMEND_JUN2013_SUPP_VERB_CLEAN.pdf

,

15/

١