

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

January 20, 2015

Mr. Matthew Feinberg Authorized Agent to Novozymes BioAg, Inc. Exponent, Inc. 1150 Connecticut Avenue NW, Suite 1100 Washington, D.C. 20036

 Subject: Non-Pesticide Registration Improvement Act (PRIA) Labeling and Formulation Amendment – Revision to the Primary Brand Name, Company Name and Contact Information, and Warranty Statement on the Labeling, Restructure of the Labeling to a Booklet Format, Addition of First Aid Statements to the Labeling, Other Minor Revisions to the Labeling, Minor Revisions to the Basic Confidential Statement of Formula, and Minor Revisions to the Manufacturing Process Product Name: Actinovate[®] STP Biological Fungicide EPA Registration Number: 73314-4 Application Date: 07/18/2013 OPP Decision Number: 481153

Dear Mr. Feinberg:

The amended labeling, Confidential Statement of Formula (CSF), and manufacturing process referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

At this time, the U.S. Environmental Protection Agency (EPA) is not requiring a change to the restricted-entry interval (REI) of 1 hour as it appears on your labeling in the Agricultural Use Requirements Box. The EPA is currently developing guidance and criteria for when it will allow a REI of less than 4 hours and might require a change to the REI for this product in the future. This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Within three (3) months of the date of this amendment, you must submit the following information to the EPA to ensure the records for Actinovate[®] STP Biological Fungicide are up-to-date:

- (1) A revised EPA Form 8570-35 (Data Matrix EPA Internal Use and Public File Copies) that includes the MRID Number for the updated manufacturing process.
- (2) Compositional information on trade name inert ingredients in Actinovate[®] STP Biological Fungicide that are not yet in the EPA's confidential database. See questions #12, #13, #14, #17, and #24 in the

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EPA's May 6, 2014, document entitled "<u>Inert Ingredient Frequently Asked Questions</u>" for additional details.

Please note that the record for this product currently contains the following CSF:

• Basic CSF dated 12/16/2014

Any CSFs other than those listed above are superseded/no longer valid.

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 product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the 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 EPA 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 Assurance.

Your release for shipment of the product constitutes acceptance of these terms. If these terms are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact me by phone at (703) 347-8920 or via email at kausch.jeannine@epa.gov.

Sincerely,

Jeannine Kausch, Regulatory Action Leader Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs

{NOTE TO REVIEWER: {} – DENOTES COMMENTS TO THE REVIEWER, AND [] – DENOTES OPTIONAL STATEMENTS AND/OR IMAGES. NOTE: THIS LABEL REFLECTS THE UNIT PACKAGE LABELING AND WILL BE PRESENTED AS A BOOKLET ON THE FRONT OF THE PRODUCT CONTAINER.}

ACTINOVATE[®] STP FUNGICIDE

[ALTERNATE BRAND NAMES: ACTINOVATE[®] STP BIOLOGICAL FUNGICIDE, ACTINOGRO ST]

FOR USE AS A DRY COATING (PLANTER BOX APPLICATION) OR IN SLURRY SEED TREATMENT

APPLICATION

ACTIVE INGREDIENT:

Streptomyces lydicus WYEC 108*	00.33%
OTHER INGREDIENTS:	. <u>.99.67%</u>
TOTAL:	.100.00%

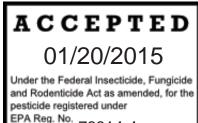
*End-use product contains not less than 1 X 10⁸ colony forming units per gram *Streptomyces lydicus* WYEC 108

KEEP OUT OF REACH OF CHILDREN CAUTION

See inside this booklet for [additional Precautionary Statements, and] complete First Aid,

Directions for Use, and the Warranty.

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 eye. Call a poison control center or doctor for treatment advice. 	
If inhaled:	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. Call a poison control center or doctor for further 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. 	
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 by mouth to an unconscious person. 	
treatment. For no	HOT LINE NUMBER t container or label with you when calling a poison control center or doctor, or going for on-emergency information concerning this product, call the National Pesticide er (NPIC) at 1-800-858-7378 (NPIC Web site: <u>www.npic.orst.edu</u>). For emergencies, ison control center at 1-800-222-1222.	



^{eg. No.} 73314-4

Information regarding the contents and levels of metals in this product is available on the Internet at <u>http://www.aapfco.org/metals.htm.</u>

US Patent Number: 5,403,584	Novozymes BioAg, Inc.
EPA Reg. No.: 73314-4	13100 W. Lisbon Road, Suite 600
EPA Establishment No.: 73314-TX-001	Brookfield, WI 53005
	1-800-245-4104
Net Weight:	
Batch code: {Batch code to be inserted}	[NOVOZYMES RETHINK TOMORROW][LOGO]
[Expiration Date:]	[Made in the][USA]

PRECAUTIONARY STATEMENTS

Personal Protective Equipment (PPE): Applicators and other handlers must wear a long-sleeved shirt, long pants, shoes, and socks. Mixer/loaders and applicators must wear a dust/mist-filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are available for washables, 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. If gloves are worn, wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards: For terrestrial uses: 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 contaminate water when disposing of equipment washwaters or rinsate.

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 State or Tribal agency responsible for pesticide regulation.

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) and restricted-entry interval (REI). 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 one (1) hour or until solution has dried. Exception: If the product is 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, waterproof gloves and shoes plus socks.

Non-Agricultural Use Requirements

The requirements in this box apply to uses of the product that are not within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treatment area until seeds have dried or been packaged.

PRODUCT INFORMATION

Actinovate[®] STP Fungicide is a biological fungicide for the suppression of root rot and damping-off fungi. Actinovate[®] STP Fungicide is specifically formulated to adhere to seeds either as a dry coating (planter box application) or in a slurry. When used as a seed coating, soil borne fungi suppressed include *Fusarium, Rhizoctonia, Pythium, Phytophthora, Phymatotrichum omnivorum* (cotton root rot), *Aphanomyces, Monosporascus, Armillaria, Sclerotinia, Postia, Verticillium, Geotrichum*, and other root-decay fungi. The active ingredient in Actinovate[®] STP Fungicide colonizes the seed and root system protecting them from harmful fungi.

INTEGRATED PEST MANAGEMENT (IPM)

Users may integrate Actinovate[®] STP Fungicide into an overall disease and pest management strategy whenever fungicide use is necessary. Actinovate[®] STP Fungicide may be used with in combination with chemical seed treatment fungicides and/or insecticides.

APPLICATION DIRECTIONS

Compatibility:

Actinovate[®] STP Fungicide is compatible with chemical fungicides, insecticides, fertilizers and can be tank mixed with these substances unless otherwise restricted. Follow the most restrictive of the labeling limitations and precautions of all products used in mixtures.

Application Uses:

Actinovate[®] STP Fungicide is a powdered biological fungicide for use in seed coating applications in or on all raw agricultural commodities, food and fiber crops, and other agricultural production crops to suppress/control the following fungi: *Fusarium, Rhizoctonia, Pythium, Phytophthora, Phymatotrichum omnivorum* (cotton root rot), *Aphanomyces, Monosporascus, Armillaria, Sclerotinia, Postia, Verticillium, Geotrichum*, and other root-decay fungi.

Seed Treatment:

Apply Actinovate[®] STP Fungicide as a dry coating (in planter box) or in a slurry at a rate of 1.0 - 32.0 oz of Actinovate[®] STP Fungicide per cwt (0.25 – 8.0 grams of Actinovate[®] STP Fungicide per lb) of seed. Refer to the tables below for specific use rates by crop.

Preparation of the slurry:

Fill a slurry tank with the required volume of water. Use between 500mL and 1L of water per 100kg of seed (between 16.9 fl oz and 33.8 fl oz water per 220.5 lbs of seed). Pour the required amount of Actinovate[®] STP Fungicide onto the water surface. Wait until the product has disappeared in the water without stirring. Switch on the stirring system. Use the slurry within 1 day of preparation.

Crops on which Actinovate[®] STP Fungicide may be used

CROPS	SEED APPLICATION RATE FOR DRY COATING (IN PLANTER BOX) OR SLURRY
Wheat (Drill Box Application – Wheat only)	0.35-0.70 oz (9.8-19.6 grams) per cwt of seed
Alfalfa	1.8- 3.7 oz (52-104 grams) per cwt of seed
Corn, Field	1-2 oz (28-56 grams) per cwt of seed
Corn, Silage	1-2 oz (28-56 grams) per cwt of seed
Corn, Sweet	1.76-3.5 oz (50-100 grams) per cwt of seed
Cotton	4-8 oz (112-224 grams) per cwt of seed
Peanuts	0.74- 1.5 oz (21-42 grams) per cwt of seed
Popcorn	1.41-2.82 oz (40-80 grams) per cwt of seed
Sorghum	1-2 oz (28-56 grams) per cwt of seed
Soybeans	0.32–0.64 (9-18 grams) per cwt of seed
Sugar Beets	3.8-7.6 oz (107-214 grams) per cwt of seed
Sunflower	1.41-2.82 oz (40-80 grams) per cwt of seed

CROPS	SEED APPLICATION RATE FOR DRY COATING (IN PLANTER BOX) OR SLURRY
Other Cereal Grain, Oilseed, and Legume Vegetable Crops: buckwheat, rye, millet, canola, safflower, snap and dry beans, succulent and dry peas, lentil, and other cereal grains, oilseeds, and legume vegetables	1-4 oz per cwt (0.25-1.00 grams per lb) of seed
Other Nongrass Animal Feed (Forage, Fodder, Straw, and Hay) Crops: clover, vetch, and trefoil	

CROPS	SEED APPLICATION RATE FOR DRY COATING (IN PLANTER BOX) OR SLURRY
<i>Cucurbit Vegetables:</i> cucumbers, melons, gourds, squash, cantaloupe, and other cucurbit vegetables	
<i>Fruiting Vegetables (except cucurbits):</i> eggplant, sweet peppers, hot peppers, tomatoes, tomatillos, and other fruiting vegetables	
<i>Herb, Spices, and Mints:</i> sage, rosemary, thyme, peppermint, dill, basil, oregano, and other herbs, spices, and mints	
<i>Leafy Vegetables and Brassica (Cole) Leafy</i> <i>Vegetables:</i> broccoli, brussels sprouts, cabbage, cauliflower, celery, collards, endive, kale, kohlrabi, lettuce, mustard greens, parsley, spinach, and other leafy and brassica (cole) leafy vegetables	4-32 oz per cwt (1-8 grams per lb) of seed
Root and Tuber Vegetables and Bulb Vegetables (Except Sugar Beets):	
garlic, onions, white potatoes, sweet potatoes, carrot, ginger, ginseng, horseradish, turnip, beets, radish, and other root, tuber, and bulb vegetables	

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a dry, cool place out of direct sunlight and away from heat sources. Keep from overheating or freezing. Optimum storage temperature is 40° F to 85° F.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then, offer for recycling if available, dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY

The Directions for Use of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and must be followed carefully. Novozymes BioAg, Inc. warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions under normal growing conditions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes BioAg, Inc.

EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESSED REFERENCE TO THIS WARRANTY AND LIMITATION OF DAMAGES, SELLER MAKES NO OTHER EXPRESSED OR IMPLIED WARRANTY OR GUARANTEE TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESSED OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO. {Note: The following information will be affixed to the unit package}

ACTINOVATE[®] STP FUNGICIDE [ALTERNATE BRAND NAMES: ACTINOVATE[®] STP BIOLOGICAL FUNGICIDE, ACTINOGRO ST]

FOR USE AS A DRY COATING (IN A PLANTER BOX) OR IN SLURRY SEED TREATMENT APPLICATION

ACTIVE INGREDIENT:

Streptomyces lydicus WYEC 108*	00.33%
OTHER INGREDIENTS:	<u>.99.67%</u>
TOTAL:	100.00%
*End-use product contains not less than 1 X 10 ⁸ colo	ny forming units per gram Streptomyces lydicus

WYEC 108

KEEP OUT OF REACH OF CHILDREN CAUTION

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US Patent Number: 5,403,584 EPA Reg. No.: 73314-4 EPA Establishment No.: 73314-TX-001

Net Weight: Batch code: {Batch code to be inserted} [Expiration Date:] Novozymes BioAg, Inc. 13100 W. Lisbon Road, Suite 600 Brookfield, WI 53005 1-800-245-4104

[NOVOZYMES RETHINK TOMORROW][LOGO] [Made in the][USA]