10/13/2011



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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Jan Brill Registrations Manager Bayer CropScience 2 T.W. Alexander Drive Research Triangle Park, NC 27709

RE:

Product Name: BES0531

EPA Reg. No: 432-1515

Applications for Notification Dated: September 23, 2011 add Alternate Brand

Name: FFASTTM Bti as per PR Notice 98-10.

Dear Ms Brill:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticides Registration Notice (PRN) 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped as "Notification Accepted" and will be placed accordingly in our records.

Questions concerning this action should be directed to Mary Paden (703) 308-0411 or email at <u>paden.mary@epa.gov</u>.

Sincerely,

Sheryl K. Reilly

Sheryl K. Reilly, Ph.D., Chief Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P)

OCT 1 3 2011

CONCURRENCES									
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DATE	>	130011							

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Please read instructions on reverse before completing form. Form Approved, OMB No. 2070-0060 **United States OPP Identifier Number** □ Registration **Environmental Protection Agency** ☐ Amendment Washington, DC 20460 Other: Application for Pesticide - Section I-2. EPA Product Manager 3. Proposed Classification 1. Company/Product Number Sheryl Reilly 432-1515 4. Company/Product (Name) PM# None Restricted **BES0531** 5. Name and Address of Applicant (Include ZIP Code) 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) **Baver CropScience** (b)(l), my product is similar or identical in composition and labeling 2 T.W. Alexander Dr. to: **Notification** Accepted EPA Reg. No. Research Triangle Park, NC 27709 Check if this is a new address **Product Name** Section - II Amendment - Explain below. Final printed labels in response to Agency letter dated Resubmission in response to Agency letter dated _ "Me Too" Application Notification - Explain below. Other - Explain below Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Notification of Alternate Brand Name per PR Notice 98-10 = "FFAST™ Bti" This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA Section - III 1. Material This Product Will Be Packaged In: Unit Packaging Water Soluble Packaging Child-Resistant Packaging Type of Container Yes Metal Yes Yes* Nο No No Plastic If "Yes" No. per If "Yes" No. per Glass Unit Packaging wgt. container Package wgt. container *Certification must Paper be submitted Other (Specifiy) 3. Location of Net Contents Information 4. Size(s) Retail Container 5. Location of Label Directions Label Container On Label On labeling accompanying product -6. Manner in Which Label is Affixed to Product Lithograph ☐ Other Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application); Title Telephone No. (Include Area Name Manager, Registrations Code) Jan Brill 919/549-2421 Certification Date Application I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I Received acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both (Stamped) under applicable law. 2. Signature Manager, Registrations 5. Date 4. Typed Name Jan Brill 23 September 2011

Bayer CropScience



Document Processing Desk (NOTIF) Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

ATTN:

Sheryl Reilly, PM #92

Subject:

BES0531, EPA Reg. No. 432-1515 Notification of Alternate Brand Name

Dear Ms. Reilly,

With this submission, Bayer CropScience hereby notifies EPA of an Alternate Brand Name for the subject product. The new Alternate Brand Name is;

FFAST[™] Bti

The new name identifies the product as containing our proprietary evaporation retardant technology trademarked under the FFAST name, which is an acronym for Film Forming Aqueous Spray Technology.

To effect this action, enclosed please find the following;

- 1. EPA Form 8570-1
- 2. 1 copy of labeling bearing the new Alternate Brand Name
- 3. 1 highlighted copy of labeling bearing the new Alternate Brand Name

I trust that this completes the documentation for this registration action. If you have any questions, or require further information, please contact me either by telephone at 919/549-2421 or email at jan.brill@bayer.com

Sincerely,

Mr. Jan Brill

Manager, Registration

23 September 2011

Bayer CropScience P.O. Box 12014 2 T.W. Alexander Drive Research Triangle Park, NC 27709

Tel. 919 549-2421 Fax. 919-549-3969

BES0531

(ABN: FFAST™ Bti)

ſ	Notification Accepted
(Date: 10/13/2011
(Pate: 10/13/2019 Reviewer: 111 Jaken

ACTIVE INGREDIENT:		
	Strain BMP 144 solids, spores and insecticidal toxins*	10.0%
OTHER INGREDIENTS:		<u>90.0%</u>
TOTAL:		100.0%
	TU) / mg (1.02 Billion ITU / gallon or 253 Million ITU / liter). Potential in the Directions for Use Section. <u>Note:</u> The percent active ingressasurements are not federally standardized.	

EPA Reg. No. 432-1515

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN CAUTION

For MEDICAL and TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-800-331-2867

FIRST AID

If 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.
	r or label with you when calling a poison control center or doctor or going for treatment. In case of Bayer Environmental Science Emergency Response Telephone No. 1-800-334-7577.
Note To Physician: No spe	ecific antidote is available. Treat the patient symptomatically.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if absorbed through skin. Avoid contact with skin, eyes 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. As a general precaution when exposed to potentially high concentrations of living microbial products such as this, all mixer/loaders and applicators not in enclosed cabs or aircraft 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. Wear water-proof gloves.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human gensumption.

Do not apply when ground wind speed exceeds 10 mph or favors drift beyond the treatment areas. Avoiding spray 'f' drift at the application site is the responsibility of the applicator. The interaction of many equipment and water related factors determines the potential for spray drift. The applicator and the treatment coordinator are responsible for considering all these factors when making decisions.

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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 through any type of irrigation system.

PRODUCT INFORMATION

BES0531 is a selective, microbial insecticide effective against mosquitoes in a variety of habitats. This product is specifically designed to optimize applications by ultra-low volume (UEV) or space spray equipment. When appropriate equipment is used, with flow rates and nozzles optimized for these applications, this product can be used to control mosquitoes that are known be or suspected of breeding in standing waters within a 300 foot swath width of the application equipment.

Treatment areas include: abandoned swimming pools or spas, bird baths, buckets, drains, flood water, flower pots, garbage cans, hollow trees, lagoons, lakes, marshes or swamps, old tires, ornamental fountains, plant trays, planters, plastic covers, ponds, pool covers, rain barrels, roof gutters, standing water, statuary, stock tanks, swamps, tree holes, urns, water gardens, wheelbarrows, or any other water holding receptacles or locations where water collects and mosquito breeding is known or suspected.

Mosquito Habitat	Suggested Rate Range		
Treat areas with flood water, roadside ditches, irrigation ditches, standing pond, woodland pools, snow melt pools and pastures. Urban, suburban or residential areas where the control of container breeding mosquitoes is desired.	0.25 – 1.0 pints per acre (4 – 16 fluid ounces per acre)		
Treat areas with catch basins, storm water retention areas, tidal water, salt marshes and rice fields.	0.5 – 1.0 pints per acre (8 – 16 fluid ounces per acre)		
Treat areas with polluted water (such as sewage lagoons, animal waste lagoons), water with moderate organic matter and water with a high concentration of suspended solids. When late 3 rd and early 4 th instar larvae predominate, when mosquito populations are high, or when algae is abundant.	1.0 – 2.0 pints per acre (16 – 32 fluid ounces per acre)		

In addition, standing water containing mosquito larvae, in fields growing crops such as alfalfa, almonds, asparagus, corn, cotton, dates, grapes, peaches or walnuts may be treated at recommended rates.

Where dense vegetation is present or large area of coverage is required, use higher rates of application and/or a slower speed for best results.

APPLICATION DIRECTIONS

Ground Application:

BES0531 is designed to be applied undiluted (i.e., "neat") from vehicle-mounted ULV cold aerosol generator or vehicle-mounted non-thermal aerosol (cold fog) may be modified to allow high flow rates. For undiluted applications, apply 0.25 to 2.0 pints per acre of BES0531.

BES0531 may also be diluted with water before application; the amount of water will depend on weather spray equipment, and mosquito habitat characteristics. If diluted in water before application, maintain rates of application at 0.25 to 2.0 pints of BES0531 per acre.

Aerosol droplet size of a BES0531 application may be determined using magnesium oxide slides. The optimum droplet size range is from 15 to 45 microns by the volume median diameter (VMD) calculation, where 70% or greater of the spray droplets shall be no more than 30 microns. A spread factor of 0.86 should be used; A:I:M.S. or PC-DC-III are not suitable for BES0531 droplet sizing.

An optimum swath of up to 300 feet is created when BES0531 is applied from a truck that is being driven a perpendicular to the wind direction. Direct the spray head of equipment to ensure even distribution of the spray cloud throughout the area. For best results, apply when meteorological conditions are conductive to keep the spray cloud close to the ground. Do not apply when ground wind speed exceeds 10 mph.

The desired application rate may be obtained under different conditions by altering the flow rates or vehicle speed. Examples are given in the following table based on 300 foot swath width when BES0531 is applied undiluted.

Applicati	on Rate	Flow Rate (Fluid Ounce/Minute) at a Vehicle Speed of:		
Pints/Acre	Flow Ounce/Acre	5 mph	10 mph	
0.25	4	12	24	
0.5	8	24	48	
1.0	16	48	96	
2.0	32	96	-	

• Backpack or Handheld Sprayer Application:

Examples of dilution rates are given in the following table when BES0531 is diluted with water.

Applica	tion Rate	Fluid Ounce Needed per Gallon of Spray When Applied at a Rate of:			
Pints/Acre	Fluid Ounce/Acre	10 Gallon/Acre	25 Gallon/Acre	50 Gallon/Acre	
0.25	4	0.4	0.16	0.08	
0.5	8	0.8	0.32	0.16	
1.0	16	1.6	0.64	0.32	
2.0	32	3.2	1.28	0.64	

Apply through non-thermal ULV application or mist blower equipment and based acreage calculations on a 50 foot swath. Examples are given in the following table when BES0531 is applied undiluted.

Appl	ication Rate	Flow Rate (Fluid Ounce/Minute) at a Walking Speed of:				
Pints/Acre	Fluid Ounce/Acre	1 mph	2 mph	3 mph	4 mph	
0.25	4	0.4	0.8	1.2	1.6	
0.5	8	0.8	1.6	2.4	3.2	
1.0	16	1.6	3.2	4.8	6.4	
2.0	32	3.2	6.4	9.6	[12.3]	

BES0531 may be applied either undiluted or diluted with water using a non-thermal ULV, backpack or handheld sprayer. The amount of water will depend on weather, spray equipment, and mosquito habitat characteristics. For most ground spraying, apply in 5-100 gallons of water per acre using hand pump, airblast, mist blower, etc., spray equipment.



STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool (59 – 86 F°; 15 – 30 C°), dry place.

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

Container Disposal: 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 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 reconditioning, or puncture and dispose of in a sanitary landfill or by incineration. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

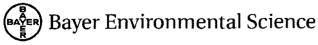
CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience LP. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience LP is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE LP'S ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS: NOT FOR SALE AFTER:

PRODUCED FOR



A Division of Bayer CropScience, LP PO Box 12014 2 T.W. Alexander Drive Research Triangle Park, NC 27709

BES0531 (MASTER) Approved 06/28/11, Notification 08/01/11



Label Claims:

- Biolarvicide
- · Biological larvicide
- Biological mosquito control
- A microbial insecticide effective against mosquitoes in a variety of habitats
- Does not persist in soil, water or the environment like many chemical larvicides
- A naturally occurring larvicide, safe for use in sensitive environments
- No toxic effects on beneficial insects such as lady bird beetles, honeybees, mayflies, dragonflies, damselflies, stoneflies, or caddisflies
- Easy to use
- A unique formulation, specifically designed for application by ultra low volume (ULV) equipment
- A unique formulation, specifically designed for labor saving application by ultra low volume (ULV)
 equipment
- Use in standing water where mosquitoes may breed
- Use in containerized water where mosquitoes breed
- Effective year-round when mosquito larvae are present
- Control mosquitoes
- Controls mosquito larvae in standing water
- · Quickly controls mosquito larvae
- · Kills mosquito larvae rapidly, often within hours after application at field use rates
- Controls mosquito larvae within 24 hours
- · When ingested by mosquito larvae, (product name) prevents the development of adults
- · When ingested by mosquito larvae, (product name) prevents emergence of breeding, biting adults
- Kills mosquito larvae upon ingestion of Bt toxins
- · Kills mosquito larvae upon ingestion by destroying the cellular lining of the insect digestive tract
- Kills mosquitoes (mosquito larvae) before they hatch, including those that may (can) transmit (carry)
 West Nile virus, Dengue fever (Dengue hemorrhagic fever), encephalitis or equine encephalitis
- Kills developing mosquitoes (mosquito larvae) before they become breeding, biting adults, including those which may (can) transmit (carry) West Nile virus, Dengue fever (Dengue hemorrhagic fever), encephalitis or equine encephalitis
- Kills mosquitoes (mosquito larvae) before they hatch, including those that may (can) transmit heartworm disease to dogs and cats

