

432-1515

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: FFAST™ 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 paden.mary@epa.gov.

Sincerely,

Sheryl K. Reilly

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

OCT 13 2011

CONCURRENCES

SYMBOL	▶ 7511(P)						
SURNAME	▶ Pader						
DATE	▶ 13 OCT 11						

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060

 EPA United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other:	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 432-1515	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BES0531	PM# 92	
5. Name and Address of Applicant (include ZIP Code) Bayer CropScience 2 T.W. Alexander Dr. Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: Notification Accepted EPA Reg. No. _____ Product Name _____ Date: 10/13/2011	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

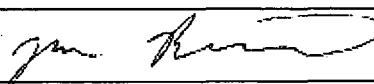
Notification of Alternate Brand Name per PR Notice 98-10 = "FFAST™ Bti"

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:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No			
*Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Jan Brill	Title Manager, Registrations	Telephone No. (Include Area Code) 919/549-2421
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager, Registrations	
4. Typed Name Jan Brill	5. Date 23 September 2011	

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Notification Accepted

Date: 10/13/2011

Reviewer: mg baker

BES0531

(ABN : FFAST™ Bti)

ACTIVE INGREDIENT:

Bacillus thuringiensis subspecies israelensis Strain BMP 144 solids, spores and insecticidal toxins* 10.0%

OTHER INGREDIENTS: 90.0%

TOTAL: 100.0%

*Equivalent to 380 International Toxic Units (ITU) / mg (1.02 Billion ITU / gallon or 253 Million ITU / liter). Potency units should not be used to adjust rates beyond those specified in the Directions for Use Section. Note: The percent active ingredient does not indicate product performance and potency measurements 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:	<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.
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. In case of emergency call toll free the Bayer Environmental Science Emergency Response Telephone No. 1-800-334-7577.</p> <p>Note To Physician: No specific antidote is available. Treat the patient symptomatically.</p>	

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 consumption.

Do not apply when ground wind speed exceeds 10 mph or favors drift beyond the treatment areas. Avoiding spray 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.

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 (ULV) 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.F.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 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 conducive to keep the spray cloud close to the ground. Do not apply when ground wind speed exceeds 10 mph.

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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.

Application 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:

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.

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

Application 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.

Application 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	12.8

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

