

73049-63

07-22-2009
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/5

Ms. Doina Bujor
Regulatory Manager
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

JUL 22 2009

Re: Valent BioSciences Corporation; *Bacillus thuringiensis* subsp. *aizawai* Slurry
EPA Registration No. 73049-63
Minor Label ("Fast Track") Amendment
Submission dated 02/19/2009
Decision #406680

Dear Ms. Bujor:

The Agency has reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1) Correction of minor formatting and typographical errors.
- 2) Addition of "Manufactured for:" before the company name in accordance with Chapter 15 of the Label Review Manual and 40 Code of Federal Regulations (CFR) § 156.10(c).
- 3) Modification of EPA File Symbol 73049-AG to EPA Registration Number 73049-63.
- 4) Addition of "Net Contents:" to the label in accordance with Chapter 17 of the Label Review Manual.
- 5) Modification of the Note to Physician statement in the First Aid Box to "Probable mucosal may contraindicate the use of gastric lavage" in accordance with Chapter 7 of the Label Review Manual.
- 6) Revision of the Storage and Disposal statements in accordance with Pesticide Registration (PR) Notices 2007-4 and 83-3.

CONCURRENCES

SYMBOL	7511P	7511P	7511P				
SURNAME	KAUSCH	Burchard	Wulf				
DATE	07/21/09	7/21/09	7/22/09				

2
5

Ms. Doina Bujor
EPA Registration Number 73049-63

-2-

The changes referred to above, submitted in connection with registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable provided that you:

- 1) Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2) Submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of a final printed label.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any questions, contact Jeannine Kausch at 703-347-8920 or by email at kausch.jeannine@epa.gov.

A stamped copy of the label is enclosed for your records.

Sincerely,



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

Enclosures (2):
- A-79 Enclosure
- Acceptable Label

Bacillus thuringiensis subsp. *aizawai* Slurry

BIOLOGICAL INSECTICIDE

FOR MANUFACTURING USE ONLY

KEEP OUT OF REACH OF CHILDREN

DANGER

ACTIVE INGREDIENT:

Bacillus thuringiensis subsp. *aizawai* strain ABTS-1857 solids, spores and insecticidal toxins18.0% w/w

OTHER INGREDIENTS: 82.0% w/w

Total: 100.0% w/w

The % active ingredient does not indicate product performance

EPA Registration No. 73049-63

Lot No.: _____

EPA Establishment No.

Manufactured for: Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048
1-800-323-9597

Net Contents:

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER

Cause irreversible eye damage. Do not get in eyes or on clothing. Wear goggles or face shield when handling the product. 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. 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.

ACCEPTED

JUL 22 2009

FIRST AID	
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.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies, you may also call toll-free 1-877-315-9819 for treatment information.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This slurry is intended for formulation into insecticidal products for use on food and non-food crops.

5/5

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE:

Store in cool, dry conditions.

PESTICIDE DISPOSAL:

Pesticide wastes may be hazardous. Improper disposal of excess pesticide 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 at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed, these containers may be acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

2009