

73049-63

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

03/02/2006

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

EPA Reg.
Number:
73049-63

Date of Issuance:
3/2/06

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Bacillus thuringiensis subsp.
aizawai Slurry Biological
Insecticide

Name and Address of Registrant (include ZIP Code):

Valent BioSciences Corporation
870 Technology Way
Suite 100
Libertyville, IL 60048

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1) Conduct the following production quality control measures to detect contamination or changes in the parent strain:

a) Spore preparations of *Bacillus thuringiensis* Berliner shall be produced by pure culture fermentation procedures with adequate quality control measures during production to detect any changes from the characteristics of the parent strain or contamination by other microorganisms.

(continued on page 2)

Signature of Approving Official:

Janet Andersen

Date:

3/2/06

Janet Andersen, Director, Biopesticides and Pollution Prevention Division (7511C)

EPA Form 8570-6

CONCURRENCES

SYMBOL	7511C	7511C						
SURNAME	Reynolds	Szuhay						
DATE	3/1/06	3-2-06						

b) Each lot of spore preparation, prior to the addition of other materials, shall be tested by subcutaneous injection of at least 1 million spores into each of five laboratory mice weighing 17 grams to 23 grams. Such test shall show no evidence of infection or injury in the test animals when observed for 7 days following injection.

c) Spore preparations shall be free of the *Bacillus thuringiensis* β -exotoxin when tested with the fly larvae toxicity test ("Microbial Control of Insects and Mites," R.P.M. Bond et al., p. 280 ff., 1971). This specification can be satisfied either by determining that each master seed lot brought into production is a *Bacillus thuringiensis* strain which does not produce β -exotoxin under standardized manufacturing conditions or by periodically determining that β -exotoxin synthesized during spore production is eliminated by the subsequent spore-harvesting procedure.

To satisfy the β -exotoxin monitoring requirement (item "c" above), Valent Biosciences Corporation will conduct periodic fly larvae assays on production batches. β -exotoxin (fly larvae) monitoring will be conducted for each production campaign on the first batch and every tenth batch thereafter.

2) Maintain records of the quality control tests described in #1 above for a period of at least five years from the date each batch is released for production.

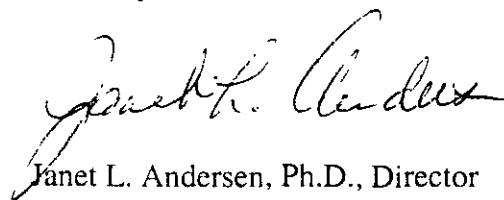
3) Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

4) Add the phrase "EPA Reg. No. 73049-63" to the product label.

5) Submit five (5) copies of your final printed labeling before release of the product for shipment.

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

Sincerely,



Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution Prevention
Division (7511C)

Enclosure

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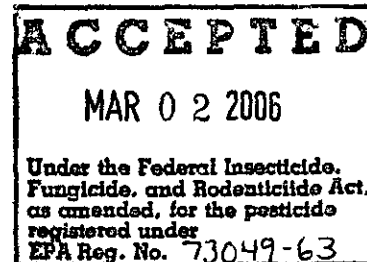
***Bacillus thuringiensis* subsp. *aizawai* Slurry**

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% w/w

OTHER INGREDIENTS:.....82% w/w

Total: 100% w/w

The % active ingredient does not indicate product performance

EPA Registration No. 73049-AG
EPA Establishment No.

Registrant Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048
1-800-323-9597

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

DANGER

Causes 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, or using tobacco. 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.

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.

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 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.

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.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in cool, dry conditions.

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

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.