

73049-64

11/24/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

NOV 24 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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

Re: *Bacillus thuringiensis* subsp. *tenebrionis* Slurry Biological Insecticide
EPA Reg. No. 73049-64
Submission dated 4/15/09 and subsequent revisions
Decision No. 409035

Dear Ms. Bujor:

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

1. Label format revised in accordance with the Label Review Manual (LRM).
2. Addition of "Manufactured for" before the registrant name and address, in accordance with 40CFR156.10(c).
3. Addition of "Net Contents" in accordance with 40CFR156.10(d).
4. Revision of Container Handling statements in accordance with PR Notices 2007-4 and 83-3.
5. Addition to the label of EPA Reg. No. 73049-62 in accordance with the Registration Notice dated 2/9/06.

In addition, the data matrix was updated.

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A), is 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.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

If you have questions, please contact Ann Sibold by phone at 703 305-6502 or by email at sibold.ann@epa.gov.

Sincerely,



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

Enclosures (2):
A-79
Stamped Label

Bacillus thuringiensis subsp. tenebrionis Slurry

BIOLOGICAL INSECTICIDE

FOR MANUFACTURING USE ONLY

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

ACTIVE INGREDIENT:

Bacillus thuringiensis subsp. *tenebrionis* strain NB-176 fermentation solids,
spores and insecticidal toxins.....17.0% w/w

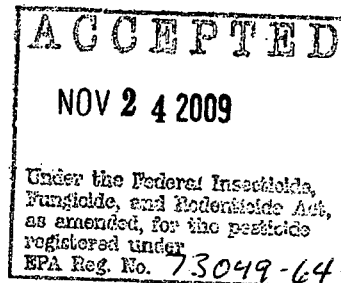
OTHER INGREDIENTS:.....83.0% w/w
Total 100% w/w

The % active ingredient does not indicate product performance

EPA Registration No. 73049-64
EPA Establishment No.

Lot 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**

CAUTION

Harmful if inhaled. Causes moderate eye irritation. Avoid breathing mist. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash 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.

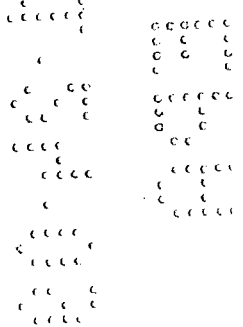
FIRST AID	
If inhaled:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: 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.
HOT LINE NUMBER	
<p>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</p>	

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.



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 must be disposed of on-site or at an approved waste disposal facility.

CONTAINER DISPOSAL

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 incineration. Do not burn, unless allowed by state and local ordinances.

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