

73049-68

09/04/2009

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SEP 4 2009

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

Re: Florbac Slurry Biological Insecticide
EPA Reg. No. 73049-68
Submission dated 4/27/09 and subsequent revisions
Decision No. 408786

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 the Precautionary Statements in accordance with Chapter 7 of the LRM to add the following: "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.
5. Revision of the first sentence of the Environmental Hazards Statements in accordance with PR Notice 93-10 and Chapter 8 of the LRM to read as follows: "Do not discharge effluent containing this product into lakes, streams ponds, estuaries, oceans or other water 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."
6. Revision of Container Handling statements in accordance with PR Notices 2007-4 and 83-3.
7. Addition to the label of EPA Reg. No. 73049-68.

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 explanation of a final printed label.

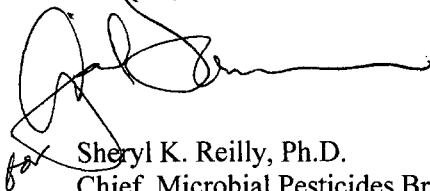
SYMBOL	7511P	7511P					
SURNAME	Sebold	KASCH					
DATE	9/4/09	09/04/2009					

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

Revised 5/82

A-79 ENCLOSURE

Final printed labeling is defined as that labeling which will accompany the pesticide product to market, and includes not only the container label, but also all accompanying technical information, brochures, etc.

Final printed labeling for the Agency's files should be of a size that can be stored conveniently in 8 1/2 x 11 inch files. Labels may be mounted or photoreduced to meet the size requirements provided the printing is legible and is of microfilm reproduction quality. Should photo reduction make any of the text illegible, the text must be typed out on an accompanying sheet of paper.

PASTE-ON LABELING: This should be submitted as is, unless it requires photo reduction.

SCREEN PRINTED LABELING: These labels should be printed by taping paper on the container as it goes through the printing process. The actual container should not be submitted.

EMBOSSSED LABELING: These labels should be photocopied.

UNUSUAL SIZE LABELING: Large bags or boxes must be photoreduced, either the entire label on one reduction or in sections so that each section is 8 1/2 x 11 inches.

Type Size Requirements for 3 Front Panel Headings

<u>Size of front panel square inches</u>	<u>Minimum type size for "RESTRICTED USE PESTICIDE" (if required) and Signal Word in capital letters</u>	<u>Minimum type for "Storage and Disposal" heading & "Keep Out of Reach of Children" warning</u>
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

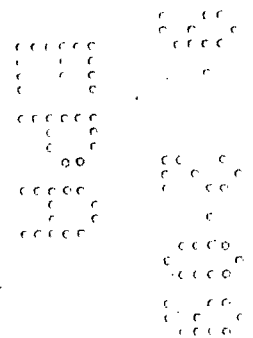
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**Florbac Slurry
BIOLOGICAL INSECTICIDE**

FOR MANUFACTURING USE ONLY

KEEP OUT OF REACH OF CHILDREN

CAUTION



ACTIVE INGREDIENT:

Bacillus thuringiensis subsp. *aizawai* strain NB200 solids, spores and
Insecticidal toxins18.0% w/w

OTHER INGREDIENTS:..... 82.0% w/w

Total: 100% w/w

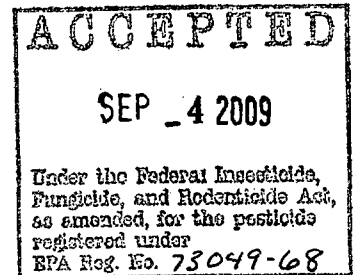
The % active ingredient does not indicate product performance

EPA Registration No. 73049-68
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 absorbed through skin. Causes moderate eye irritation. 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 re-use.

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.

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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.
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.
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>	

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

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