UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511C) 401 M St., S.W. Washington, D.C. 20460

73049-68

EPA Req.

NOTICE OF PESTICIDE:

<u>x -</u> Registration ____ Reregistration

Unconditional

Term of Issuance:

Name of Pesticide Product:

Florbac Slurry Biological Insecticide

(under FIFRA, as amended)

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

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

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.
 - 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 no evidence of infection or injury in the test animals when observed for 7 days following injection.

(continued on page 2)

Signature of Approving Official A 6/17/25	Date: 6/0/05	
CONCURRENCES		
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SYMBDane L. Andersen, Director, Biopesticides and Pollution	Reynolds 524/144	
surname vention Division (7511C)	1 1000 1 2 25	
DATE Vierniss 70-6	16/0/03/ 18-3-02/	

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 HPLC (High Performance Liquid Chromatography) assays for batch monitoring. Should the HPLC assays reveal extraneous or unexpected peaks (possibly variants of β -exotoxin), a fly larvae test will be also be used to supplement the HPLC assay before releasing the batch for production. β -exotoxin (HPLC/fly larvae) monitoring will be conducted for each production run on the first batch and every third 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. 73049-68" 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,

Lanet L. Andersen, Ph.D., Director Biopesticides and Pollution Prevention

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Division (7511C)

Florbac Slurry BIOLOGICAL INSECTICIDE

FOR MANUFACTURING USE ONLY

KEEP OUT OF REACH OF CHILDREN

CAUTION

JUN 1 0 2005
Under the Federal Insecticides.
Fungicide. and Rodenticide Act.
as amended, for the pesticide registered under
EPA Reg. No. 73049-68

ACTIVE INGREDIENT:	
Bacillus thuringiensis subsp. aizawai strain NB200 solids, spores and	
Insecticidal toxins	18% w/w
OTHER INGREDIENTS;	82% w/w
Total:	100% w/w

The % active ingredient does not indicate product performance

EPA Registration No. 73049-XX 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

CAUTION

Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Remove and wash contaminated clothing before reuse. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

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 active ingredient into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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FIRST AID

If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutesRemove contact lenses, if present, after the first 5 minutes, then continue rinsing eyeCall a poison control center or doctor for treatment advice.
If on skin or clothing:	Take off contaminated clothingRinse skin immediately with plenty of water for 15-20 minutesCall 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.

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.