



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 31, 2022

Maria Herrero
Director of Regulatory Affairs
Valent Biosciences LLC
1910 Innovation Way, Suite 100
Libertyville, IL 60048-6316

Subject: PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Amendment – To Add a New Production Site for the Product and a New Supplier of the Active Ingredient to the Basic Confidential Statement of Formula (CSF), and Make Changes to the Label Requested by EPA (e.g., Add Potency Claim, Remove Respirator Requirements, and Revise Container Handling Instructions)
Product Name: *Bacillus thuringiensis* subsp. *israelensis* Slurry (for Liquid VectoBac Formulations)
EPA Registration Number: 73049-477
EPA Receipt Date: 03/16/2022
Action Case Number: 00347605

Dear Ms. Herrero:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 10/17/2022

Any CSFs other than that listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 § CFR 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements EPA may consider false or misleading.

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In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Hannah Dean via email at dean.hannah@epa.gov.

Sincerely,

 Digitally signed by
ALEXANDRA BOUKEDES
Date: 2022.10.31
14:11:51 -04'00'

Alexandra Boukedes, Product Manager 92
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511M)
Office of Pesticide Programs

Enclosure

***Bacillus thuringiensis* subsp. *israelensis* Slurry
(for liquid VectoBac formulations)**

BIOLOGICAL INSECTICIDE

FOR MANUFACTURING USE ONLY

KEEP OUT OF REACH OF CHILDREN

CAUTION

ACTIVE INGREDIENT:

Bacillus thuringiensis subsp. *israelensis* strain AM 65-52 solids, spores and insecticidal toxins* 14.00% w/w

OTHER INGREDIENTS: 86.00% w/w

Total: 100.00% w/w

*Contains a minimum of 1400 International Toxic Units (ITU) per mg of product
The % active ingredient does not indicate product performance and potency measurements are not federally standardized.

EPA Registration No. 73049-477
EPA Establishment No.

Lot No: _____

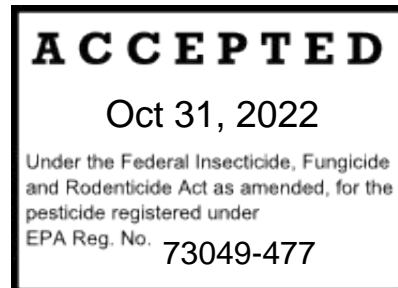
Manufactured for: Valent BioSciences LLC
1910 Innovation Way
Libertyville, IL 60048
1-800-323-9597

Net Contents:

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

CAUTION

Causes moderate eye irritation. 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.



FIRST AID	
If in eyes:	<p>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</p> <p>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</p> <p>Call a poison control center or doctor for treatment advice.</p>
HOTLINE 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> <p>For information on this pesticide product (including general health concerns or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378, Monday through Friday, 8:00 AM to 12:00 PM Pacific Time (NPIC Website: www.npic.orst.edu).</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 control of mosquito larvae.

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:

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. It is the responsibility of the truck hauler/refiller to clean the entire tank system before refilling.