



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

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

November 17, 2022

Shuichi Nagaoka
Regulatory Manager
Valent BioSciences LLC
1910 Innovation Way, Suite 100
Libertyville, IL 60048

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment –
Add application to nuisance flies around wastewater treatment plants, update the registrant’s address, and make changes requested by the Agency (e.g., list the species of nuisance flies, updated precautionary statement language, clarify the conversion of application rates and instructions, and update storage and disposal instructions)
Product Name: Bactimos WG
EPA Registration Number: 73049-504
EPA receipt Date: 06/03/2021
Action Case Number: 00304818

Dear Mr. Nagaoka:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is 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.

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) *or* 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. 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 Bibiana Oe by phone at (202) 566-1538 or via email at oe.bibiana@epa.gov.

Sincerely,

 Digitally signed by
ALEXANDRA BOUKEDES
Date: 2022.11.17
15:57:13 -06'00'

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

Enclosure:

**BACTIMOS® WG
BACTERIAL LARVICIDE**

For Organic Production

ACTIVE INGREDIENT:

Bacillus thuringiensis, subsp. *israelensis*, strain AM 65-52

fermentation solids and solubles⁺ 37.4%

OTHER INGREDIENTS.....62.6%

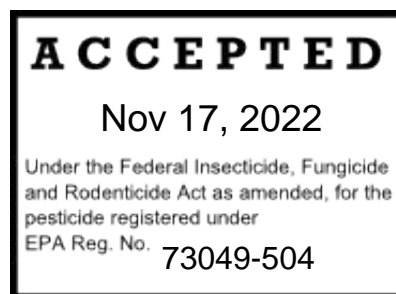
Total..... 100.0%

Potency⁺: 3000 International toxic units (ITU) per mg. Equivalent to 1.36 billion ITU/lb.

The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Produced for: Valent BioSciences LLC
1910 Innovation Way, Suite 100
Libertyville, IL 60048



EPA Reg. No. 73049-504
EPA Establishment No. 33762-IA-1

Lot No.: _____
Net Weight

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 by mouth to mouth, if possible. • Call a poison control center or doctor for further 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 label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-877-315-9819 (24 hours) for emergency medical treatment and or transportation emergency information. For all other information, call 1-800-323-9597.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if inhaled. Causes moderate eye irritation. Avoid breathing dust. 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 and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants.
- Water proof gloves
- Shoes plus socks
- Protective eyewear

Mixers/loaders and applicators must wear a minimum of a NIOSH-approved particulate filtering face piece respirator with any N, R or P filter; or a NIOSH-approved elastomeric articulate respirator with any N, R or P filter; or a NIOSH-approved powered air-purifying respirator with an HE filter. Repeated exposures to high concentrations of microbial proteins can cause allergic sensitization.

Follow manufacturers instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing

ENVIRONMENTAL HAZARDS

Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

Do not apply directly to treated finished drinking water reservoirs or drinking water receptacles

when water is intended for human consumption.

Bactimos WG is for commercial use in community abatement programs to control non-biting midges in all listed midge habitats; including bodies of water on or near farming operations.

APPLICATION METHOD

Bactimos WG is suspended in water and applied as spray application over the larval habitat or suspended in wastewater which goes through a trickling filter system. It is suspended into required volume of water that is able to provide complete and uniform coverage of the larval habitat.

Nuisance Flies (*Psychoda* and *Chironomus* spp.) Habitat

Rate Range:

0.00053 ounces per 1 gallon of wastewater which goes through the trickling filter system or a previous dilution of the product which can be made as 1 % solution*, then 0.0512 – 0.1024 liquid ounces of the 1 % solution are added to 1 liter of wastewater which goes through the trickling filter system.

or

4 – 8 mg of the product per 1 liter of wastewater which goes through the trickling filter system or a previous dilution of the product which can be made as 1 % solution*, then 0.4 – 0.8 ml of the 1 % solution are added to 1 liter of wastewater which goes through the trickling filter system.

*1% solution = 0.0834540445 pounds / gallon or 1000 mg / 100 ml.

Non-Biting Midge Habitat (such as the following examples): Man-made or natural lakes, reservoirs, ponds, lagoons, sewage oxidation ponds, channels

Rate Range:

3.57 – 7.14 lbs./acre or 4 kg – 8 kg/ha

Apply Bactimos WG in a spray mix using a suitable equipment that can deliver the spray mix onto the larval habitat. A uniform application over the larval habitat is essential for optimum midge population reduction. For application to Non-Biting Midge Habitat, use the below tables for preparing the spray mix.

Gallons of the diluted solution per 1 acre (gallon/acre)

Concentrations of the diluted solution (lbs./gallon)	Gallons of the diluted solution per 1 acre (gallon/acre)		
	0.5	7.14	10.72
1.0	3.57	5.36	7.14
1.5	2.38	3.57	4.76
2	1.79	2.68	3.57
Applied concentration per 1 acer (lbs./acre)	3.57	5.36	7.14

Concentrations of the diluted solution (lbs./gallon)

Gallons of the diluted solution	Concentrations of the diluted solution (lbs./gallon)
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per 1 acre (gallon/acre)			
5	0.714	1.072	1.428
10	0.357	0.536	0.714
25	0.143	0.214	0.286
50	0.0714	0.107	0.143
Applied concentration per 1 acre (lbs./acre)	3.57	5.36	7.14

NON-BITING MIDGES CONTROLLED WITH BACTIMOS WG

Only a small percentage of the thousands of pestiferous species of “non-biting midges” have been tested for susceptibility to Bactimos WG. Members of the subfamily Chironomini and Tanytarsini are generally susceptible; members of the subfamily Tanypodinae are not susceptible at the Bactimos WG labeled-use rate. When initially using Bactimos WG in a non-biting midge control program, it is recommended that only a small test area be treated if the species of midge(s) to be controlled has not been identified.

STORAGE AND DISPOSAL

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

Storage: Store in cool [59-86°F (15-30°C)], dry place.

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 container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

NOTICE TO USER

To the extent consistent with applicable law, seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning use of this product other than as indicated on this label. To the extent consistent with applicable law, user assumes all risks of use, storage or handling not in accordance with accompanying directions.