

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 11, 2019

Jayne Walz Senior Regulatory Manager Valent BioSciences LLC 870 Technology Way Libertyville, IL 60048

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Notification

to Correct Typographical Error, Company Name and Address per PR Notice 98-10.

Product Name: VectoBac 12AS Biological Larvicide Aqueous Suspension

EPA Registration Number: 73049-38 Application Date: January 10, 2019 OPP Decision Number: 548579

Dear Ms. Walz:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The labeling submitted with this application has been stamped "Notification" and will be placed in our records. You must submit one (1) copy of the final printed labeling with the modifications.

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 the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the 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 the 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 the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

If you have any questions, please contact Joseph Mabon by phone at (703) 347-0177 or via email at mabon.joseph@epa.gov.

Page 2 of 2 EPA Reg. No. 73049-38 OPP Decision No. 548579

Sincerely,

Seiichi Murasaki, Senior Regulatory Advisor

Microbial Pesticides Branch

Biopesticides and Pollution Prevention Division (7511P)

Office of Pesticide Programs

Enclosure: Stamped Label

VECTORBAC® 12AS BIOLOGICAL LARVICIDE AQUEOUS SUSPENSION

Active Ingredient:

Potency: 1200 International Toxic Units (ITU) per mg (Equivalent to 4.84 Billion ITU per gallon, 1.279 billion ITU per liter).

There is no direct relationship between intended activity (potency) and the Percent Active Ingredient Weight.

KEEP OUT OF REACH OF CHILDREN CAUTION

See side panel for additional precautionary statements and statement of practical treatment.

Valent BioSciences <u>LL</u>Corporation 870 Technology Way, Suite 100 Libertyville, IL 60048

EPA Registration No. 73049-38 EPA Est. No. 33762-IA-001

Net Contents:

NOTIFICATION

73049-38

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

Lot No.:

03/11/2019

FIRST AID			
If in eyes	 Hold eyes and rinse slowly and gently with water for 15-20 minutes Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes Call a poison control center or doctor for treatment advice. 		
If on skin or clothing	 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. 		
HOT LINE NUMBER			

Have the product container or 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 transport emergency information. For all other information, call 1-800-323-9597

PRECAUTIONARY STATEMENT HAZARD 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. Remove contaminated clothing and wash contaminated clothing before reuse.

Mixers/loaders and applicators not in enclosed cabs or aircraft 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.

PHYSICAL AND CHEMICAL HAZARDS

Diluted or undiluted VectoBac[®] 12 AS can cause corrosion if left in prolonged contact with aluminum spray system components. Rinse spray system with plenty of clean water after use. Care should be taken to prevent contact with aluminum aircraft surfaces, structural components and control systems, In case of contact, rinse thoroughly with plenty of water. Inspect aluminum aircraft components regularly for signs of corrosion.

DIRECTIONS FOR USE

It is in violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply directly to treated finished drinking water reservoirs or drinking water receptacles when water is intended for human consumption.

Do not apply when weather conditions favor drift from treated areas. Do not apply to metallic painted objects, such as automobiles, as spotting may occur. If spray is deposited on metallic painted surfaces, wash immediately with soap and water to avoid spotting.

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather related factors determine the potential for spray drift. The applicator and the treatment coordinator are responsible for considering all these factors when making decisions.

CHEMIGATION

Do not apply this product through any irrigation system unless the labeling on chemigation is followed.

STORAGE AND DISPOSAL

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

Storage: Store in a cool, [less than 86°F (30° C)] dry place.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal Handling: 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 ½ 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. Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recyclingor 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. Do not reuse container.

APPLICATION DIRECTIONS

Do not apply when wind speed favors drift beyond the area of treatment.

Mosquito Habitat

Suggested Rate Range*

(Such as the following examples): Irrigation ditches, roadside ditches, flood water, standing ponds, woodland pools, snow melt pools, pastures, catch basins, storm water retention areas, tidal water, salt marches and rice fields.

20.25 - 2 pts/acre

In addition, standing water containing mosquito larvae, in fields growing crops such as: Alfalfa, almonds, asparagus, corn, cotton, dates, grapes, peaches and walnuts, may be treated at the recommended rates.

When applying this product to standing water containing mosquito larvae in fields growing crops. do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Polluted water 1 - 2 pts/acre

(such as sewage lagoons, animal waste lagoons).

*Use higher rate range in polluted water and when late 3rd and early 4th instar larvae predominate, mosquito populations are high, water is heavily polluted, and/or algae are abundant.

Blackflies Habitat	Suggested Rate Range*	
Streams		
Stream water** (=ppm for 1 minute exposure time.	0.5 – 25 mg/liter	
Stream water** (=ppm for 10 minute exposure time.	0.05 – 2.5 mg/liter	

^{**} Use higher rate range when stream contains high concentration of organic materials, algae, or dense aquatic vegetation.

(NUISANCE FLIES)

For control of nuisance flies (*Pschoda* spp., *Chironomus* spp.) in sewage treatment facilities utilizing trickling filter systems.

APPLICATION DIRECTIONS

Nuisance Fly Habitat Suggested Rate Range* Trickling filter system of wastewater treatment plants Suggested Rate Range* 10-20 mg.(0.833-1.67 ml) per liter of wastewater fed to the filter per 30 minutes

^{**} Discharge is a principle factor determining carry of Bti. Use higher rate or increase volume by water dilution in low discharge rivers or streams under low volume (drought) conditions.

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*Use high rate for control of *Chironomus* spp. Apply undiluted with pre-calibrated pump or other device into the wastewater feeding into the filters for a period of 30 minutes. Repeat applications as needed after 2-4 weeks. Control of *Chironomus* spp. may take up to 2 weeks.

(NUISANCE AQUATIC MIDGES)

For control of *Chironomine* midges (*Chironominae: Chironomini*) inhabitin shallow, man-made and natural lakes or ponds.

APPLICATION DIRECTIONS

Nuisance Midge Habitat

Suggested Rate Range*

Shallow Lakes and Ponds Per sewage oxidation ponds (less than acre 6 feet deep) 1 gallon (3,785.5 ml) per acre

*Apply diluted with water in total volume of 5 gallons/acre by pouring or spraying over the surface to be treated with pre-calibrated device. Repeat application as needed after 204 weeks. Control of *Chironomine* midges may take up to 2 weeks.

Ground and Aerial Application

VectoBac 12AS may be applied in conventional ground or aerial application equipment with quantities of water sufficient to provide uniform coverage of the target area. The amount of water will depend on weather, spray equipment, and mosquito habitat characteristics. Do not mix more VectoBac 12AS than can be used in a 72 hour period.

For most ground spraying, apply in 5-100 gallons of water per acre using hand pump, airblast, mist blower, etc., spray equipment.

For aerial application, VectoBac 12AS may be applied either undiluted or diluted with water. For undiluted applications, apply 0.25 to 2.0 pts/acre of VectoBac 12AS through fixed wing or helicopter aircraft equipped with either conventional boom and nozzle systems or rotary atomizers.

For diluted application, fill the mix tank or plane hopper wit the desired quantity of water. Start the mechanical or hydraulic agitation to provide moderate circulation before adding the VectoBac 12AS. VectoBac 12AS suspends readily in water and will stay suspended over normal application periods. Brief recirculation may be necessary if the spray mixture has sat for several hours or longer. AVOID CONTNUOUS AGITATION OF THE SPRAY MIXTURE DURING SPRAYING.

Rinse and flush spray equipment thoroughly following each use.

For blackfly aerial applications, VectoBac 12AS can be applied undiluted via fixed wing or helicopter aircraft equipped with either conventional boom and nozzle systems or open pipes. Rate of application will be determined by the stream discharge and the required amount of VectoBac 12AS necessary to maintain a .5-25 ppm concentration in the stream water. VectoBac 12AS can also be applied diluted with similar spray equipment. Do not mix more VectoBac 12AS that can be used in a 72 hour period.

SMALL QUANTITY DILUTION RATES Gallons Spray Solution/Acre (Ounces Needed per Gallon of Spray)

VectoBac 12AS

Rate in Pints

Per acre	10 Gal/A	25 Gal/A	50 Gal/A
0.25 (4oz)	0.4	0.16	0.08
0.5 (8oz)	0.8	0.32	0.16
1.0 (16 oz)	1.6	0.64	0.32
2.0 (32 oz)	3.2	1.28	0.64

CHEMIGATION

Apply this product through flood (basin) irrigation system. Do not apply this product through any other type of irrigation system.

Crop injury, lack of effectiveness or illegal pesticide residues in crop result from non-uniform distribution of treated water.

If you have any questions about calibration, you should contact State Extension Service Specialist, equipment manufacturers or other experts.

A person knowledgeable if this chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Rice - Flood (Basin) Chemigation

Systems using a gravity flow pesticide dispensing system must meter the pesticide into the water at the head of the field and downstream of a hydraulic discontinuity such as a drop structure or weir box to decrease potential for water source contamination from backflow if water flow stops.

VectoBac 12AS is metered or dripped into rice floodwater at application stations positioned at the point of introduction (levee cut) of water into each rice field or pan. Two to 3 pints of VectoBac 12AS are diluted in water to a final volume of 5 gallons. The diluted solution is contained in a 5 gallon container and metered or dispersed into the irrigation water using a constant flow devise at the rate of 80 ml per minute. Introduction of the solution should begin when $\frac{1}{2}$ to $\frac{1}{2}$ of the pan or field is covered with floodwater. Delivery of the solution should continue for a period of approximately 4 $\frac{1}{2}$ hours. Floodwater depth should not exceed 10 – 12 inches to prevent excessive dilution of VectoBac 12AS which could result in reduced larval kill. Agitation is not required during the period in which the VectoBac 12AS suspension is being dispersed. Application of VectoBac 12AS into rice floodwater is not permitted using a pressurized water and pesticide injection system.

NOTICE TO USER

Seller makes no warranty, express or implied, or merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. User assumes all risk or use, storage or handling not in strict accordance with accompanying directions.