

73049-57

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

MAR 14 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Jayne Walz
Registration Manager
Valent Biosciences Corporation
870 Technology Way
Libertyville, IL 60048

Re: Label Amendments for VectoLex CG, VectoLex WDG, and Bacillus sphaericus Slurry to Change the Active Ingredient Name to *Bacillus sphaericus* 2362, serotype H5a5b, strain ABTS 1743 EPA Registration Nos. 73049-20, 73049-57, and 73049-65

Dear Ms. Walz:

The amendments referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable and subject to the following comments.

- 1) Submit updated Confidential Statements of Formula and corrected labels for the subject products within thirty (30) days.
- 2) On the VectoLex WDG label, correct the spelling of Non-rigide container to read Non-rigid container.
- 3) On page two (2) of the Vectolex CG master label, place the statement "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 sensitizations." Directly after the statement "Wash thoroughly with soap and water after handling." Additionally, replace the storage and disposal block on the residential use sublabel to read as follows.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place.

Pesticide Disposal and Container Handling: Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash and offer for recycling if available. If partly filled: Call your local solid waste agency or (800) 858-7378 (National Pesticide Information Center) for disposal instructions. Never place unused product down any indoor or outdoor drain.

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Ms. Jayne Walz
EPA Registration Nos. 73049-20, -57, -65

Submit five (5) copies of your final printed labeling before you release the amended products for shipment. Your release for shipment of these products constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Sincerely,



Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures

VECTOLEX® WDG
BIOLOGICAL LARVICIDE

Active Ingredient:

<i>Bacillus sphaericus</i> 2362, Serotype H5a5b, Strain ABTS 1743 dried concentrate.....	51.2% w/w
Other Ingredients.....	48.8% w/w
Total.....	100.0% w/w

Potency: This product contains 650 BsITU/mg or 0.299 Billion BsITU/lb.

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

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048

EPA Reg. No. 73049-57
EPA Est. No. 33762-IA-1

Batch Code: _____

Net Contents:

FIRST AID	
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. <p>Call a poison control center or doctor for treatment advice.</p>
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 for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-323-9597.	

**ACCEPTED
with COMMENTS
In EPA Letter Dated
MAR 14 2011**

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
73049-57**

**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.

Mixer/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.

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

Chemigation

Do not apply this product through any type of irrigation system.

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 may be disposed of on site or at an approved waste disposal facility.

Container Disposal:

Rigid container: 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 flow begins to drip. Repeat this procedure two more times. Once cleaned, offer container 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.

Non-rigide container: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available.

APPLICATION DIRECTIONS

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

I. For control of mosquito larvae species* in the following non-crop sites.

<u>Habitats</u>	<u>Rate Range</u>
Wastewater: Sewage effluent, sewage lagoons, oxidation ponds, septic ditches, animal waste lagoons, impounded wastewater associated with fruit and vegetable processing	0.5-1.5 lbs/acre (8oz-24oz/acre)
Stormwater/Drainage Systems: Storm sewers, catch basins, drainage ditches, retention, detention and seepage ponds	0.5-1.5 lbs/acre (8oz-24oz/acre)
Marine/Coastal Areas: Salt marshes, mangroves, estuaries	0.5-1.5 lbs/acre (8oz-24oz/acre)
Water Bodies: Natural and manmade aquatic sites such as lakes, ponds, rivers, canals and streams	0.5-1.5 lbs/acre (8oz-24oz/acre)

Habitats

Dormant Rice Fields:

Impounded water in dormant rice fields (For application only during the interval between harvest and preparation of the field for the next cropping cycle)

Rate Range

0.5-1.5 lbs/acre
(8oz-24oz/acre)

II. For control of mosquito larvae species* in agricultural/crop sites where mosquito breeding occurs.

Habitats

Rice, pastures/hay fields, orchards, citrus groves, irrigated crops.

Rate Range

0.5-1.5 lbs/acre
(8oz-24oz/acre)

Use higher rates (1 to 1.5 lbs/acre) in areas where extended residual control is necessary, or in habitats having deep water or dense surface cover.

Apply uniformly by aerial or conventional ground equipment. Reapply as needed after 1-4 weeks.

*Mosquito species effectively controlled by VectoLex WDG.

Culex spp.

Aedes vexans

Ochlerotatus melanimon (*Aedes melanimon*)

Ochlerotatus stimulans (*Aedes stimulans*)

Ochlerotatus nigromaculis (*Aedes nigromaculis*)

Psorophora columbiae

Psorophora ferox

Ochlerotatus triseriatus (*Aedes triseriatus*)

Ochlerotatus sollicitans (*Aedes sollicitans*)

Anopheles quadrimaculatus

Coquillettidia perturbans

GROUND AND AERIAL APPLICATION

VectoLex WDG may be applied using conventional ground or aerial application equipment with quantities of water sufficient to provide uniform coverage of the target area. For application, first add the VectoLex WDG to water to produce a final spray mixture.

The amount of water will depend on weather, spray equipment, and mosquito habitat characteristics. For application, fill the mix tank or plane hopper with the desired quantity of water. **Start the mechanical or manual agitation to provide moderate circulation of water before adding the VectoLex WDG.** Backpack and compressed air sprayers may be agitated by shaking after adding VectoLex WDG to the water in the sprayer. VectoLex WDG 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. Do not mix more VectoLex WDG than can

be used in a 48 hour period. AVOID CONTINUOUS AGITATION OF THE SPRAY MIXTURE DURING SPRAYING.

For ground spraying, apply 8-24 oz./acre (227-680 g/acre) of VectoLex WDG in 5-100 gallons of water per acre using hand-pump, airblast, mist blower, or other spray equipment. For aerial application, apply 8-24 oz./acre (227-680 g/acre) of VectoLex WDG through fixed wing or helicopter aircraft equipped with either conventional boom and nozzle systems or rotary atomizers at a convenient dilution rate. For aerial application, apply 0.5-10 gallons/acre of the final spray mixture to provide uniform coverage of the target area.

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 spray drift. The applicator and treatment coordinator are responsible for considering all these factors.

Rinse and flush spray equipment thoroughly following each use.

Amount of VectoLex WDG needed to treat small areas:

Area to Treat	Rate of VectoLex WDG/Acre		
	8 oz	16 oz	24 oz
¼ Acre	2 oz	4 oz	6 oz
½ Acre	4 oz	8 oz	12 oz
10 Acres	5 lb	10 lb	15 lb
20 Acres	10 lb	20 lb	30 lb

NOTICE TO USER

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

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