1/26/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JAN 2 6 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Ms. Jayne Walz Regulatory Manager Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048

Re: VectoBac WDG EPA Reg. No. 73049-56 Submission dated 1/6/2011 Decision No. 444132

Dear Ms. Waltz:

The Agency has reviewed your request to amend the subject product registration, which includes the following changes to the product's label:

- 1. Label format revised in accordance with the Label Review Manual (LRM).
- 2. Deletion of a statement from the application directions on the VectoBac WDG sub-label concerning public health protection.
- 3. Addition of two mosquito habitats (artificial containers and natural containers) to the application directions on the same sub-label.

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A), is acceptable provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2. Submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of a final printed label.

If these conditions are not complied with, then the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

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ACCEPTED

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Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Rog. No. 73049 - 56

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MASTER LABEL

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VECTOBAC[®] WDG (GNATROL DG- Alternate Brand Name) BIOLOGICAL LARVICIDE

For Organic Production

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Active Ingredient:	
Bacillus thuringiensis, subsp. israelensis, strain AM 65-52	
fermentation solids and solubles	
Other Ingredients	<u>62.6%</u>
Total	
[Potency: 3000 International toxic units (ITU) per mg]. Ed	quivalent 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

Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048

EPA Reg. No. 73049-56 EPA Est. No. Batch Code:_____

Net Contents:

FIRST AID			
If inhaled	• 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	• 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 advised of a		
HOT LINE NUMBER			
Have the product of	container label with you when calling a poison control center or doctor or		
going for treatmen	t. You may also contact 1-877-315-9819 (24 hours) for emergency medical		
treatment and or tr 323-9597.	ansportation emergency information. For all other information, call 1-800-		

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if inhaled. Avoid breathing dust. Remove contaminated clothing and wash before reuse. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

Personal Protective Equipment

Applicators and other handlers must wear:

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

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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.

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:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- User should remove clothing/PPE immediately if pesticide get inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

For terrestrial Uses: Do not contaminate water when cleaning equipment or disposing of equipment washwaters. Do not apply directly to treated finished drinking water reservoirs or drinking water receptacles when water is intended for human consumption.

AGRICULTURAL USE REQUIREMENTS

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Use this product only in accordance with its labeling and with the worker Protection Standard, 40 CFR Part 170. this Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and the restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of $\underline{4}$ hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

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

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 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.

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AGRICULTURAL USE SITE DIRECTIONS FOR USE (Gnatrol DG)

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.

Chemigation

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

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APPLICATION DIRECTIONS

For control of mushroom fly larvae.

Mushroom Flies (Sciaridae)

Conventional Agaricus bisporus mushrooms

For the control of the larval stage of Sciarid mushroom flies when mixed into, or applied to mushroom casing. Gnatrol DG should be thoroughly mixed into the mushroom casing material with a mechanical mixer until granules are evenly dispersed throughout all of the material or applied in a suspended solution mixed with water. Typically casing soils should be formulated prior to use and brought to the appropriate moisture content prior to the addition of the Gnatrol DG. Use sufficient water and/or proper application and mixing equipment to obtain good distribution of Gnatrol DG throughout the growth medium.

If the casing material is steamed, pasteurized or fumigated, the addition of Gnatrol DG should occur after this practice.

Watering-in Gnatrol DG: Follow normal watering practices after casing. The Gnatrol DG will solubilize and disperse throughout the casing and compost during the routine water management process.

For the control of the larval stage of Sciarid mushroom flies when mixed into mushroom compost at spawning/supplementation: Gnatrol DG should be thoroughly mixed into compost during spawning and supplementation. Gnatrol DG can be mixed with supplement or spawn using a mechanical mixer just before application to beds or trays. Gnatrol DG can be mixed directly with supplement or mixed with up to 6 lbs. of gypsum/1000 sq. ft. for mixing with spawn or supplement.

SUGGESTED RATE RANGE:

Casing Application - Use 1.5 - 3.0 lbs./1000 sq. ft. of bed. Compost Application - Use 2.5 - 3.0 lbs./1000 sq. ft of bed.

Use higher rates when pest pressure is heavy.

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Gnatrol DG has not been tested for mycotoxicity on all strains of common commercial mushrooms (*Agaricus*). Since strains may vary in their sensitivity, this product should be tested on a section of bed prior to whole house treatment.

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NOTICE TO USER

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To the fullest extent permitted by law, 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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Sub Label

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Vectobac[®] WDG Biological Larvicide

Public Health Labeling for Mosquito Control

(Non Worker Protection Standard)

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VECTOBAC[®] WDG BIOLOGICAL LARVICIDE

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For Organic Production

Active Ingredient:	
Bacillus thuringiensis, subsp. israelensis, strain AM 65-52	
fermentation solids and solubles	37.4%
Other Ingredients	<u>62.6%</u>
Total	100.0%
[Potency: 3000 International toxic units (ITU) per mg]. Equivalent to 1.36 billion IT	U/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 Libertyville, IL 60048

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EPA Reg. No. 73049-56 EPA Est. No. Batch Code:_____

Net Contents:

FIRST AID			
If inhaled	• 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	• Hold eye open and rinse slowly and gently with water for 15-20		
	minutes.		
	• Remove contact lenses, if present, after then first 5 minutes, then		
	continue rinsing eye.		
	• Call a poison control center or doctor for treatment advise.		
HOT LINE NUMBER			
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 for emergency medical treatment			
and/or transport emergency information. For all other information, call 1-800-323-9597.			

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if inhaled. Avoid breathing dust. Remove contaminated clothing and wash before reuse. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

Personal Protective Equipment

Applicators and other handlers must wear:

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

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.

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:

• Wash hands before eating, drinking, chewing gum, using tobacco products or using the toilet.

ENVIRONMENTAL HAZARDS

Do not apply directly to treated finished drinking water reservoirs or drinking water receptacles when water is intended for human consumption.

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.

Chemigation

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

STORAGE AND DISPOSAL

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

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 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.

APPLICATION DIRECTIONS

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

Mosquito Habitat

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

Suggested Rate Range*

1.75 – 7.0 oz/acre (50 – 200 g/acre) (125 – 500 g/ha)

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.

Polluted water 7.0 - 14.0 oz/acre (such as sewage lagoons, animal waste lagoons)(200 - 400 g/acre) (0.5 - 1.0 kg/ha)

*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.

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The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure to the point where pesticide distribution is adversely affected.

Dilute VectoBac WDG in water prior to injection. Agitation of the material to be injected is required to keep the product suspended during the injection cycle.

Where supply tanks are used for continuous application, fill the supply tank with the desired quantity of water. Start mechanical or hydraulic agitation to provide moderate circulation before adding VectoBac WDG. VectoBac WDG suspends readily in water and will stay suspended over normal application periods. Avoid continuous agitation of spray mixture during spraying. Brief recirculation may be necessary if the spray mixture has sat for several hours.

APPLICATION DIRECTIONS

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Fungus Gnat Control

Fungus Gnat Habitat	Suggested Range Rate
Ornamental and nursery	Light infestation:
plantings in greenhouse or	3.2 to 6.4 oz/100 gallons
potting soil mixtures.	applied as a soil drench
Vegetable plants such as the	Heavy infestation:
following: Tomatoes, leafy and	13 to 26 oz/100 gallons
cole crops, cucumbers, peppers	applied as a soil drench
and eggplants	

Apply VectoBac WDG with adequate water by soil drench to sufficiently wet the soil surface above and under benches where larvae are found. Areas under benches should be treated at high rates as this is one of the primary breeding areas. Reapply as needed. In situations where all life forms (eggs, larvae, pupae and adults) are present, such as with existing infestations, make three (3) weekly applications at the suggested rate range for heavy infestations. Regular follow-up applications using the suggested light infestation rates, will establish a long term maintenance program.

For best results, apply drenches toward the end of irrigation period.

VectoBac WDG is a larvicide and will not control adult gnats, therefore, applications must be timed for a stage of development when larvae are present in the soil.

Fungus gnat larvae generally respond to VectoBac WDG treatment within 24 hours following application.

USE RESTRICTIONS

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VectoBac WDG is not known to be phytotoxic to ornamental plant species. However, since all ornamental plant species have not been evaluated, sensitivity to VectoBac WDG should be checked on several plants prior to wide scale usage.

Important: VectoBac WDG should not be injected in combination with fertilizers or fungicides containing copper or chlorine, as this may neutralize the active ingredients. (Chlorine levels in potable water supplies should not present a problem with VectoBac WDG performance).

Do not apply soil drenches to plants under stress, or follow application with excessive amounts of water.

NON-AGRICULTURAL USE SITE 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.

For use on plants intended for aesthetic purposes and being grown in interior plant scapes and indoor ornamental gardens. Not for use on plants being grown for sale or other commercial use, or for commercial seed production, or for research purposes.

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

Do not apply this product to the non-agricultural use sites through any type of irrigation system.

APPLICATION DIRECTIONS

Fungus Gnat Control in Indoor ornamental and plant scape use.

Fungus Gnat Habitat	Suggested Range Rate
Indoor ornamental and plant scape use.	Light infestation: 3.2 to 6.4 oz/100 gallons applied as a soil drench
	Heavy infestation: 13 to 26 oz/100 gallons applied as a soil drench

Apply VectoBac WDG with adequate water by soil drench to sufficiently wet the soil surface. Reapply as needed. In situations where all life forms (eggs, larvae, pupae and adults) are present, such as with existing infestations, make (3) weekly applications at the suggested rate range for heavy infestations. Regular follow-up using suggested light infestation rates will establish a long term maintenance program. VectoBac WDG is a larvicide and will not control adult gnats, therefore, applications must be timed for a stage of development when larvae are present in the soil.

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Fungus gnat larvae generally respond to VectoBac WDG treatment within 24 hours following application.

VectoBac WDG is not known to be phytotoxic to ornamental species. However, since all ornamental plant species have not been evaluated, sensitivity to VectoBac WDG should be checked on several plants prior to wide scale usage.

NOTICE TO USER

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