



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 22, 2014

Ms. Jayne Walz
Regulatory Manager
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048-6316

Subject: Amendment – Addition of Two Patent References (U.S. Patents 7,989,180 and 8,454,983) to the Labeling, Other Minor Revisions to the Labeling, and Minor Revisions to the Basic Confidential Statement of Formula (CSF)
Product Name: VectoMax[®] FG Biological Larvicide Fine Granule
EPA Registration Number: 73049-429
Application Date: June 25, 2013
Decision Number: 480702

Notification – Change to the Primary Brand Name on the Labeling and Basic CSF
Product Name: VectoMax[®] FG Biological Larvicide Fine Granule
EPA Registration Number: 73049-429
Application Date: September 19, 2012
Decision Number: 470386

Dear Ms. Walz:

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable. The acceptable amendment also includes labeling and CSF modifications proposed in a notification that you submitted to the U.S. Environmental Protection Agency (EPA) with an application dated September 12, 2012 (Decision No. 470386). This approval does not affect any conditions or terms that were previously imposed on this registration. You continue to be subject to existing conditions or terms on your registration and any deadlines connected with them.

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

- Basic CSF dated 12/08/2014

Any CSFs other than those listed above are superseded/no longer valid.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 copy of the final printed labeling before you release the 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 § 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act and is subject to review by the EPA. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA § 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.

Your release for shipment of the product constitutes acceptance of these terms. If these terms are not complied with, the registration will be subject to cancellation in accordance with FIFRA § 6. If you have any questions, please contact Jeannine Kausch of my team by phone at (703) 347-8920 or via email at kausch.jeannine@epa.gov.

Sincerely,



for

Shannon Borges, Team Leader
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

[Text in brackets [] indicates optional language or language intended for explanatory purposes to facilitate label review. Thus, this language will often not appear on final printed labeling. Also, this page is present (page 1) to delineate sub-labels and will not appear on the final printed labeling.]

VECTOMAX[®] FG Biological Larvicide Fine Granule

[Alternate Brand Names: V60035 FG, V60035 Water Soluble Pouches (WSP), VectoMax[®] WSP Water Soluble Pouches Biological Larvicide, and VectoMax[®] G Biological Larvicide Granules]

MASTER LABEL

Sub-label A: VectoMax[®] Products NOT in Water Soluble Packaging

Sub-label B: VectoMax[®] Products in Water Soluble Packaging

Active Ingredients:

<i>Bacillus sphaericus</i> 2362, Serotype H5a5b, Strain ABTS 1743 Fermentation Solids, Spores, and Insecticidal Toxins.....	2.7%
<i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> , Serotype H-14, Strain AM 65-52 Fermentation Solids, Spores, and Insecticidal Toxins.....	4.5%
Other Ingredients	92.8%
Total	100.0%

Potency: This product contains 50 BsITU/mg or 0.023 Billion BsITU/lb.

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

EPA Registration No. 73049-429

EPA Est. No. 33762-IA-001

US Patent No. 7,989,180

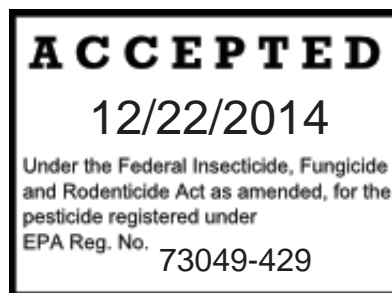
US Patent No. 8,454,983

Produced for:

Valent BioSciences Corporation

870 Technology Way


Libertyville, IL 60048



**VectoMax® FG
Biological Larvicide
Fine Granule**

[Sub-label A]

[Alternate Brand Names: V60035 FG and VectoMax® G Biological Larvicide Granules]

 **FOR ORGANIC PRODUCTION**
Made with BioFuse Technology

ACTIVE INGREDIENTS:

<i>Bacillus sphaericus</i> 2362, Serotype H5a5b, Strain ABTS 1743 Fermentation Solids, Spores, and Insecticidal Toxins.....	2.7%
<i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> , Serotype H-14, Strain AM 65-52 Fermentation Solids, Spores, and Insecticidal Toxins.....	4.5%
OTHER INGREDIENTS	92.8%
TOTAL	100.0%

Potency: This product contains 50 BsITU/mg or 0.023 Billion BsITU/lb.
Expiration Date: (Two years from date of manufacture).

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 Corporation
870 Technology Way
Libertyville, IL 60048

EPA Registration No. 73049-429
EPA Est. No. 33762-IA-001
Net Weight:
Lot No.

US Patent No. 7,989,180
US Patent No. 8,454,983

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. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • 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.
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.
HOT LINE NUMBER	
<p>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.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Harmful if absorbed through the skin or inhaled. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. 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.

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.

ENVIRONMENTAL HAZARDS

Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the 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 use only by federal, state, tribal or local government officials responsible for public health or vector control, or by persons certified in the appropriate category or otherwise authorized by the state or tribal lead pesticide regulatory agency to perform mosquito control applications, or by persons under their direct supervision.

IN CALIFORNIA: This product is to be applied by County Health Department, State Department of Health Services, Mosquito and Vector Control or Mosquito Abatement District personnel, or persons under contract to these entities only.

APPLICATION DIRECTIONS

MOSQUITO CONTROL

VectoMax[®] FG Biological Larvicide Fine Granule (hereafter referred to as VectoMax FG) is a selective microbial insecticide for use against mosquito larvae in a variety of habitats. VectoMax FG can be applied to areas that contain fish, other aquatic life and plants. VectoMax FG can be applied to areas used by or in contact with humans, pets, horses, livestock, birds, or wildlife.

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

<u>Habitat</u>	<u>Application Rate Range</u>
Wastewater: Sewage effluent, sewage lagoons, oxidation ponds, septic ditches, animal waste lagoons, and impound wastewater associated with fruit and vegetable processing.	5-20 lbs/acre*
Storm Water/Drainage Systems: Storm sewers, catch basins, drainage ditches, roadside ditches, retention ponds, detention ponds, and seepage ponds.	5-20 lbs/acre*
Marine/Coastal Areas: Tidal water, salt marshes, mangroves, and estuaries.	5-20 lbs/acre*
Water Bodies: Natural and manmade aquatic sites such as lakes, ponds, canals, rivers and streams (including river & stream edges), floodplains, swamps, marshes, irrigation ditches, flood water, woodland pools, snow melt pools, and livestock watering ponds and troughs.	5-20 lbs/acre*
Waste Tires: Tires stockpiled in dumps, landfills, recycling plants, and other similar sites.	0.5 – 2 lbs/1000 sq ft

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

Habitat	Application Rate Range
Rice fields, pastures/hay fields, orchards (including citrus groves, peaches, almonds, dates, and walnuts), asparagus fields, corn fields, cotton fields, alfalfa fields, and vineyards.	5-20 lbs/acre*

Apply VectoMax FG uniformly by aerial or conventional ground equipment. Reapply VectoMax FG as needed (after 1-4 weeks under typical environmental conditions).

* Use higher application rates (10-20 lbs/acre) in areas where 4th instar *Aedes* or *Ochlerotatus* spp. larvae predominate, or in areas where very high densities of late instar mosquito larvae are present, or under conditions where local experience indicates the need for higher application rates to achieve extended residual control.

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

Storage and Disposal

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

PESTICIDE STORAGE

Store in a cool, dry place.

PESTICIDE DISPOSAL

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. If burned, stay out of smoke.

Warranty and Disclaimer

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

**VectoMax® FG
Biological Larvicide
Fine Granule**

**[Alternate Brand Names: V60035 Water Soluble Pouches (WSP) and VectoMax®
WSP Water Soluble Pouches Biological Larvicide]**

[Sub-label B]

 FOR ORGANIC PRODUCTION
Made with BioFuse Technology

ACTIVE INGREDIENTS:

<i>Bacillus sphaericus</i> 2362, Serotype H5a5b, Strain ABTS 1743 Fermentation Solids, Spores, and Insecticidal Toxins.....	2.7%
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OTHER INGREDIENTS	92.8%
TOTAL	100.0%

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Expiration Date: (Two years from date of manufacture).

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

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870 Technology Way
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US Patent No. 7,989,180
US Patent No. 8,454,983

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If on skin or clothing	<ul style="list-style-type: none"> • 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	
<p>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.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Harmful if absorbed through the skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, 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.

ENVIRONMENTAL HAZARDS

Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the 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. Once the foil bag containing VectoMax[®] FG Biological Larvicide Fine Granule is opened, use pouches within one day.

For use only by federal, state, tribal or local government officials responsible for public health or vector control, or by persons certified in the appropriate category or otherwise authorized by the state or tribal lead pesticide regulatory agency to perform mosquito control applications, or by persons under their direct supervision.

IN CALIFORNIA: This product is to be applied by County Health Department, State Department of Health Services, Mosquito and Vector Control or Mosquito Abatement District personnel, or persons under contract to these entities only.

APPLICATION DIRECTIONS

MOSQUITO CONTROL

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I. For control of mosquito larvae in the following sites:

Habitat	Application Rate
Drainage/Drainage Systems¹:	
Catch basins and storm drains	1 water soluble pouch/for up to 50 sq ft
Treatment Areas (For Use in)²:	
Ponds	Flood water Abandoned swimming pools
Lagoons	Standing water Unused swimming pools or spas
Hollow trees and tree holes	Storm water Flooded basements Pool covers
Urns	Birdbaths Gutters and drains
Rain barrels	Fountains Wheelbarrows
Livestock watering troughs/ ponds/tanks	Flowerpots and planters Garbage cans and covers Discarded tires
Irrigation ditches	Snowmelt pools
Roadside ditches	Septic tanks
Water gardens	
Impounded wastewater associated with fruit and vegetable processing	
Retention, detention and seepage ponds	
Animal waste lagoons	

Any location where water accumulates and remains standing for periods of time, except treated, finished water reservoirs or drinking water receptacles when the water is intended for human consumption.

⁽¹⁾ Treat on basis of surface area of potential mosquito breeding sites by placing one (1) water soluble pouch for up to 50 square feet of treatment area. Reapply VectoMax FG as needed (after 6-8 weeks under typical environmental conditions).

⁽²⁾ Treat on basis of surface area of potential mosquito breeding sites by placing one (1) water soluble pouch for up to 50 square feet of treatment area. Reapply VectoMax FG as needed (after 1-4 weeks under typical environmental conditions).

Longer periods of mosquito population suppression may result where sufficient numbers of non-target aquatic invertebrate parasites and predators are present since these are not affected by the product and contribute to mosquito population reduction.

Storage and Disposal

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

PESTICIDE STORAGE

Store in a cool, dry place.

PESTICIDE DISPOSAL

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER HANDLING

Offer foil pouch for recycling if available or, dispose of empty pouch in the trash as long as the water soluble pouch is unbroken.

Warranty and Disclaimer

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

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