

73049-429

09-06-2011

1/14

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

SEP 06 2011

Re: V60035 CG
EPA Registration No. 73049-429
Minor Label ("Fast Track") Amendment
Submission dated 7/27/2011
Decision No. 452894

Dear Ms. Walz:

The Environmental Protection Agency (EPA) has reviewed your request to amend the subject product registration, which included the following change to the product label:

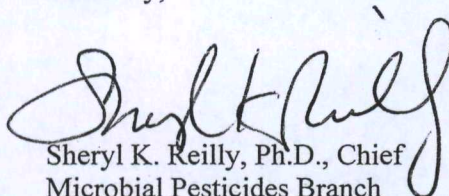
- 1) Modification to name of Active Ingredient to comply with request from Agency and detailed in a letter sent to Agency dated 11/19/2010. Active Ingredient name changed to *Bacillus sphaericus* 2362, Serotype H5a5b, Strain ABTS 1743

The change referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you 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.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any questions regarding this letter, please contact Ms. Sally Johnson by telephone (703-347-0278) or email (johnson.sally@epa.gov).

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: (1) V60035 Accepted Label
(2) A-79 Enclosure

CONCURRENCES

SYMBOL	7511P	7511P	7511P					
SURNAME	Johnson	Reynolds	Reilly					
DATE	9/6/11	9/6/11	9/6/11					

V60035 CG Biological Larvicide

{Alternate Brand Names: VectoMax CG, V60035 Water Soluble Pouches (WSP), VectoMax WSP, VectoMax G}

MASTER LABEL

Sub-label A: VectoMax CG – Alternate Brand Name
Sub-label B: VectoMax WSP – Alternate Brand Name
Sub-label C: VectoMax G – Alternate Brand Name

Active Ingredients:

Bacillus sphaericus 2362, Serotype H5a5b, Strain ABTS 1743 Fermentation Solids, Spores, and Insecticidal Toxins.....2.7%
Bacillus thuringiensis subsp. *israelensis* Serotype H-14, Strain AM65-52 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.

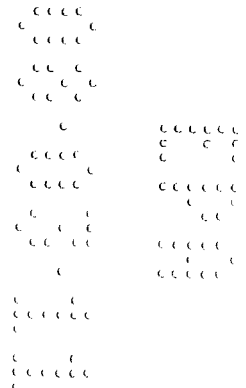
EPA Registration No. 73049-429
EPA Est. No. 33762-IA-001

ACCEPTED

SEP 06 2011

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 73049-429


Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048



VectoMax CG

Biological Larvicide

(Sub-label A)

 **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 AM65-52 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**

PATENT PENDING

Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

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



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 frequent 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.

APPLICATION DIRECTIONS

MOSQUITO CONTROL

VectoMax CG is a selective microbial insecticide for use against mosquito larvae in a variety of habitats. VectoMax CG can be applied to areas that contain fish, other aquatic life and plants. VectoMax CG 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>Rate Range</u>
Wastewater: Sewage effluent, sewage lagoons, oxidation ponds, septic ditches, animal waste lagoons, 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, detention, and seepage ponds.	5-20 lbs/acre*
Marine/Coastal Areas: Tidal water, salt marshes, mangroves, 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 the control of mosquito larvae in agricultural / crop sites where mosquito breeding occurs.

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

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

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

Non-refillable 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.

Warranty and Disclaimer

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

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V60035 WSP
Water Soluble Pouches
Biological Larvicide
{Alternate Brand Name: **VectoMax WSP**}

(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%
<i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> Serotype H-14, Strain AM65-52 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

PATENT PENDING

Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

EPA Registration No. 73049-429

EPA Est. No. 33762-IA-001

Net Weight:

Lot No.

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.
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 frequent 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.

VECTOMAX WATER SOLUBLE POUCHES (WSP): Once the foil bag containing Water Soluble Pouches is opened, minimize exposure of WSP to humidity.

APPLICATION DIRECTIONS

MOSQUITO CONTROL

VectoMax WSP is a selective microbial insecticide for use against mosquito larvae in a variety of habitats. VectoMax WSP can be applied to areas that contain fish, other aquatic life and plants. VectoMax WSP 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 sites:

<u>Habitat</u>	<u>Rate Range</u>	
Drainage/ Drainage Systems¹:		
Catch basins and storm drains	1 pouch/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	Storm water	Flooded basements
and tree holes	retention areas	Pool covers
Urns	Birdbaths	Gutters and drains
Rain barrels	Fountains	Wheelbarrows
Livestock watering troughs/ ponds/tanks	Flowerpots and planters	Garbage cans and covers
Irrigation ditches	Snowmelt pools	Discarded tires
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 drinking water for human consumption.

⁽¹⁾ Treat on basis of surface area of potential mosquito breeding sites by placing one (1) VectoMax Water Soluble Pouch for up to 50 square feet of treatment area. Re-apply as needed (after 1-4 weeks under typical environmental conditions).

⁽²⁾ Treat on basis of surface area of potential mosquito breeding sites by placing one (1) VectoMax Water Soluble Pouch for up to 50 square feet of treatment area. Re-apply 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

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available or, dispose of empty outer foil pouch in the trash as long as the WSP is unbroken.

Warranty and Disclaimer

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

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VectoMax G

Biological Larvicide / Granules

(Sub-label C)

 FOR ORGANIC PRODUCTION

Made with BioFuse Technology

ACTIVE INGREDIENTS:

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Spores, and Insecticidal Toxins.....2.7%

Bacillus thuringiensis subsp. *israelensis* Serotype H-14, Strain AM65-52
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).

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measurements are not federally standardized.

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CAUTION**

PATENT PENDING

Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

EPA Registration No. 73049-429

EPA Est. No. 33762-IA-001

Net Weight:

Lot No.

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DIRECTIONS FOR USE

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APPLICATION DIRECTIONS

MOSQUITO CONTROL

VectoMax G is a selective microbial insecticide for use against mosquito larvae in a variety of habitats. VectoMax G can be applied to areas that contain fish, other aquatic life and plants. VectoMax G can be applied to areas used by or in contact with humans, pets, horses, livestock, birds, or wildlife.

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