

73049-429

02-03-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 03 2010

Ms. Maria Pilar Herrero  
Regulatory Affairs Manager  
Valent BioSciences Corporation  
870 Technology Way  
Libertyville, IL 60048

Re: Valent BioSciences Corporation; V60035 CG  
EPA Registration No. 73049-429  
Minor Label ("Fast Track") Amendment  
Submission dated 09/18/2009  
Decision #420766

Dear Ms. Herrero:

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

- 1) Correction of minor formatting and typographical errors.
- 2) Addition of the phrase, "Made with BioFuse Technology," to all of the sub-labels.
- 3) Modification of the application rate range for Waste Tires on sub-labels A and C to ensure consistency with the size of retail container (i.e., 40 pounds) presented on EPA Form 8570-1.
- 4) Revision of the Storage and Disposal Container Handling statements in accordance with Pesticide Registration (PR) Notices 2007-4 and 83-3 on all of the sub-labels.

The changes referred to above, submitted in connection with registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable provided that you:

- 1) 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.

CONCURRENCES							
SYMBOL	▶	7511P	7511P				
SURNAME	▶	Kausch	Reynolds				
DATE	▶	02/01/2010	2/3/10				

Ms. Maria Herrero  
EPA Registration Number 73049-429

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Your release for shipment of the product bearing the amended labeling constitutes acceptance of this condition. If you have any questions, contact Jeannine Kausch at 703-347-8920 or by email at [kausch.jeannine@epa.gov](mailto:kausch.jeannine@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 (2):  
- A-79 Enclosure  
- Acceptable Label

# 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:

<i>Bacillus sphaericus</i> Serotype H5a5b, Strain 2362 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%
<b>Other Ingredients</b> .....	92.8%
<b>Total</b> .....	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

Valent BioSciences Corporation  
870 Technology Way  
Libertyville, IL 60048

# ACCEPTED

FEB 03 2010


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

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**VectoMax CG**

**Biological Larvicide**

(Sub-label A)

 FOR ORGANIC PRODUCTION  
Made with BioFuse Technology

**ACTIVE INGREDIENTS:**

*Bacillus sphaericus* Serotype H5a5b, Strain 2362 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.

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.

<b>FIRST AID</b>	
If in eyes	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
If on skin or clothing	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
If inhaled	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>HOT LINE NUMBER</b>	
<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:**

<b>Habitat</b>	<b>Rate Range</b>
<b>Wastewater:</b> Sewage effluent, sewage lagoons, oxidation ponds, septic ditches, animal waste lagoons, impound wastewater associated with fruit and vegetable processing.	5-20 lbs/acre*
<b>Storm Water/Drainage Systems:</b> Storm sewers, catch basins, drainage ditches, roadside ditches, retention, detention, and seepage ponds.	5-20 lbs/acre*
<b>Marine/Coastal Areas:</b> Tidal water, salt marshes, mangroves, estuaries.	5-20 lbs/acre*
<b>Water Bodies:</b> 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*
<b>Waste Tires:</b> 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.**

<b>Habitat</b>	<b>Rate Range</b>
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 4<sup>th</sup> 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.

**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> Serotype H5a5b, Strain 2362 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%
<b>OTHER INGREDIENTS</b> .....	92.8%
<b>TOTAL</b> .....	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.



<b>FIRST AID</b>	
If in eyes	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
If on skin or clothing	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>HOT LINE NUMBER</b>	
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 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.

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

Any location where water accumulates and remains standing for periods of time, except treated, finished drinking water for human consumption.

<sup>(1)</sup> 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.

**VectoMax G**

**Biological Larvicide / Granules**

(Sub-label C)

 FOR ORGANIC PRODUCTION  
Made with BioFuse Technology

**ACTIVE INGREDIENTS:**

<i>Bacillus sphaericus</i> Serotype H5a5b, Strain 2362 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%
<b>OTHER INGREDIENTS</b> .....	92.8%
<b>TOTAL</b> .....	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.

<b>FIRST AID</b>	
If in eyes	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
If on skin or clothing	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
If inhaled	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>HOT LINE NUMBER</b>	
<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 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.

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

<b><u>Habitat</u></b>	<b><u>Rate Range</u></b>
<b>Wastewater:</b> Sewage effluent, sewage lagoons, oxidation ponds, septic ditches, animal waste lagoons, impound wastewater associated with fruit and vegetable processing.	5-20 lbs/acre*
<b>Storm Water/Drainage Systems:</b> Storm sewers, catch basins, drainage ditches, roadside ditches, retention, detention, and seepage ponds.	5-20 lbs/acre*
<b>Marine/Coastal Areas:</b> Tidal water, salt marshes, mangroves, estuaries.	5-20 lbs/acre*
<b>Water Bodies:</b> 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*
<b>Waste Tires:</b> 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.**

<b><u>Habitat</u></b>	<b><u>Rate Range</u></b>
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 4<sup>th</sup> 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.