

73049-18

06-17-2008

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

June 17, 2008

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Doina Bujor  
Regulatory Manager  
Valent BioSciences Corp.  
870 Technology Way  
Libertyville, IL 60048

RE: Product Name: Vectobac 12AS-II Biological Larvicide Aqueous Suspension.  
EPA Reg. No: 73049-18  
Your Application Dated May 16, 2008 to Update Container Disposal Statement  
per PR Notice 2007-4

Dear Ms. Bujor:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

Questions concerning this action should be directed to Ms. Diana Hudson at (703) 308-8713 or email at [HUDSON.DIANA@EPA.GOV](mailto:HUDSON.DIANA@EPA.GOV).

Sincerely,

*Linda Hollis*

Linda Hollis, Chief  
Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention  
Division (7511P)





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May 16, 2008

Sheryl Reilly  
 Biopesticides & Pollution Prevention Division  
 Document Processing Desk (NOTIF)  
 Office Of Pesticide Programs (7504P)  
 U.S. Environmental Protection Agency  
 Room S-4900, One Potomac Yard  
 2777 South Crystal Drive  
 Arlington, VA 22202-4501  
 703-308-8269

**RE: VectoBac® 12AS-II (EPA Reg. No. 73049-18) Notification**

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Dear Ms. Reilly:

Valent BioScience Corporation is submitting a notification for VectoBac 12AS-II (EPA Reg. No. 73049-18) in accordance with PR Notice 2007-4 and PR. The changes made to the label are to the Storage and Disposal statement and include the container disposal language for nonrefillable rigid container (plastic bottle).

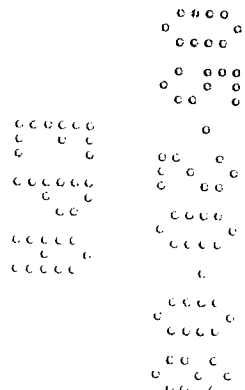
Present submission consists of:

- Application for Registration (EPA form 8570-1)
- One copy of the red-lined label
- One copy of the clean label.

Please contact me if you have any questions at 847-968-4724 or by e-mail at [doina.bujor@valent.com](mailto:doina.bujor@valent.com).

Sincerely,

Doina Bujor  
 Regulatory Manager



**NOTIFICATION**

Date Reviewed: 6-17-08 <sup>5</sup>/<sub>15</sub>

Reviewed By: D. Hudson

**VECTOBAC® 12AS - II  
BIOLOGICAL LARVICIDE  
AQUEOUS SUSPENSION**

**Active Ingredient:**

<i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> strain AM 65-52 fermentation solids, spores, and insecticidal toxins.....	11.61%
Other Ingredients.....	88.39%
Total.....	100.00%

Potency: 1200 International Toxic Units (ITU) per mg (Equivalent to 4.84 billion ITU per gallon, 1.279 billion ITU per liter)

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

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

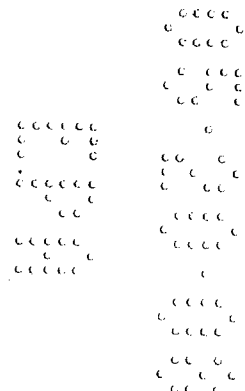
See side panel for additional precautionary statements and statement of practical treatment.

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

EPA Reg. No. 73049-18  
EPA Est. No. 33762-IA-1

Batch Code: \_\_\_\_\_

Net Contents:



<b>FIRST AID</b>	
<b>If in eyes</b>	<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>
<b>If on skin or clothing</b>	<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>	
<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 1-800-892-0099 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-6-Valent.</p>	

**PRECAUTIONARY STATEMENTS  
HAZARD TO HUMANS (& DOMESTIC ANIMALS)  
CAUTION**

Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

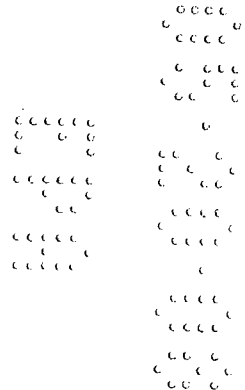
**Personal Protective Equipment**

Applicators and other handlers must wear:

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

Mixer/loaders and applicators not in enclosed cabs or aircraft must wear a dust/mist filtering respirator meeting HIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow manufacturer's 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.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- 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**

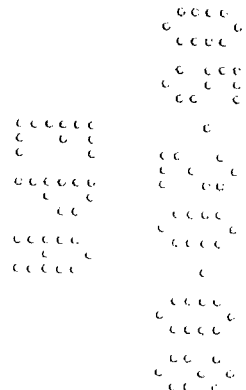
Do not contaminate water when cleaning equipment or disposing of equipment washwaters. Do not apply directly to treated finished drinking water reservoirs or drinking water receptacles intended for human consumption.

**PHYSICAL AND CHEMICAL HAZARDS**

Diluted or undiluted VectoBac 12AS - II can cause corrosion if left in prolonged contact with aluminum spray system components. Rinse spray system with plenty of clean water after use. Care should be taken to prevent contact with aluminum aircraft surfaces, structural components and control systems. In case of contact, rinse thoroughly with plenty of water. Inspect aluminum aircraft component regularly for signs of corrosion.

**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.



### AGRICULTURAL USE REQUIREMENTS

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 restricted entry intervals. 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 4 hours.

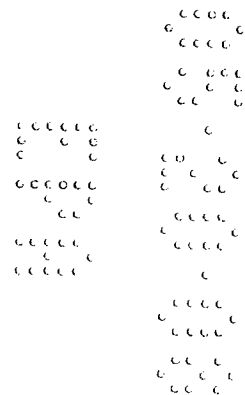
Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

PPE required for early entry into 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.

### CHEMIGATION

Do not apply this product through any irrigation system unless the labeling on chemigation is followed.





**STORAGE AND DISPOSAL**

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

**Storage:** Store in a 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. 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. Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer, or contact Ag Container Recycling Council at 202-861-3144 or [www.acrecycle.org](http://www.acrecycle.org) . If recycling is not available puncture and dispose of the container in a sanitary landfill, or by other procedures approved by state and local authorities.

**APPLICATION DIRECTIONS**

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

**Mosquito Habitat**

**Suggested Rate Range\***

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

0.25 - 1 pt/acre

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.

When applying this product to standing water containing mosquito larvae in fields growing crops, do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Polluted water 1 - 2 pts/acre

(such as sewage lagoons, animal waste lagoons).

\*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.

**Blackflies Habitat**

**Suggested Rate Range**

Streams

Stream water\*\* (=ppm) for 1 minute exposure time.

0.5 - 25 mg/liter

Stream water\*\* (=ppm) for 10 minutes exposure time.

0.05 - 2.5 mg/liter

\*\*Use higher rate range when stream contains high concentration of organic materials, algae, or dense aquatic vegetation.

**Ground and Aerial Application**

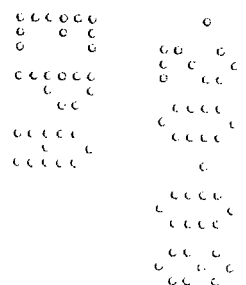
VectoBac 12AS - II may be applied in conventional ground or aerial application equipment with quantities of water sufficient to provide uniform coverage of the target area. The amount of water will depend on weather, spray equipment, and mosquito habitat characteristics. Do not mix more VectoBac 12AS - II than can be used in a 72 hour period.

For most ground spraying, apply in 5 - 100 gallons of water per acre using hand pump, airblast, mist blower, etc., spray equipment.

For aerial application, VectoBac 12AS - II may be applied either undiluted or diluted with water. For undiluted applications, apply 0.25 to 2.0 pts./acre of VectoBac 12AS - II through fixed wing or helicopter aircraft equipped with either conventional boom and nozzle systems or rotary atomizers.

For diluted application, fill the mix tank or plane hopper with the desired quantity of water. Start the mechanical or hydraulic agitation to provide moderate circulation before adding the VectoBac 12AS - II. VectoBac 12AS - II 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. AVOID CONTINUOUS AGITATION OF THE SPRAY MIXTURE DURING SPRAYING.

Rinse and flush spray equipment thoroughly following each use.



For blackfly aerial applications, VectoBac 12AS - II can be applied undiluted via fixed wing or helicopter aircraft equipped with either conventional boom and nozzle systems or open pipes. Rate of application will be determined by the stream discharge and the required amount of VectoBac 12AS - II necessary to maintain a .5 - 25 ppm concentration in the stream water. VectoBac 12AS - II can also be applied diluted with similar spray equipment. Do not mix more VectoBac 12AS - II than can be used in a 72 hour period.

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 of these factors when making decisions.

**Mushroom Flies (Sciaridae and Phoridae)**

Conventional *Agaricus* (button) mushrooms:

For the control of the larval stage of mushroom flies when applied to mushroom compost or casing. When used as a compost drench, apply at spawn or up to 14 days after spawn. The casing treatment should be applied at casing or up to 7 days after casing. Use sufficient water (20 - 50 gallons per 1000 square feet of bed) and proper application equipment to obtain good distribution of the treatment through the growth medium.

**SUGGESTED RATE RANGE:**

Compost Only Treatment: Use 2.5 - 5.5 gal/1000 sq. ft. of bed.

Combination Compost and Casing Treatment: Use 2.5 - 4.5 gal/1000 sq. ft. of bed at spawn or up to 14 days after spawn plus 0.5 - 1.5 gal/100 sq. ft. of bed at casing or up to 7 days after casing.

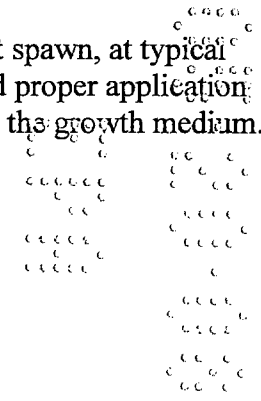
Use higher rate when pest pressure is heavy.

VectoBac 12AS - II 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.

**Exotic and Specialty Mushrooms**

(Such as Shiitake, Oyster, and other varieties)

For control of the larval stage of mushroom flies when product is applied at spawn, at typical watering time, or when growth medium is soaked. Use sufficient water and proper application equipment to obtain good coverage and distribution of the material through the growth medium.



**SUGGESTED RATE RANGE:**

Drench or Soak Treatment: Use 20 - 80 ounces per gallon of water.

Use higher rate when pest pressure is heavy.

VectoBac 12AS - II has not been tested for mycotoxicity on all types of exotic and specialty mushrooms. This product should be tested on a portion of the crop prior to large scale commercial treatment.

Compatibility: VectoBac 12AS - II should not be mixed with water containing chlorine levels in excess of those found in potable water supplies. Materials containing copper and chlorine should not be mixed with this product.

**Fungus Gnat Habitat**  
(All states except California)

**Suggested Rate Range**

Ornamental Plants in greenhouse, on nursery plantings in potting soil mixtures with high percent peat.

Light Infestation:  
8 - 16 oz/100 gallons\*  
applied as a soil drench.

Heavy Infestation:  
32 - 64 oz/100 gallons\*\*  
applied as a soil drench.

\*8 - 16 oz/100 gallons = 0.5 - 1 tsp/gallon.

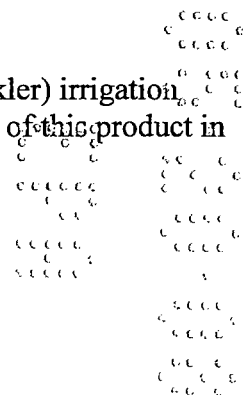
\*\*32 - 64 oz/100 gallons = 2 - 4 tsp/gallon.

Apply with adequate water by soil drench to sufficiently wet the soil surface above and under greenhouse benches where larvae are found. Areas under benches should be treated where larvae are found. Areas under benches should be treated at high rate 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.

VectoBac 12AS - II 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 12AS - II within 24 hours following application.

VectoBac 12AS - II can be applied by injection into drip or overhead (sprinkler) irrigation systems. See Chemigation Section for further instructions regarding the use of this product in these systems.



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VectoBac 12AS - II is not known to be phytotoxic to ornamental plant species. However, since all ornamental plant species have not been evaluated, sensitivity to VectoBac 12AS - II should be checked on several plants prior to wide scale usage.

**PRECAUTIONS**

Important: VectoBac 12AS - II 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 12AS - II performance).

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

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

**SMALL QUANTITY DILUTION RATES**

**Gallons Spray Solution/Acre  
(Ounces Needed per Gallon of Spray)**

**VectoBac 12AS - II  
Rate in Pints**

Per acre	10 Gal/A	25 Gal/A	50 Gal/A
0.25	0.2	0.1	0.04
0.5	0.4	0.2	0.08
1	0.8	0.33	0.16
2	1.6	0.65	0.32

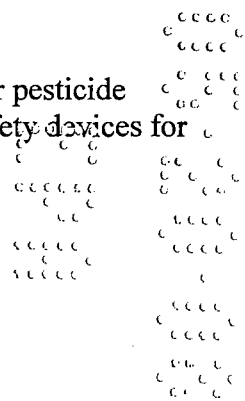
**CHEMIGATION**

Apply this product only through: sprinkler including solid set; flood (basin); or drip (trickle) irrigation systems. Do not apply this product through any other type of irrigation system.

Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from nonuniform distribution of treated water.

If you have questions about calibration, you should contact State Extension Service Specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.



A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

**Rice - Flood (Basin) Chemigation**

Systems using a gravity flow pesticide dispensing system must meter the pesticide into the water at the head of the field and downstream of a hydraulic discontinuity such as a drop structure or weir box to decrease potential for water source contamination from backflow if water flow stops.

VectoBac 12AS - II is metered or dripped into rice floodwater at application stations positioned at the point of introduction (levee cut) of water into each rice field or pan. Two to 3 pints of VectoBac 12AS - II are diluted in water to a final volume of 5 gallons. The diluted solution is contained in a 5 gallon container and metered or dispersed into the irrigation water using a constant flow device at the rate of 80 ml per minute. Introduction of the solution should begin when 1/3 to 1/2 of the pan or field is covered with floodwater. Delivery of the solution should continue for a period of approximately 4 1/2 hours. Floodwater depth should not exceed 10-12 inches to prevent excessive dilution of VectoBac 12AS - II which could result in reduced larval kill. Agitation is not required during the period in which the VectoBac 12AS - II suspension is being dispersed.

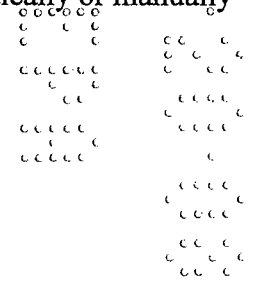
Application of VectoBac 12AS - II into rice floodwater is not permitted using a pressurized water and pesticide injection system.

**Drip (Trickle) and Sprinkler Chemigation, (Greenhouses and Mushroom Houses)**

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventor (RPZ) or a functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.



The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a meter pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.

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

If VectoBac 12AS-II needs to be diluted prior to injection, material may be mixed separately and then put into the injector. Agitation may be necessary, if materials are kept more than one day. VectoBac 12AS-II may be applied continuously.

Where supply tanks are used for continuous application, fill the supply tank with the desired quantity of water. Start the mechanical or hydraulic agitation to provide moderate circulation before adding VectoBac 12AS-II.

VectoBac 12AS-II 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.

**NOTICE TO USER**

Seller makes no warranty, expressed 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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