

73049-38

04/28/2009

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

April 28, 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

RE: Product Name: Vectobac 12AS
EPA Reg. No: 73049-38
Application for Label Notification Dated March 12, 2009 to Update Storage and
Disposal Language per PR Notice 2007-4

Dear Ms. Bujor:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration (PR) Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested falls within the scope of PR Notice 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.

Sincerely,

Sheryl K. Reilly

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)

Please read instructions on reverse before completing form.

Form Approved, AB No. 2070-0060

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-38	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VectoBac 12 AS	PM# <u>92</u>	
5. Name and Address of Applicant (Include ZIP Code) Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION Date Reviewed: <u>4-28-09</u> Reviewed By: <u>D. Hudson</u>
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. NO other changes have been made to the labeling or the Confidential Statement of Formula for this product. (see next page)

Section - III

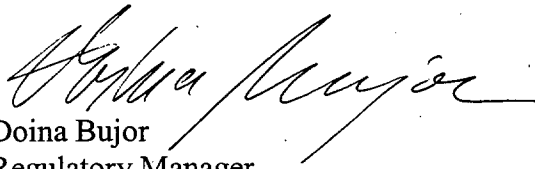
1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Doina Bujor	Title Regulatory Manager	Telephone No. (Include Area Code) 847-968-4724	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment, both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Manager		
4. Typed Name Doina Bujor	5. Date Mar 12, 2009		

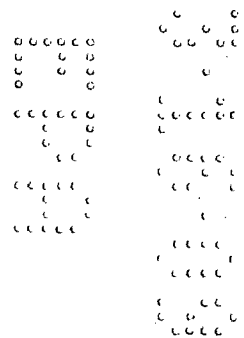
Notification of Storage and Disposal Statement (PR Notice 2007-4) for VectoBac 12 AS, EPA Reg. No. 73049- 38 (continuation from the previous page)

I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§152.46, 56.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and may be subject to enforcement action and penalties under section 12 and 14 of FIFRA.



Doina Bujor
Regulatory Manager

03-12-2009





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March 12, 2009

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® 12 AS (EPA Reg. No. 73049-38) Notification

Dear Ms. Reilly:

Valent BioScience Corporation is submitting a notification for VectoBac 12 AS (EPA Reg. No. 73049-38) in accordance with PR Notice 2007-4. The changes made to the label are to the Storage and Disposal statement and include the changes to the container disposal language required by the PR Notice 2007-4.

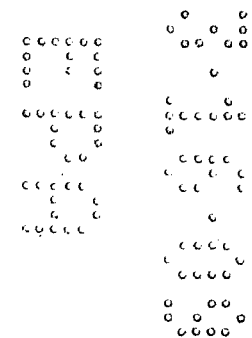
Present submission consists of:

- 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.

Sincerely,


Doina Bujor
Regulatory Manager



List No. 5605

**VECTORBAC® 12AS
BIOLOGICAL LARVICIDE
AQUEOUS SUSPENSION**

NOTIFICATION

Date Reviewed: 4-28-09

Reviewed By: D. Hudson

Active Ingredient:

<i>Bacillus thuringiensis</i> , subsp. <i>israelensis</i> , strain AM 65-52, fermentation solids and solubles.....	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).

There is no direct relationship between intended activity (potency) and the Percent Active Ingredient Weight.

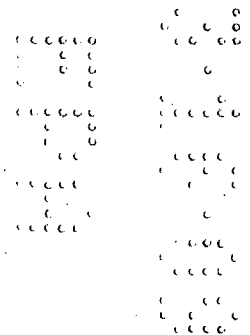
**KEEP OUT OF REACH OF CHILDREN
CAUTION**

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

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

EPA Registration No. 73049-38 _____ Lot No.:
EPA Est. No. 33762-IA-1

Net Contents:



FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eyes and rinse slowly and gently with water for 15-20 minutes • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes • 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 STATEMENT
HAZARD TO HUMANS (AND DOMESTIC ANIMALS)
CAUTION**

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

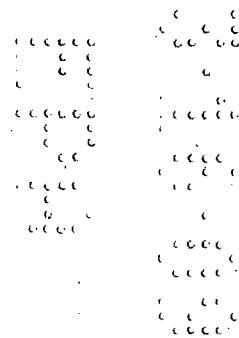
PHYSICAL AND CHEMICAL HAZARDS

Diluted or undiluted VectoBac® 12 AS 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 components regularly for signs of corrosion.

DIRECTIONS FOR USE

It is in violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply directly to treated finished drinking water reservoirs or drinking water receptacles when water is intended for human consumption.

Do not apply when weather conditions favor drift from treated areas. Do not apply to metallic painted objects, such as automobiles, as spotting may occur. If spray is deposited on metallic painted surfaces, wash immediately with soap and water to avoid spotting.



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.

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, [less than 86°F (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, 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. Do not reuse container.

- Formatted: Font: (Default) Arial, 10 pt
- Formatted: Border: Top: (No border), Bottom: (No border), Left: (No border), Right: (No border)
- Formatted: Default Text
- Deleted: Triple rinse (or equivalent). Then
- Formatted: Font: (Default) Arial, 10 pt

APPLICATION DIRECTIONS

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

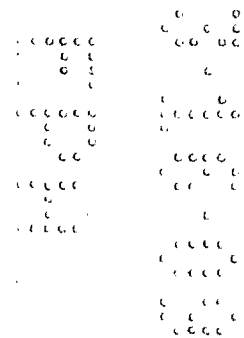
Mosquito Habitat

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 marches and rice fields.

2.25 – 2 pts/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.



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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 minute 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.

** Discharge is a principle factor determining carry of Bti. Use higher rate or increase volume by water dilution in low discharge rivers or streams under low volume (drought) conditions.

(NUISANCE FLIES)

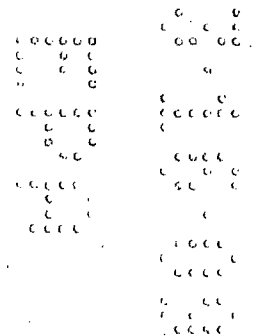
For control of nuisance flies (*Psychoda* spp., *Chironomus* spp.) in sewage treatment facilities utilizing trickling filter systems.

APPLICATION DIRECTIONS

Nuisance Fly Habitat Suggested Rate Range*

Trickling filter system of wastewater treatment plants 10-20 mg/liter a.(0.833-1.67 ml) per liter of wastewater feed to the filter per 30 minutes

*Use high rate for control of *Chironomus* spp. Apply undiluted with pre-calibrated pump or other device into the wastewater feeding into the filters for a period of 30 minutes. Repeat applications as needed after 2-4 weeks. Control of *Chironomus* spp. may take up to 2 weeks.



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(NUISANCE AQUATIC MIDGES)

For control of *Chironomine* midges (*Chironominae: Chironomini*) inhabitin shallow, man-made and natural lakes or ponds.

APPLICATION DIRECTIONS

Nuisance Midge Habitat

Suggested Rate Range*

Shallow Lakes and Ponds
Per sewage oxidation ponds
(less than acre 6 feet deep)

1 gallon (3,785.5 ml) per acre

*Apply diluted with water in total volume of 5 gallons/acre by pouring or spraying over the surface to be treated with pre-calibrated device. Repeat application as needed after 204 weeks. Control of *Chironomine* midges may take up to 2 weeks.

Ground and Aerial Application

VectoBac 12AS 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 than can be used in a 72 hour period.

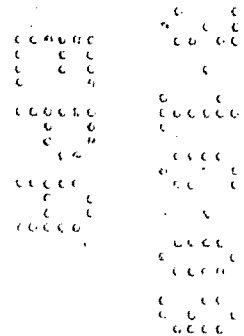
For most ground spraying, apply in 5-100 gallons of water per acre using hand pump, airblast, mist blower, etc., spray equipment.

For aerial application, VectoBac 12AS may be applied either undiluted or diluted with water. For undiluted applications, apply 0.25 to 2.0 pts/acre of VectoBac 12AS 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 wit the desired quantity of water. Start the mechanical or hydraulic agitation to provide moderate circulation before adding the VectoBac 12AS. VectoBac 12AS 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 CONTNUOUS AGITATION OF THE SPRAY MIXTURE DURING SPRAYING.

Rinse and flush spray equipment thoroughly following each use.

For blackfly aerial applications, VectoBac 12AS 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 necessary to maintain a .5-25 ppm concentration in the stream water. VectoBac 12AS can also be applied diluted with similar spray equipment. Do not mix more VectoBac 12AS that can be used in a 72 hour period.



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SMALL QUANTITY DILUTION RATES
Gallons Spray Solution/Acre
(Ounces Needed per Gallon of Spray)

VectoBac 12AS

Pate in Pints

Per acre	10 Gal/A	25 Gal/A	50 Gal/A
0.25 (4oz)	0.4	0.16	0.08
0.5 (8oz)	0.8	0.32	0.16
1.0 (16 oz)	1.6	0.64	0.32
2.0 (32 oz)	3.2	1.28	0.64

CHEMIGATION

Apply this product through flood (basin) irrigation system. Do not apply this product through any other type of irrigation system.

Crop injury, lack of effectiveness or illegal pesticide residues in crop result from non-uniform distribution of treated water.

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

A person knowledgeable if this 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 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 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 devise at the rate of 80 ml per minute. Introduction of the solution should begin when 1/4 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 which could result in reduced larval kill. Agitation is not required during the period in which the VectoBac 12AS suspension is being dispersed. Application of VectoBac 12AS into rice floodwater is not permitted using a pressurized water and pesticide injection system.

NOTICE TO USER

Seller makes no warranty, express or implied, or merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. User assumes all risk or use, storage or handling not in strict accordance with accompanying directions.

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