

73049-435

2/17/2011

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Jayne Walz
Regulatory Manager
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

RE: Product Name: Teknar® HP – Biological Larvicide Aqueous Suspension
EPA Reg. No: 73049-435
Application for Notification Dated: September 8, 2010 removal of specific temperature reference in the Storage and Disposal section as per PRN 98-10.

Dear Ms. Walz,

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticides Registration Notice (PRN) 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 as "Notification, received and accepted" and will be placed accordingly in our records.

Questions concerning this action should be directed to Mary Paden (703) 308-0411 or email at paden.mary@epa.gov.

Sincerely,

Sheryl K. Reilly

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

FEB 17 2011

CONCURRENCES							
SYMBOL	7511(P)						
SURNAME	Paden						
DATE	17 FEB 11						

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Please read instructions on reverse before completing form.

Form Approved, OMB 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 73049-435	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Teknar HP	PM# 92	
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. <u>Notification Accepted</u> Product Name <u> </u> Date: <u>02/17/2010</u>

Section - II

Reviewer: Harry Padon

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated <u> </u>
<input type="checkbox"/> Resubmission in response to Agency letter dated <u> </u>	<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 deletion of temperature reference in Storage Instructions per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. (see next page)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container:	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) <u> </u>		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input 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 <u> </u>			

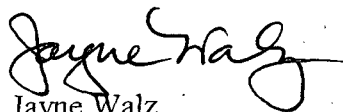
Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name Jayne Walz		Title Regulatory Manager	
		Telephone No. (Include Area Code) 847-968-4771	
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 or both under applicable law.			6. Date Application Received (Stamped)
2. Signature <u>Jayne Walz</u>		3. Title Regulatory Manager	
4. Typed Name Jayne Walz		5. Date September 8, 2010	

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Notification of removal of temperature reference for Teknar HP, EPA Reg. No. 73049-435 (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 the EPA. I further understand that if the amended label is not consistent with the requirements of 40CFR §§ 152.46, 56.10, 156.140, 156.144, 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.



Jayne Walz
Regulatory Manager

September 8, 2010

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September 8, 2010

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: TEKNAR® HP (EPA Reg. No. 73049-435) Notification

Dear Ms. Reilly:


Valent Biosciences Corporation is submitting a notification for TEKNAR HP (EPA Reg. No. 73049-435) in accordance with PR Notice 98-10. The only change made to the label is in the Storage and Disposal section and is solely the removal of the references to specific temperatures for product storage.

Present submission consists of:

- Completed 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 847-968-4771 or by e-mail at jayne.walz@valentbiosciences.com

Sincerely,


Jayne Walz
Regulatory Manager

5 of 11

**TEKNAR® HP
BIOLOGICAL LARVICIDE
AQUEOUS SUSPENSION**

Notification Accepted

Date: 02/17/2011

Reviewer: Mary Pader

Active Ingredient: *Bacillus thuringiensis*, subsp. *israelensis*, strain SA3A, fermentation solids, spores and insecticidal toxins.....5.6%
Other Ingredients.....94.4%
Total.....100%

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**

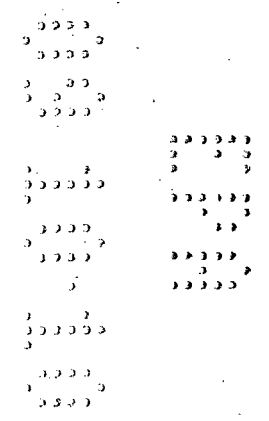
See side panel for additional precautionary statements and statement of practical treatment.

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

Lot No.: _____

EPA Reg. No. 73049-435
EPA Est. No. 33762-IA-1

Net Contents:



FIRST AID	
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 mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water of 15-20 minutes. • Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
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
HAZARD TO HUMANS (AND DOMESTIC ANIMALS)
CAUTION

Harmful if inhaled or absorbed through the skin. Avoid breathing spray mist. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash contaminated clothing before reuse.

Mixer/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 Teknar HP 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. 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, dry place.

Deleted: [less than 86° F (30° C)]

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. Clean container promptly after emptying. 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 $\frac{1}{4}$ 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. Offer for recycling, if available or 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.

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 - 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.

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.

**Discharge is a principal 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

<u>Nuisance Fly Habitat</u>	<u>Suggested Rate Range*</u>
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.

(NUISANCE AQUATIC MIDGES)

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

APPLICATION DIRECTIONS

<u>Nuisance Midge Habitat</u>	<u>Suggested Rate Range*</u>
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 2-4 weeks. Control of *Chironomine* midges may take up to 2 weeks.

Ground and Aerial Application

Teknar HP 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 Teknar HP 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, Teknar HP may be applied either undiluted or diluted with water. For undiluted applications, apply 0.25 to 2.0 pts./acre of Teknar HP 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 Teknar HP. Teknar HP 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, Teknar HP 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 Teknar HP necessary to maintain a .5 - 25 ppm concentration in the stream water. Teknar HP can also be applied diluted with similar spray equipment. Do not mix more Teknar HP than can be used in a 72 hour period.

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

Teknar HP Rate in Pints

Per acre	10 Gal/A	25 Gal/A	50 Gal/A
0.25 (4 oz)	0.4	0.16	0.08
0.5 (8 oz)	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 systems. Do not apply this product through any other type of irrigation system.

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

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

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A person knowledgeable of 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.

Teknar HP 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 Teknar HP 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 Teknar HP which could result in reduced larval kill. Agitation is not required during the period in which the Teknar HP suspension is being dispersed. Application of Teknar HP into rice floodwater is not permitted using a pressurized water and pesticide injection system.

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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