2011

UNITED STARD

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

> OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

APR 2 7 2011

Nasser Assaf, Ph.D. Valent BioSciences Corporation. 870 Technology Way Libertyville, IL 60048

Dear Dr. Assaf:

Subject: Application for Pesticide Notification (PRN 98-10) Comply with Agency pyrethroid labeling letter dated June 4, 2009, Revise per Pesticide Registration Notice 2007-4 (Container Disposal), and update Warranty Statement General Purpose Aqueous Insecticide II EPA Reg. No. 73049-305 Your submission dated February 4, 2011

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated February 4, 2011 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds the action requested falls within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on <u>nonrefillable</u> containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions regarding this letter, please contact Dana Pilitt, PhD of my staff at (703) 305-7071 or via e-mail at <u>pilitt.dana@epa.gov</u>.

Sincerely,

& Gobh

Richard Gebken Product Manager 10 Insecticide Branch Registration Division (7505P)

Please read instruction		w erse before compl U Environmental			 Regis	<u>AB No. 2070-006</u> Registration Amendment		2 0. Approvel expires 2-28-95 OPP Identifier Number		
	•	Washir				Other		-		
· · · · ·	4,		Applicatio	on for Pestic	ide - Sectio					
I. Company/Product N	umber	······································			Product Manage		3	. Proposed	Classification	
73049-305				Ma	Mark Suarez			None	Restricted	
4. Company/Product (Name) General Purpose Aqueous Insecticide II				PM#	PM# []					
 Name and Address of Applicant (Include ZIP Code) Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048 				6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No.						
Check if this is a new address				Product Name						
				Section -						
Amendment - Explain below. Resubmission in response to Agency letter dated					Final printed labels in repsonse to Agency letter dated "Me Too" Application. Other - Explain below.					
-Revise Storage & I -Updated warranty	ard and Disposa	ents on cover letter. d General labeling requ al Statements in Compl ent in agreement with L sen made to the label of	iance with PR I JS EPA OPP G	Notice 2007-4, Juidance on Warran Se clearly marked.	ty Statements (O	ct. 17, 2006)				
				Section -						
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6. Manner in Which Label is Affixed to Product Image: Standard Standar				glued iled						
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I. Contact Point (Con	nplete i	tems directly below f	or identificatio	n of individual to l	be contacted, if I	necessary, t	o process	this applica		
Name Nasser A. Assaf, Ph.D				Title Manager, Product Safety and Regulatory Affairs			Telephone No.: (Include Area Code) (8:47) 968:4788			
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2. Signature NAASSAF				3. Title Manager, Product Safety and Regulatory Affairs			ί ιιι 			
4. Typed Name Nasser A. Assaf, Ph.D				5. Date February 4, 2011				ί ίί ί	ι ι ι ι	
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VALENT BIOSCIENCES.



ENVIRONMENTAL SCIENCE DIVISION

870 TECHNOLOGY WAY LIBERTYVILLE, IL 60048 - 800-323-9597

February 4, 2011

Document Processing Desk (NOTIF-Pyrethroid) Registration Division Office of Pesticide Programs (7504P) US Environmental Protection Agency Room S-4900, One Potomac Yard 2777 S. Crystal Drive Arlington, VA 22202

- ATTN: Mark Suarez Product Manager 13 Insecticide Branch
- SUBJECT: APPLICATION FOR PESTICIDE LABEL NOTIFICATION No PRIA Service Fee Required Submission of Revised Labeling Per:
 - June 4, 2009 Environmental Hazard and General labeling for Pyrethroid Non-agricultural Outdoor Products
 - PR-Notice 2007-4, Container Disposal
 - PR-Notice 98-10, Warranty Statement update

General Purpose Aqueous Insecticide II; EPA Reg. No. 73049-305

Dear Mr. Suarez:

This application for label notification for the above subject product is being submitted to comply with the Agency's letter of June 4, 2009 Environmental Hazard and General labeling for Pyrethroid Non-agricultural Outdoor Products Notification; PR Notice 2007-4, Labeling Revisions Required by the Final Rule "Pesticide Management and Disposal; Standards for Pesticide Containers and Containment Revision of Container Disposal and US EPA OPP Guidance on Warranty Statements (Oct. 17, 2006) among other minor changes which are clearly marked.

General Purpose Aqueous Insecticide II; EPA Reg. No. 73049-305; is ready-to-use liquid pyrethroid product for commercial/agricultural use.

Due to the limited space on EPA Form 8570-1, Section II, the self certification statements are as follows:

Agency's letter of June 4, 2009 Environmental Hazard and General labeling for Pyrethroid Non-agricultural Outdoor Products Notification

Notification of label change per June 4, 2009, letter from Environmental Protection Agency. This notification is consistent with the guidance in the June 4, 2009 letter and the requirements of EPA's regulations at 40 CFR part 156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. 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 156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

- PR Notice 2007-4, Labeling Revisions Required by the Final Rule "Pesticide Management and Disposal Notification of label change per PR-Notice 2007-4. This notification is consistent with the quidance-in-PR Notice 2007-4 and the 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. 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 §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.
- US EPA OPP Guidance on Warranty Statements (Oct. 17, 2006)

This notification is consistent with the provisions of PR Notice 98-10 and the EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula for this product. 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 this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Notification of warranty statements per PR Notice 98-10 II J.

Two (2) copies of revised draft labeling with changes clearly marked are enclosed. Additions are noted in underlined italics. Deletions are shown struck through.

If you need additional information or have any questions regarding this submission, please do not hesitate to contact me at (847) 968-4844 or e-mail to: Nasser.assaf@valent.com.

Sincerely,

NAASSAF

Nasser A. Assaf, Ph.D. Manager, Product Safety and Regulatory Affairs

Enclosures cc: VBC Regulatory File



PERMANONE[®] GÉNERAL PURPOSE AQUEOUS

NOTIFICATION APR 2 7 2011

• For Commercial/Agricultural Use Only

INSECTICIDE H

- [A Ready-To-Use Permanone[®] Stable Emulsion Insecticide
- For Use Outdoors, In Homes And Non-Food Areas Of Food/Feed Processing Establishments, Kennels, Commercial Buildings, Warehouses, Theaters, Office Buildings, Schools, Motels, And Hotels
- For Control Of Fleas, Brown Dog Ticks And Lice On Premises And On Dogs
- For Control Of Ticks Which May Cause Lyme Disease On Premises
- Controls Fleas And Ticks On Dogs For 14 Days]

ACTIVE INGREDIENT:

Permethrin ¹	0.50 %
OTHER INGREDIENTS:	. 99.50 %
	100.00 %

¹ Cis/trans ratio: min. 35% (+/-) cis and max. 65% (+/-) trans.

PRECAUCION AL CONSUMIDOR: Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

(TO THE USER: If you cannot read English, do not use this product until the label has been fully explained to you.)

EPA REG. NO. 73049-305

EPA EST. NO.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Rear Panel For Additional Precautions

Master Label

February 4, 2011 Page 2 of 5

READ ENTIRE LABEL BEFORE EACH USE PET USE APPLIES TO USE ONLY ON DOGS

PRECAUTIONARY STATEMENTS Hazards To Humans & Domestic Animals

CAUTION

Wash thoroughly after handling and before smoking or eating. Avoid contamination of feed and foodstuffs. Remove pets and birds and cover fish aquaria before space spraying or surface applications. Do not use on humans. Vacate room after treatment and ventilate before reoccupying. Do not allow children or pets to contact treated areas until surfaces are dry.

Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing animals. Do not use on dogs under 12 weeks. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

Environmental Hazards

This product is toxic to fish. <u>To protect the environment</u>, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutter or surface waters. Apply this product in calm weather when rain in not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Application is prohibited into sewer drains or to any area like a gutter where drainage to sewers, storm drains, water bodies or aqualic habitat can occur. Do not allow this product to enter any drain during or after applications.

Not for use on plants being grown for sale or other commercial use, or for commercial seed production, or for research purposes. For use on plants intended for aesthetic purposes or climatic modification and being grown in ornamental gardens or parks, or on golf courses or lawns and grounds.

SHAKE WELL BEFORE USING

INDOOR APPLICATION

Do not use in food/feed areas of food/feed handling establishments, restaurants or other areas where food/feed is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared foods are served such as dining rooms but excluding areas where foods may be prepared or held. In the home, cover all food processing surfaces and utensils during treatment or thoroughly wash before use. Cover or remove exposed food/feed.

Non-food/feed areas are areas such as garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets and storage (after canning or bottling).

Vacate treated areas and ventilate before reoccupying. For maximum effectiveness, a combination of spot, surface treatment and fogging is recommended.

Do not apply to classrooms while in use. Do not use on electrical equipment or on surfaces that can be harmed or stained by water.

SURFACE SPRAYING:

TO CONTROL Cockroaches, Waterbugs, Palmetto Bugs, Scorpions, Millipedes, Centipedes, Sowbugs, Pillbugs, Ants, Silverfish, Firebrats, Spiders, Crickets, Clover Mites, Cheese Mites, Granary Weevils, Rice Weevils, Confused Flour Beetles, Rust Red Flour Beetles, Drugstore Beetles, Meal Worms, Grain Mites and Cadelles: Direct the spray into hiding places, cracks and crevices, and behind shelves and drawers. For Silverfish, spray bookcases. For Ants, spray trails, nests and points of entry.

Master Label

February 4, 2011 Page 3 of 5

TO CONTROL Carpet Beetles: Spray edges of carpeting and under carpeting and rugs. Make localized application to floor and baseboards. Spray directly into cracks, crevices and infested areas of shelving.

TO CONTROL Bedbugs: Spray mattresses lightly, particularly around tufts and seams. Take beds apart and spray in all joints. Treat baseboards, moldings and floors.

TO CONTROL Fleas (Adults and Larvae) and Ticks, Including Ticks Which May Carry Lyme Disease (Adults and Larvae): Thoroughly spray infested areas, pet beds, resting quarters, nearby cracks and crevices, along and behind baseboards, moldings, window and door frames, and entire areas of floor and floor covering. Fresh bedding should be placed in animal quarters following treatment. Allow to dry thoroughly before allowing pets to contact treated areas.

TO CONTROL Clothes Moths: Remove any infested articles from storage, brush thoroughly, and air for several hours in sunlight, if possible. Apply spray liberally to empty chests, closets, bureaus and other storages directing the spray into cracks, joints and crevices. After airing, infested articles may be treated lightly, keeping nozzle at least three feet from fabric to avoid staining.

TO KILL Lice and Louse Eggs: Spray in an inconspicuous area to test for possible staining or discoloration. Inspect again after drying, then proceed to spray entire area to be treated. Spray from a distance of 8 to 10 inches. Treat only those garments and parts of bedding, including mattresses and furniture that cannot be either laundered or dry cleaned. Allow all treated articles to dry thoroughly before use.

SPACE SPRAYING:

Close doors and windows and shut off ventilating systems. Apply with a good machine adjusted to deliver a fine mist or fog. For rapid control of Houseflies, Fruit Flies, Gnats, Mosquitoes, Skipper Flies, Wasps, Hornets, Bees, Black Flies, Angoumois Grain Moths, Mediterranean Flour Moths, Indian Meal Moths and Tobacco Moths: Direct spray at an upward angle, distributing it uniformly throughout the entire area at a rate of 1 ounce per 1000 cubic feet of space. Keep area closed for 2 hours. Ventilate before reoccupying.

FOGGING

To kill exposed or accessible stages of the above named crawling insects, use a rate of 1 gallon to 20,000 to 40,000 cubic feet of space. Contact insects directly when possible. Keep area closed for 2 hours. Ventilate before reoccupying.

ON LIVESTOCK:

Do not contaminate animal feed or water during application.

To protect cattle (beef and dairy), goats, sheep, hogs and horses from Horn Flies, Face Flies, Houseflies, Mosauitoes and Gnats: Apply a light mist sufficient to wet the surface of the hair. For face flies, spray face and head, but do not spray into eyes.

TO CONTROL Stable Flies, Horse Flies and Deer Flies: Apply at a rate of 2 ounces per adult animal, sufficient to wet the hair thoroughly. Repeat treatment daily or at intervals necessary to give continued protection.

TO CONTROL Blood-Sucking Lice: Apply to the infested areas of the animal, using a stiff brush to get the spray to the base of the hair. Repeat every 3 weeks if required.

TO CONTROL Poultry Lice: Spray roosts, walls and nests or cages thoroughly. This should be followed by spraying over the birds with a fine mist.

TO CONTROL Bedbugs and Mites IN POULTRY HOUSES: Spray crevices of roost poles, cracks in walls, and cracks in nests where the bedbugs and mites hide.

ON DOGS:

TO CONTROL Fleas, Ticks, and Lice: Start spraying at the tail, moving the dispenser rapidly and making sure that the animal's entire body is covered, including the legs and underbody. While spraying, fluff the hair so that the spray will penetrate to the skin. Make sure spray wets thoroughly, but do not saturate animal. Do not spray into eyes or face. Avoid contact with genitalia. Use protective gloves or mitts when applying product. Repeat application every two weeks, if necessary. DO NOT USE ON CATS OR KITTENS.

OUTDOOR APPLICATION

All outdoor applications must be limited to spot or crack-and-crevice treatments only except for the following permitted uses:

- If:
 Treatment to soil or vegetation around structures

 2:
 Applications to lawns, turf, and other vegetation
- 3. Applications to building foundations, up to a maximum height of 3 feet

Other than applications to building foundations, all outdoor applications to impervious surfaces such as sidewalks, driveways, patios, porches and structural surfaces (such as windows, doors and eaves) are limited to spot and crackand-crevice applications, only.]

Master Label

February 4, 2011 Page 4 of 5

TO CONTROL Ticks, Including Ticks Which May Carry Lyme Disease (PERIMETER TREATMENT): Use Permanone® General Purpose Aqueous Insecticide II as a residual treatment to control Ticks including the Deer Tick (Ixodes scapularis), Lone Star Tick (Amblyomma americanum), Brown Dog Tick (Rhipicephalus sanguineus), American Dog Tick (Dermacentor variabilis) and Western Black-Legged Tick (Ixodes pacificus).

For each area listed below, apply until surface is wet (approximately 1 gal/750-1000 f^2).

Treat around windows and doors, porches, screens, eaves, patios, garages, under stairways and in crawl spaces where these pests may enter.

Treat a band of vegetation and leaf litter 6 to 10 feet wide around the outside of buildings to help control ticks occurring there.

To help control ticks in outdoor activity areas, treat a band of vegetation and leaf litter 6-10 feet wide and adjacent to activity areas, especially where dense vegetation occurs.

FOR CONTROL OF ORNAMENTAL GARDEN INSECTS:

For use on roses, dahlias, asters and other ornamentals to kill *Japanese Beetles* hit by spray as well as *Whiteflies, Aphids, Exposed Thrips, Spiders, Red Mites* and *Leafminers.* May be used on plants as a multi-purpose spray in small gardens and for spot treatments of incipient insect infestations to prevent spreading in large garden areas.

May also be used on other plants such as African violets, asters, azaleas, begonias, carnellias, carnations, chrysanthemums, dahlias, delphiniums, dogwoods, English ivy, eunonymus, fuschia, geraniums, crassula, grape vines, Kentia palms, laurels, marigolds, rhododendrons, roses, rubber plants, snapdragons, stocks, wandering Jews and zinnias.

EFFECTIVE WHEN USED AS DIRECTED AGAINST *Whiteflies, Aphids, Spider* and *Red Mites, Exposed Thrips, Lace Bugs, Japanese Beetles, Pavement Ants, Clover Mites* and *Armyworms*: When spraying plants, do not operate closer than 18 inches. Use sweeping motion. Be cautious about wetting tender foliage, young plants and new growth. Do not spray plants when temperatures exceed 90°F. Contact insects directly whenever possible.

Adult Mosquito CONTROL: Apply as a fine mist to thoroughly treat the entire area. For best results, treat when the wind velocity does not exceed 5 miles per hour but do not apply when wind speeds exceed 10 miles per hour. Treat shrubbery or vegetation where mosquitoes may rest. Apply at a rate of 2.5 pints per acre (0.9 ounce per 1000 square feet). Using truck-mounted conventional misting equipment such as Rotomist models 51C, 91 or 100 HT traveling at 5 mph to treat a 300 foot swath, calibrate equipment to deliver 0.95 gallon per minute. Under no conditions should open water be treated with this product. Not to be used within 100 feet (30 meters) of lakes and streams.

STORAGE AND DISPOSAL

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

Pesticide Storage And Spill Procedures: Store upright at room temperature. Avoid exposure to extreme temperatures. In case of spill or leakage, soak up with an absorbent material such as sand, sawdust, earth, fuller's earth, etc. Dispose of with chemical waste. **Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINERS LARGER THAN ONE GALLON:

Container Disposal: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available.

Metal Containers - Triple rinse or equivalent. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Plastic Containers - Triple rinse or equivalent, then offer for recycling or reconditioning, 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.

Glass Containers - Triple rinse or equivalent. Then dispose of in a sanitary landfill or by other approved state and local procedures.

CONTAINERS ONE GALLON AND SMALLER:

Disposal: If empty: <u>Non-refillable container</u>. Do not reuse <u>or refill</u> this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800 CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

Master Label

February 4, 2011 Page 5 of 5

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following conditions, disclaimer of warranties and limitations of liability. **CONDITIONS:** The directions for use of this product are believed to be adequate and should <u>must</u> be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Valent BioSciences Corporation. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, VALENT BIOSCIENCES CORPORATION MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Valent BioSciences Corporation is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. <u>To the extent consistent with applicable law</u>, Valent BioSciences Corporation disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product. LIMITATIONS OF LIABILITY: <u>TO THE EXTENT CONSISTENT WITH APPLICABLE LAW</u>, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT VALENT BIOSCIENCES CORPORATION'S ELECTION, THE REPLACEMENT OF PRODUCT.

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Valent BioSciences Corporation Environmental Science Division 870 Technology Way Libertyville, IL 60048 List No. 73049305 02-0735/R3