



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

APR 28 2011

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
Permanone General Purpose Aqueous Insecticide
EPA Reg. No. 73049-303
Your submission dated December 16, 2010

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated December 16, 2010 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 nonrefillable 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 pilitt.dana@epa.gov.

Sincerely,

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



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-303	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Permanone General Purpose Aqueous Insecticide	PM# 13	
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 to NOTIFICATION in composition and labeling to: EPA Reg. No. <u>APR 28 2011</u> Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<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.)

Label Notification - No Fee; e-mail: Nasser.Assaf@valent.com; Fax: (925) 817-5160

See Self Certifications statements on cover letter.

Changes include:

- Environmental Hazard and General labeling requirement per Agency's letter of June 4, 2009
- Revise Storage & Disposal Statements in Compliance with PR Notice 2007-4,
- Updated warranty statement in agreement with US EPA OPP Guidance on Warranty Statements (Oct. 17, 2006)
- No other changes have been made to the label other than those clearly marked.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* 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 checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 to 128 ounces		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" 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 Nasser A. Assaf, Ph.D	Title Manager, Product Safety and Regulatory Affairs	Telephone No. (Include Area Code) (847) 968-4788	
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 <i>MASSAF</i>	3. Title Manager, Product Safety and Regulatory Affairs		
4. Typed Name Nasser A. Assaf, Ph.D	5. Date December 16, 2010		

3048



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

December 16, 2010

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
Permanone General Purpose Aqueous Insecticide; EPA Reg. No. 73049-303

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.

Permanone General Purpose Aqueous Insecticide; EPA Reg. No. 73049-303; is ready-to-use liquid pyrethroid product for homeowners, indoor/outdoor 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 guidance 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,



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

Enclosures

cc: VBC Regulatory File

PERMANONE[®]

GENERAL PURPOSE

AQUEOUS INSECTICIDE

NOTIFICATION**APR 28 2011**

- *[For Domestic Use both Indoors And Outdoors*
- *A Ready-To-Use Permanone Stable Emulsion Insecticide*
- *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*
- *Provides 60-Day (Two Months) Control Of Cockroaches*
- *Provides 60-Day (Two Months) Control Of Fleas*
- *Provides 60-Day (Two Months) Control Of Stored Product Pests*
- *For Livestock And Premise Use]*

ACTIVE INGREDIENT:Permethrin¹0.50%**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. 73049-303**EPA EST. NO.****KEEP OUT OF REACH OF CHILDREN****CAUTION****See rear panel for additional precautions.****NET CONTENTS:**

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

In case of *Medical* emergencies or health and safety inquiries or in case of fire, leaking or damaged containers, information may be obtained by calling 1-877-315-9819.

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 surface applications. Do not use on humans. Do not allow children or pets to contact treated areas until surfaces are dry.

Do not use on dogs under twelve (12) weeks old. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing animals. 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. ~~Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is 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.~~

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.

Affix trigger, pump or other type sprayer to container for application. Do not transfer to another container.

SHAKE WELL BEFORE USING

Do not use on electrical equipment or on surfaces that can be harmed or stained by water.

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

INDOOR APPLICATION

For spot application only. Do not use as a space spray indoors. Do not apply to classrooms while in use. In the home, cover all food processing surfaces and utensils during treatment or thoroughly wash before use. Cover or remove exposed food/feed.

SURFACE SPRAYING:

For 60-Day [Two Months] control of *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.

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.

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*, *Mosquitoes* 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: Treatment to soil or vegetation around structures; applications to lawns, turf, and other vegetation; and applications to building foundations up to a maximum height of 3 feet. Other than application 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 crack-and-crevice applications only.

TO CONTROL *Ticks*, Including *Ticks Which May Carry Lyme Disease* (perimeter treatment):

Use Permanone General Purpose Aqueous Insecticide 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 ft²).

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:

Not for use on plants grown for sale or other commercial or research purposes. Not for use in commercial greenhouses, nurseries, on sod farms or grass grown for seed.

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 multipurpose 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, camellias, 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.

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STORAGE AND DISPOSAL

Storage: Store in a cool, dry area away from children and pets.

Container Disposal: *If empty:* ~~Non-refillable container.~~ Do not reuse ~~or refill~~ 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. 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~~ **must** 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. ~~To the extent consistent with applicable law,~~ 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: ~~TO THE EXTENT CONSISTENT WITH APPLICABLE LAW,~~ 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.

~~[Or alternate text]~~

~~Note [Notice]: Seller warrants that this product complies with the specifications expressed in this label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability or default, breach or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.]~~

~~Or~~

~~NOTICE: To the extent consistent with applicable law, buyer assumes all responsibility for safety and use not in accordance with directions.]~~

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Permanone is a registered trademark of the Bayer AG.

Valent BioSciences Corporation
Environmental Science Division
 870 Technology Way
 Libertyville, IL 60048
 List No. 73049303
 02-0734/R3