

73049-379

11-4-2008

1/5



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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Dr. Nasser Assaf, Ph.D.  
Valent BioSciences Corporation  
870 Technology Way, Suite 100  
Libertyville, IL 60048

NOV 4 2008

SUBJECT: Application for Pesticide Notification (PRN 98-10)  
Request General Label Change  
EPA Reg. No. 73049-379  
Application Dated August 7, 2008

Dear Registrant:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 08/07/08 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please me directly at 703-305-6249 or Owen F. Beeder of my staff at 703-308-8899.

Sincerely,

A handwritten signature in black ink, appearing to be "Linda Arrington".

Linda Arrington  
Notifications & Minor Formulations Team Leader  
Registration Division (7505P)  
Office of Pesticide Programs



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input checked="" type="checkbox"/>	Amendment
<input type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-379	2. EPA Product Manager George LaRocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Permanone Technical 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)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>NOV 04 2008</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.) 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. 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: correction of typo (omitted statement) per PR Notice 98-10 Section IV A.

- Reinstating omitted statement from Stamped Accepted label of June 25, 2008, from previous Stamped Accepted Label dated August 20, 2007. "For mosquito control (ULV) products."

- 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 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
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
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	
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 Nasser A. Assaf, Ph.D	Title Regulatory Manager, ESD	Telephone No. (include Area Code) (847) 968-4788
<b>Certification</b> 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.		<b>6. Date Application Received</b> (Stamped)
2. Signature <i>NASSAF</i>	3. Title Regulatory Manager, ESD	
4. Typed Name Nasser A. Assaf, Ph.D	5. Date August 7, 2008	

# PERMANONE<sup>®</sup> TECHNICAL INSECTICIDE

## NOTIFICATION

NOV 04 2008

• *For The Formulation Of Insecticides Only*

<b>ACTIVE INGREDIENT:</b>	
Permethrin*.....	95.0 %
<b>OTHER INGREDIENTS:</b> .....	
	5.0 %
	100.0 %

\*Cis-trans isomers ratio: Max. 55% (+/-) cis and min 45% (+/-) 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. 73049-379  
Item No. 15838, 15433, 115333, 20856

EPA EST NO.

**KEEP OUT OF REACH OF CHILDREN**

### CAUTION

See Side Panel For Additional Precautionary Statements

FIRST AID	
<b>If Inhaled:</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, all 911 or an ambulance, then give artificial respiration, preferable mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<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 Swallowed:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</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>
HOT LINE NUMBER	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. 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.</p>	

**NET CONTENTS:**

## PRECAUTIONARY STATEMENTS Hazards To Humans & Domestic Animals

### CAUTION

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

### Environmental Hazards

This product is extremely toxic to fish. Keep out of lakes, streams, ponds, tidal marshes or estuaries. Do not contaminate water by cleaning equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional office of the EPA.

### Physical and Chemical Hazards

Do not use or store near heat or open flame.

### DIRECTIONS FOR USE

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

This material requires further mixing before use.

Formulators using this product are responsible for obtaining EPA registration for their formulated products.

**Only for formulation into an insecticide for the following uses:**

**General Outdoor Insect Control:** Do not apply more than 2 pounds active ingredient per acre per year.

**Terrestrial Food (Residential Garden Uses Only).**

**Terrestrial Non-Food & Domestic Outdoor:**

- Christmas Trees (container & field-grown)
- Chrysanthemums
- Conifers (container & field-grown)
- Domestic Farm Animals: Cattle, Horses, Hogs, Poultry
- Agricultural Premise
- Companion Animals
- Termiticide and Soil Contact Nonfumigation Treatment
- Wood Treatment & Protection
- Ornamental plants, trees, shrubs and vines (woody)
- Lawn & Turf grasses
- Ornamental Nursery Stock (field-grown)
- Pine Seed Orchards
- Roses (field-grown & greenhouse)

**General Indoor Insect Control: Residential Areas; Commercial, Industrial, Institutional; Food Handling Establishments:** Places other than private residences in which food is held, processed, prepared or served.

**Non-Food/Feed Areas:** May be used to manufacture end-use products for use as a general spot or crack and crevice treatment in non-food areas. Similar areas where insects hide or through which insects may enter can be treated. Examples of non-food areas include: 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).

**Food/Feed Areas:** May not be used to manufacture products for use in food/feed areas. Do not use in food areas of food handling establishments, restaurants or other areas where food 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, all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed food should be covered or removed. Examples of food areas are areas for receiving, storage, packing (canning, bottling, wrapping, boxing), preparing, edible wastes storage and enclosed processing systems (mills, dairies, edible oils, syrups), serving areas (when food is exposed and facility is in operation) also would be considered a food area.

Fiber Product Production; Human Articles and Materials; Human Body Hair and Skin

**Note: Not for use to formulate products to be used:**

- In greenhouses where crops for food or feed are grown
  - In warehouses where raw or cured tobacco is stored.
  - In warehouses where raw agricultural commodities for food or feed are stored.
- For mosquito control (ULV) products.

This product may be used to formulate products for any additional uses not listed on this label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such uses.

### STORAGE AND DISPOSAL

**Prohibitions:** Do not contaminate other pesticides, fertilizers, water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

**Pesticide Storage:** Keep out of reach of children and animals. Store in original containers only. Store in a cool, dry place and avoid excess heat. Protect from freezing. Do not store near food or feed. Carefully open containers. After partial use, replace lids and close tightly. Keep container closed when not in use. Do not put concentrate or dilute material into food or drink containers. In case of spill, avoid contact, isolate area and keep out animals and unprotected persons. Confine spills. To Confine spill: If liquid, dike surrounding area or absorb with sand, cat litter or commercial clay. If dry material, cover to prevent dispersal. Place damaged package in a holding container. Identify contents.

**Pesticide Disposal:** Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Disposal:** Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying.

[5 gallons or less]

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 solvent used in the end use product 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.

[Greater than 5 gallons/50 lbs.]

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with solvent used in the end use product. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

### 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 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.

©Valent BioSciences Corporation, 2008

Permanone is a registered trademark of Bayer AG.

Valent BioSciences Corporation  
Environmental Science Division  
870 Technology Way  
Libertyville, IL 60048  
List No. 73049379

02-0824/R3

