

73049-300

2/21/2009

1 of 8



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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Mr. Nasser A. Assaf PhD  
Valent Biosciences Corporation  
870 Technology Way  
Libertyville, IL 60048

FEB 21 2009

Subject: Label Notification(s) for Pesticide Registration Notices 2007-4 and 98-10  
Storage Disposal change and Warranty Statement Update

Dear Registrant:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notices (PRN) 2007-4 and 98-10 dated January 20, 2009 for:

**EPA Registration 73049-300**

**Pyrenone Flea & Tick Dip**

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and 98-10, and finds that the label change(s) requested falls within the scope of PRN-2007-4 and 98-10. The label has been date-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, please contact me directly at 703-305-6249 or Banza Djapao of my staff at 703-305-7269.

Sincerely,

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

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 73049-300	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Pyrenone Flea & Tick Dip	PM# 10	
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 <b>NOTIFICATION</b> (b)(1), my product is similar or identical in composition and labeling to: 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 _____
<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 change per PR-Notice 2007-4 and PR Notice 98-10. This notification is consistent with the guidance in PR Notice 2007-4, PR Notice 98-10 and the requirement of EPA regulations at 40 CFR 152.46, 156.10, 156.140, 156.144, 156.146, and 153.156. 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 the amended label is not consistent with the terms of 40 CFR 152.46, 156.10, 156.140, 156.144, 156.146, and 153.156 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.

**NOTIFICATION OF:** Addition of "non-refillable container" and "Do not reuse or refill this container." per PR-Notice 2007-4; Correction of warranty statement per US EPA Guidance on Warranty Statements October 17, 2006.

**Section - III**

1. Material This Product Will Be Packaged In:					
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	2. Type of Container <input 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 4 to 128 ounces		5. Location of Label Directions <input 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 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) 968-4844
<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.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Manager, ESD	
4. Typed Name Nasser A. Assaf, Ph.D.	5. Date January 20, 2009	

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**READ ENTIRE LABEL BEFORE EACH USE  
USE ONLY ON DOGS OR CATS**

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

**PRECAUTIONARY STATEMENTS  
Hazards To Humans**

**Caution**

Harmful if swallowed. Avoid contact with eyes. Do not contaminate food or feedstuffs with this concentrate or diluted solution.

**Hazards To Domestic Animals**

Do not use on dogs or cats 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.

**DIRECTIONS FOR USE**

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

FOR CONTROL OF *Ticks, Fleas* and *Lice* ON DOGS AND CATS, dilute 4 ounces of concentrate with 1 gallon of water. Dip animal into solution, making sure hair is thoroughly wet to the skin.

FOR CONTROL OF *Ear Mites*, while animal is still dripping from treatment, lightly sponge inside of animal's ears. Do not rinse. Towel dry. Reapply weekly if necessary.

FOR CONTROL OF *Ticks, Fleas* and *Lice* ON DOGS AND CATS AS A SPONGE-ON, dilute 4 ounces of concentrate with 1 gallon of water (1:32). Sponge on animal, making sure hair is thoroughly wet to the skin.

For control of *Ear Mites*, lightly sponge inside of animal's ears. Do not rinse. Towel dry. Repeat application weekly if necessary.

**STORAGE AND DISPOSAL**

**STORAGE:** Store in original container in a cool dry place inaccessible to children and pets.

**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 any 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

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# PYRENONE® FLEA & TICK DIP

- *A Concentrated Dip For Dogs And Cats*
- *A Concentrated Sponge-On For Dogs And Cats*
- *Kills Fleas, Ticks, Lice And Ear Mites*
- *Alcohol Free - Prevents Dry Skin*
- *Quick Knockdown*
- *Quick Kill*
- *Moisturizes/Conditions Skin*
- *Gentle To The Skin*
- *Simple, Easy And Convenient To Use*
- *Easily Sponges On*

**NOTIFICATION**

**FEB 21 2009**

**ACTIVE INGREDIENTS:**

Pyrethrins .....	0.30%
Piperonyl Butoxide* .....	3.00%
<b>OTHER INGREDIENTS:</b> .....	<b>96.70%</b>
	100.00%

\*Equivalent to 2.4% (butylcarbityl)(6-propylpiperonyl) ether and 0.6% related compounds.

**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.)

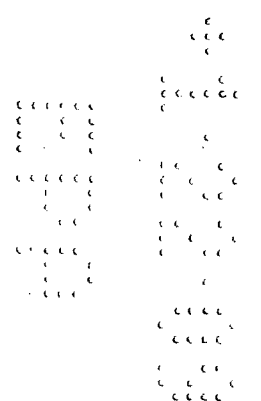
**EPA REG. NO. 73049-300**

**EPA EST. NO.**

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

**See Side Panel For Additional Precautions**

**NET CONTENTS:**



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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.

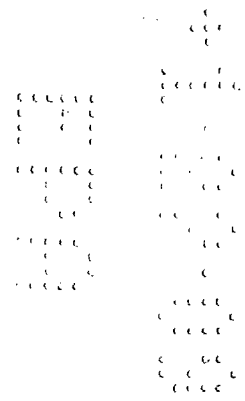
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[100% satisfaction guaranteed.]

Pyrenone is a registered trademark of Bayer AG.

**Valent BioSciences Corporation**  
**Environmental Science Division**  
870 Technology Way  
Libertyville, IL 60048

List No. 73049300  
02-0677/R5



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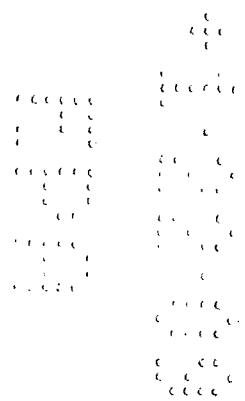
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