

73049-289

9/9/2009



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

RECEIVED

SEP 14 2009

Valent BioSciences Corporation  
OFFICE OF Regulatory Affairs  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

DOC ID# 1876

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

SEP - 9 2009

Dear Dr. Assaf:

Subject: Application for Pesticide Notification (PRN98-10)  
Revise per Pesticide Registration Notices 2008-1 (Environmental Hazards),  
2007-4 (Container Disposal), and 98-10 (Warranty Statements)  
Pyrenone Flea & Tick Spray  
EPA Reg. No. 73049-289  
Your submission dated August 6, 2009

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated August 6, 2009 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.

Sincerely,

*Dana R Pilett*  
for Richard Gebken  
Product Manager 10  
Insecticide Branch  
Registration Division (7505P)

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United States  
**Environmental Protection Agency**  
 Washington, DC 20460

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

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 73049-289	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 Spray	PM# 13 / 13 64	
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. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), 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.)

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 Statements per PR Notice 2008-1
- 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 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 ounce to 1 gallon		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 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
<p align="center"><b>Certification</b></p> <p>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.</p>		6. Date Application Received  (Stamped)
2. Signature 	3. Title Regulatory Manager, ESD	<div style="border: 2px solid black; padding: 5px; display: inline-block;"> <b>ACCEPTED</b>                  9-9-09             </div>
4. Typed Name Nasser A. Assaf, Ph.D	5. Date August 6, 2009	

# PYRENONE<sup>®</sup>

## FLEA & TICK SPRAY

- For Use On Cats And Dogs And On Premises To Control Fleas And Ticks
- An Aqueous, Stable, Micro Emulsion
- Alcohol Free - Prevents Dry Skin
- Guaranteed Results Or Your Money Back

**ACTIVE INGREDIENTS:**

Pyrethrins.....	0.06 %
Piperonyl Butoxide.....	0.60 %
<b>OTHER INGREDIENTS:</b> .....	<u>99.34 %</u>
	100.00 %

**PRECAUCION AL USUARIO:** Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada amplimente.  
**(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. 73049-289

EPA EST. NO.

**KEEP OUT OF REACH OF CHILDREN**

### CAUTION

FIRST AID	
<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 the 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>
<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>
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>	

See Side Panel For Additional Precautions

NET CONTENTS:

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

**PRECAUTIONARY STATEMENTS**  
**Hazards To Humans & Domestic Animals**

**CAUTION**

Harmful if swallowed. Avoid inhalation of vapors. Wash contaminated skin promptly with soap and water after use. Remove contaminated clothing and wash clothing before reuse. Avoid spraying food or foodstuffs. Remove birds and cover fish aquariums before spraying.

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.

**Environmental Hazards**

This product is toxic to fish. ~~Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate.~~ To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Apply 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.

**DIRECTIONS FOR USE**

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

**SHAKE WELL BEFORE USE**

**ON PETS**

Start spraying at the tail, moving the dispenser rapidly and making sure that the animal's entire body is covered, including the legs and under body. While spraying, fluff the hair so that spray will penetrate to the skin. Make sure spray wets thoroughly. Do not spray into eyes, face or genitals. Repeat application weekly if necessary.

**ON LIVESTOCK**

To protect cattle, horses and hogs from *Horn Flies*, *Houseflies*, *Mosquitoes* and *Gnats* apply a light mist sufficient to wet the surface of the hair. 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 2 to 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.

For control of *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 PREMISES**

To control *Fleas* and *Brown Dog Ticks* on premises: Thoroughly spray infested areas, pet beds, resting quarters, nearby cracks and crevices, along and behind baseboards, moldings, window and door frames, and localized areas of floor and floor covering. Place fresh bedding in animal quarters following treatment. Concurrent treatment of animals is recommended.

**STORAGE AND DISPOSAL**

**Storage:** Store in original container in a cool, dry place inaccessible to children and pets and away from heat and direct sunlight. Protect from freezing.  
**Disposal:** *If empty: Nonrefillable 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 1-877-315-9819] 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

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**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.

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*[Or alternate text*

Note: Seller warrants that this product complies with the specifications express 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 the applicable law, Seller shall have not 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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Pyrenone is a registered trademark of the Bayer AG.

Valent BioSciences Corporation  
Environmental Science Division  
870 Technology Way  
Libertyville, IL 60048  
List No. 73049289  
02-0606/R3

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