



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460-0001

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

January 21, 2010

Mr. Nasser A. Assaf, Ph.D.,  
Regulatory Manager, ESD  
Valent BioSciences Corporation  
870 Technology Way, Suite 100  
Libertyville, IL 60048-6316

**Subject: Amended Labeling, Correction of Typographical Errors & Response to SAL of October 29, 2004  
PYRENONE® Flea & Tick Spray, EPA Reg. No. 73049-289  
Your Submission Dated November 5, 2009**

Dear Mr. Assaf:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following label revision provision(s):

General Comment:

1. Delete all text throughout the label marked with "strikethrough."
2. In all instances throughout the proposed label, replace the word "control" with the word "kill."

Optional Marketing Statements section comment(s):

3. Revise optional marketing statement #1 to read "For Use on Cats and Dogs (Over 12 Weeks of Age) and on Premises To Kill Fleas and Ticks."
4. Delete optional marketing statement #3 since this statement is an implied safety claim. You cannot talk about the absence of an ingredient that was not there to begin with.

Ingredient Statement section comment(s):

5. Revise the listing for the ingredient Piperonyl Butoxide to read "Piperonyl Butoxide Technical\*"
6. Add the following footnote on the proposed label for piperonyl butoxide technical as follows: "\*Equivalent to 0.48% of (butylcarbityl)(6-propylpiperonyl) ether and 0.12% of related compounds."

First Aid Statement section comment(s):

7. Replace the 2<sup>nd</sup> sentence in the **HOT LINE NUMBER** subsection with: "For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-877-315-9819."<sup>1</sup>

<sup>1</sup> Please note that the "1-877-315-9819" number listed must be available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

Precautionary Statements section, Hazards to Humans & Domestic Animals subsection comment(s):

- 8. Revise this subsection to read: "Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing vapors. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Avoid contamination of food and foodstuffs."

Environmental Hazards section comment(s):

- 9. To facilitate inclusion of language from the REDs for pyrethrins and piperonyl butoxide, replace this section with:

**"Environmental Hazards**

This product is toxic to aquatic organisms, including fish and invertebrates. Drift and run-off may be hazardous to aquatic organisms in water adjacent to treated areas.

This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area. See Directions for Use for additional precautions and restrictions."

Directions for Use section comment(s):

- 10. To facilitate inclusion of language from the REDs for pyrethrins and piperonyl butoxide, add the following new subsection in its own text box immediately following the statement "It is a violation of Federal law ..." as follows:

<b>USE RESTRICTIONS &amp; PRECAUTIONS</b>
<ul style="list-style-type: none"> <li>• Apply this product only as specified on this label.</li> <li>• Do not contaminate of food or feedstuffs.</li> <li>• For pet care: Do not apply to pets less than 12 weeks old. Consult a veterinarian before applying 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.</li> <li>• For direct application to non-domestic animals/livestock: Do not apply more than 1 time per day.</li> <li>• Remove birds and cover fish aquariums before spraying.</li> </ul>

- 11. Replace the subsection entitled "**ON PETS**" with:

**"FOR DIRECT APPLICATION TO CATS AND DOGS (OVER 12 WEEKS OF AGE):**

Hold the container upright. Spray at a distance of 8 to 12 inches. Starting at the tail, spray over entire hair coat while moving the dispenser rapidly; making sure the coat is thoroughly wetted to the skin. While spraying, fluff the hair so the spray will penetrate to the skin. Make sure spray wets ticks thoroughly. Spray against the lay of the hair, roughing the hair on long-haired cats or dogs. Do not spray into the eyes, face or genitalia. For best results in killing ticks, spray directly on the tick. Allow cat or dog to air dry or blow dry. Do not towel dry. Do not reapply more often than once every 14 days."

Within the subsection entitled "**ON LIVESTOCK**":

- 12. Revise the subsection title "**ON LIVESTOCK**" to read "**FOR DIRECT APPLICATION TO NON-DOMESTIC ANIMALS/LIVESTOCK:**"
- 13. In the 2<sup>nd</sup> sentence of the 1<sup>st</sup> paragraph, replace the word "control" with the word "kill."
- 14. Replace the 3<sup>rd</sup> sentence of the 1<sup>st</sup> paragraph with "Do not reapply more than 1 time per day."
- 15. In the 1<sup>st</sup> sentence of the 2<sup>nd</sup> paragraph, replace the word "control" with the word "kill."
- 16. In the 1<sup>st</sup> sentence of the 3<sup>rd</sup> paragraph, replace the word "control" with the word "kill."
- 17. In the 1<sup>st</sup> sentence of the 4<sup>th</sup> paragraph, replace the words "control of" with the word "killing."

Directions for Use section comment(s), continued:

Within the subsection entitled "ON PREMISES":

- 18. Revise the subsection title "ON PREMISES" to read "FOR DIRECT APPLICATION TO RESIDENTIAL DWELLINGS, COMMERCIAL & INSTITUTIONAL INDOOR SITES AND PET PREMISES:"
- 19. In the 1<sup>st</sup> sentence of the 1<sup>st</sup> paragraph, replace the word "control" with the word "kill."

Storage and Disposal section comment(s):

- 20. To facilitate inclusion of language from PR Notice 2007-4, replace this section with:

**"STORAGE AND DISPOSAL**


**Pesticide Storage:** Do not store near heat or open flame. Store in original container in a cool, dry area that is inaccessible to children or pets.

**Container Disposal: If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain."

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at [Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov).

Sincerely Yours,

*for*  


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

*Enclosure: Label stamped "Accepted with Comments"*

073049-00289 D423900

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# 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 %

OTHER INGREDIENTS: ..... 99.34 %  
100.00 %

ACCEPTED  
With COMMENTS  
In EPA Letter Dated:  
*January 21, 2010*  
Under the Federal Insecticide, Fungicide  
and Rodenticide Act, As amended, for the  
pesticide Registered under EPA Reg. No:

73049-289

**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><u>If Inhaled:</u></b>	<ul style="list-style-type: none"> <li>• <u>Move person to fresh air.</u></li> <li>• <u>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</u></li> <li>• <u>Call a poison control center or doctor for further treatment advice.</u></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:

**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. 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:* 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 1-877-315-9819] 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 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.

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[Or alternate text

Note [Notice]: 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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