



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

AUG 9 2004

Janice K. Sharp, PhD.
Regulatory Manager, ESD
Valent Bio Sciences Corporation
870 Technology Way
Libertyville, IL 60048

**Subject: Label Amendment - Response to Agency's letter dated August 7, 2003
Pyraperm Flea & Tick Spray
EPA Reg. No. 73049-307
Your Submission Dated April 15, 2004**

Dear Dr. Sharp:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

1. Revise the Precautionary Statements as follows:
 - a. Replace "Wash thoroughly with soap and water after handling" with "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco."
 - b. Move "Avoid contamination of feed and foodstuffs" to the Directions for Use section.
2. Under Environmental Hazards revise the first sentence to read "This product is extremely toxic to fish and other aquatic organisms."

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If you have any questions regarding this action, please contact BeWanda Alexander of my team at (703) 305-7460.

Sincerely,



George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

PYRAPERM[®] FLEA & TICK SPRAY

- CONTROLS FLEAS & TICKS ON DOGS FOR 14 DAYS
- MAY BE APPLIED AS A DIRECT SPRAY TO CONTROL FLEAS, TICKS AND OTHER COMMON INSECT PESTS ON PREMISES
- CONTAINS PYRETHRINS COMBINED WITH PERMETHRIN AND PIPERONYL BUTOXIDE TO GIVE RAPID [FLUSH-OUT AND] KNOCKDOWN AND KILL
- SPECIALLY FORMULATED [DESIGNED] TO [PROVIDE FAST AND EFFECTIVE] KILL
- FAST KNOCKDOWN FORMULA
- FOR USE ON HORSES AND IN AND AROUND ANIMAL QUARTERS

**ACCEPTED
with COMMENTS
In EPA Letter Dated
AUG 9 2004**
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
73049-307

ACTIVE INGREDIENTS:

Pyrethrins	0.05 %
Piperonyl Butoxide*	0.50 %
Permethrin**	0.05 %
OTHER INGREDIENTS:	<u>99.40 %</u>
	100.00 %

* Equivalent to Min. 0.4% (butylcetyl)(6-propylpiperonyl)ether and 0.1% related compounds.
**Cis/trans ratio: min. 35% (+) cis and max. 65% (+) trans.

PRECAUCION AL USARIO: Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicado 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. 73049-307

EPA EST. NO.

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If inhaled:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferable by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If in eyes:	<ul style="list-style-type: none"> • Hold eye open and rise slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
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.	

See Side Panel For Additional Precautions

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

PRECAUTIONARY STATEMENTS
Hazards To Humans & Domestic Animals

CAUTION

Causes moderate eye irritation. Harmful if inhaled or absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Avoid contamination of feed and foodstuffs.

Environmental Hazards

This product is extremely toxic to fish. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes.

DIRECTIONS FOR USE

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

Do not use in commercial food/feed handling establishments, restaurants or other commercial establishments where food is commercially prepared, processed or served. In the home remove or cover all food processing surfaces and utensils during treatment or thoroughly wash before use. Remove or cover exposed food prior to treatment. Remove pets and birds, and cover fish aquaria.

SHAKE WELL BEFORE USING

When treating surfaces and fabrics where water alone could stain, spray in an inconspicuous area to test for possible staining or discoloration.

TO CONTROL Fleas and Ticks ON DOGS (FOR 14 DAYS)

APPLIED AS A SPRAY: Start spraying at the tail, moving the dispenser rapidly and making sure that the animal's entire body is treated, including the legs and underbody. Fluff the hair while spraying so that the spray will penetrate to the skin and thoroughly wet it. Do not spray into eyes or face. Avoid contact with genitalia. Repeat application every two weeks, if necessary.

Do not use on dogs under 12 weeks. **NOT FOR USE ON CATS.** 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.

APPLIED AS A DIP: Wet the dog with water before treatment. Sponge or pour PyraPerm on the dog until its fur and skin are thoroughly wet, making sure that the animal's entire body is treated, including the legs and underbody. Do not treat the dog's face. Avoid contact with genitalia. Repeat application every two weeks, if necessary.

TO CONTROL Fleas and Ticks ON PREMISES: Apply as a direct spray to control accessible stages of Fleas and Ticks. Spray to lightly dampen absorbent surfaces or to the point of runoff on nonabsorbent surfaces. Thoroughly spray infested areas, pet beds and resting quarters, cracks and crevices, along baseboards, moldings and window and door frames as well as localized areas of floor and floor covering. Do not use on electrical equipment or on surfaces that can be harmed or stained by water.

TO CONTROL CRAWLING INSECTS: Apply as a direct spray to control accessible stages of crawling insects including, but not limited to, *Cockroaches, Ants, Fleas, Ticks, Spiders, Silverfish* and *Crickets*. Spray to thoroughly wet exposed insects. Direct spray into hiding places, cracks and crevices, along baseboards and around door and window frames.

FOR USE ON HORSES

Use full strength. This non-oily insecticide may be applied with the trigger spray applicator, or as a wipe. Kills and repels *Horse Flies, Stable Flies, Horn Flies, House Flies, Face Flies, Deer Flies, Mosquitoes, Fleas, Gnats, Lice* and *Ticks*. Not for application if horses will be used for food. Directions for Wipe-on Use: Thoroughly brush horse to remove excess dirt and dust. Extremely dirty horses should be washed, and allowed to dry before applying product. Use a sponge or clean soft cloth or mitt. Apply PyraPerm liberally over areas to be protected. Pay special attention to legs, belly, shoulders, neck and facial areas. Avoid eyes and mucous membrane. Directions for Trigger Spray Use: Remove excess dirt and dust. Apply light mist to coat while brushing lightly against lay of hair. Avoid spraying in eyes, nose or mouth.

TO KILL AND REPEL FLYING INSECTS IN ANIMAL QUARTERS: Spray in areas where insects congregate. Direct spray to contact insects for rapid knockdown and kill. Spray around outside of door facings, around windows, and on screens to render areas unattractive to insects. This helps to repel insects and prevent entrance into buildings.

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STORAGE AND DISPOSAL

CONTAINERS LARGER THAN ONE GALLON: Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage And Spill Procedures: Store upright at room temperature. Avoid exposure to extreme temperatures. In case of spill or leakage, soak up with an absorbent material such as sand, sawdust, earth, fuller's earth, etc. Dispose of with chemical waste.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

CONTAINERS ONE GALLON AND SMALLER:

Storage: Store in original container in a cool, dry place inaccessible to children and pets.

Disposal: If empty: Do not reuse 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 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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Valent BioSciences Corporation
Environmental Science Division
870 Technology Way
Libertyville, IL 60048
List No. 73049307

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