

69407-1

3/30/2010

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 30, 2010

Ms. Kim Davis, CC, APC, Manager
Consultant/Agent for Animal Dermatology Laboratories
c/o RegWest Company, LLC
8203 West 20th Street, Suite A
Greeley, CO 80634-4696

**Subject: Amended Labeling, Updates per PR Notice 2007-4 & Addition of Marketing Statements
Flea, Tick and Ear Mite Treatment, EPA Reg. No. 69407-1
Your Submission Dated January 25, 2010**

Dear Ms. Davis:

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 provision(s):

General Comment:

1. Delete all text throughout the label marked with "strikethrough."
2. In all instances throughout this 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) to Kill Fleas, Ticks and Ear Mites."
4. Revise optional marketing statement #2 to read "For Direct Application to Residential Dwellings, Commercial & Institutional Indoor Sites and Pet Premises to Kill Fleas and Ticks."
5. Revise optional marketing statement #3 to read "Contains Pyrethrins, A Botanical Insecticide."

Ingredient Statement section comment(s):

6. Revise the listing for the ingredient "Piperonyl Butoxide, Technical (CAS No. 51-03-6)" to read "Piperonyl Butoxide, Technical (CAS No. 51-03-6)*"
7. Add the following footnote on the proposed label for piperonyl butoxide technical as follows: "*Equivalent to 1.20% of (butylcarbityl)(6-propylpiperonyl) ether and 0.30% of related compounds."

Directions for Use section comment(s):

8. 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:

USE RESTRICTIONS & PRECAUTIONS

- Apply this product only as specified on this label.
- Do not contaminate food or feedstuffs.
- 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. Do not reapply more often than once every 14 days.
- For direct application to non-domestic animals/livestock: Do not apply more than 1 time per day.
- Remove birds and cover fish aquariums before spraying.

Directions for Use section comment(s), continued:

9. Replace the subsection entitled "**For use on pets to control fleas and ticks:**" with: "**For direct application to cats and dogs (over 12 weeks of age) to kill fleas and ticks:** 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, including the legs and underbody. 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. **For direct application to cats and dogs (over 12 weeks of age) to kill ear mites:** Place 10 drops in each ear and massage. Do not reapply more often than once every 14 days."
10. Revise the subsection title "**For use on premises:**" to read "**For direct application to residential dwellings, commercial & institutional indoor sites and pet premises:**"
11. Revise the subsection title "**For use on livestock:**" to read "**For direct application to non-domestic animals/livestock:**"

Storage and Disposal section comment(s):

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

"Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals. **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: 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."

First Aid Statement section comment(s):

13. Replace the 2nd 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 1-800-521-2525." ¹

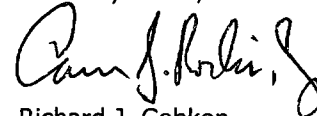
Precautionary Statements section, Hazards to Humans & Domestic Animals subsection comment(s):

14. 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."

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 Rodia at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely Yours,

For


Richard J. Gebken
 Product Manager (10)
 Insecticide Branch
 Registration Division (7504P)

Enclosure: Label stamped "Accepted with Comments"
 069407-00001 D427404

¹ Please note that the "1-800-521-2525" telephone 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.

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{Front Panel}

Flea, Tick and Ear Mite Treatment

For Use on Cats and Dogs to Control Fleas, Ticks and Ear Mites

For Use on Premises to Control Fleas and Ticks

Contains the Botanical Insecticide Pyrethrum[, an extract of the Chrysanthemum flower]

An Aqueous, Stable Microemulsion

Prevents Dry Skin

Active Ingredients:

Pyrethrins (CAS No. 8003-34-7)	0.15%
Piperonyl Butoxide, Technical (CAS No. 51-03-6)	1.50%
Other Ingredients	98.35%
Total	100.00%

Keep Out of Reach of Children

CAUTION

See back panel for First Aid and additional Precautionary Statements.

Net Contents: ____ fl. oz.

EPA Reg. No. 69407-1 EPA Est. 69407-CA-1

ADL Animal
Dermatology
Laboratories

P.O. Box 19097 Irvine, CA 92623

ACCEPTED
With COMMENTS
In EPA Letter Dated:
March 30, 2010
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No.:
69407-1

{Back Panel}

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS AND CATS [DOGS, CATS AND LIVESTOCK]

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

For use on pets to control fleas and ticks: Start by spraying at the tail, rapidly moving the dispenser and making sure that the animal's body is covered, including the legs and underbody. While spraying, fluff the hair so that spray will penetrate to the skin. Make sure spray thoroughly wets ticks. Do not spray into eyes, face or genitals. ~~Do not repeat treatment for three days.~~ **For use on pets to control ear mites:** Place ten drops in each ear and massage. Use twice a week for three weeks.

~~Do not use on puppies or kittens under 12 weeks. Consult a veterinarian before using this product on debilitated, medicated, aged, pregnant or nursing animals.~~

For use on premises: To control Fleas and Brown Dog Ticks 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. Fresh bedding should be placed in animal quarters following treatment. Concurrent treatment of animals is recommended. Repeat treatment as needed.

For use on livestock: To protect cattle, horses and hogs from Horn Flies, House Flies, 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 the rate of 2 ounces per adult animal, sufficient to thoroughly wet the hair. Repeat treatment daily or at intervals

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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** thoroughly spray roosts, walls and nests or cages, then spray a fine mist over the birds. For control of **Bedbugs** and **Mites** in poultry houses, spray crevices of roost poles, cracks in walls and cracks in nests where these insects hide.

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a cool, dry (preferably locked) place inaccessible to children and pets. Do not freeze. **Pesticide Disposal and Container Handling:** Non-refillable container; do not reuse or refill this container. **If empty:** Place in trash or 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.

First Aid

If Swallowed:	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
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, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If on Skin or Clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Immediately rinse skin with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-521-2525 for emergency medical treatment information.	

(Note: The First Aid statements' grid format will be used if market label space permits; otherwise a paragraph format will be used.)

To obtain more information or in case of an emergency call (800) 521-2525.

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

CAUTION: Humans: Harmful if swallowed. Avoid inhalation of vapors. Thoroughly wash with soap and water after use. Avoid spraying food and foodstuffs. When used as a premise spray indoors, remove pets, birds and cover fish aquariums before spraying. **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, immediately consult a veterinarian.

Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herewith.

{Per PR Notice 2007-4 the lot number or batch code will appear either on the container or label.}

[] Denotes alternate/optional language

{ } Denotes language that does not appear on the market label