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



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

5-15-13

Animal Dermatology Laboratories c/o Kimberlee Young RegWest Company, LLC 82303 West 20th Street, Suite A Greeley, CO 80634-4696

Subject:

Amended Reregistration Label

Product Name: Flea, Tick and Ear Mite Treatment

EPA Registration Number: 69407-1 EPA Decision Numbers: 410236, 411784

Dear Ms. Young,

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the Pyrethrins and Piperonyl Butoxide REDs, and has concluded that your submission is acceptable.

NOTE: This product is <u>not</u> being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time. Furthermore, any required mitigation language for pet spot-on products must be addressed in a separate amendment.

Please be aware that the record for this product currently contains the Confidential Statement of Formulation (CSF) listed below. Any previously dated CSFs are superseded.

Basic CSF, dated February 12, 2010

A copy of your label stamped "Accepted" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. Submit one copy of your final printed labeling before you release the product for shipment. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs

first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact Julie Chao at (703) 308-8735 or chao.julie@epa.gov.

Sincerely,

Richard J. Gebken

Product Manager (10)

Insecticide Branch

Registration Division (7504P)

Enclosures:

Label stamped "Accepted"

Acute Toxicity Review, dated February 28, 2011 Product Chemistry Review, dated March 30, 2012 {Front Panel}

Flea, Tick and Ear Mite Treatment

For Use on Cats and Dogs (over 12 weeks of age) to Kill Fleas, Ticks and Ear Mites
For Direct Application to Residential Dwellings, Commercial & Institutional Indoor Sites
and Pet Premises to Kill Fleas and Ticks
Contains Pyrethrins, A Botanical Insecticide
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)*	
Other Ingredients	
Total	
*(butyl carbityl)(6-propylpiperonyl) ether and related compou	ınds.

Keep Out of Reach of Children [CAUTION]

See back panel for additional Precautionary Statements.

Net Contents: ____ fl. oz. {2 fl. oz. through 1 gallon}

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

Animal Dermatology, Laboratories

P.O. Box 19097

Irvine, CA 92623

S-15-13

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Rea. No. 6 9407-/

{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.

Restrictions

- Apply this product only as specified on this label.
- Do not contaminate food or foodstuffs.
- Remove birds and cover fish aquariums before spraying.
- Only protected handlers may be in the area during application.
- Do not enter or allow others to enter until vapors, mists and aerosols have dispersed and the treated area has been thoroughly ventilated.
- Do not remain in treated area; immediately exit area and remain outside the treated area until aerosols, vapors and/or mists have dispersed.
- For direct application to non-domestic animals/livestock: Do not apply more than 1 time per day.

- When used in dairy barns or facilities: Close bulk milk container lids to prevent contamination from spray and from dead or falling insects. Remove or cover milking utensils before application. Wash animals' teats before milking.
- Do not apply directly into sewers or drains, or to any area like a gutter where drainage to storm sewers, water bodies or aquatic habitat can occur. Do not allow the product to enter any drain during or after application.

Personal Protective Equipment

All handlers must wear: long-sleeve shirt, long pants, shoes and socks.

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Users should immediately remove clothing/PPE if pesticide gets inside; then thoroughly wash and put on clean clothing.
- Users should immediately remove PPE after handling this product. Wash the outside of gloves before removing. As soon as possible, thoroughly wash and change into clean clothing.

Shake Well Before Use

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 8-10 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 thoroughly wets ticks. 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. 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.

For direct application to residential dwellings, commercial & institutional indoor sites and pet premises: To kill Fleas and Brown Dog Ticks thoroughly spray infested areas, pet beds, resting quarters, nearby cracks and crevices, along and behind baseboards, moldings, window & door frames and localized areas of floor & floor covering. Place fresh bedding in animal quarters following treatment. Concurrent treatment of animals is recommended. Repeat treatment as needed.

For direct application to non-domestic animals/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 kill 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 necessary to give continued protection. To kill 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 kill **Poultry Lice**: Thoroughly spray roosts, walls and nests or cages, then spray a fine mist over the birds. To kill **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: Keep this product in its tightly closed, original container when not in use. Store in a cool, dry (preferably locked) place 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.

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

PRECAUTIONARY STATEMENTS

Hazards to Domestic Animals

[CAUTION:] Do not use on puppies or kittens under 12 weeks of age: Consult a veterinarian before using this product on debilitated, medicated, 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, immediately consult a veterinarian.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-521-2525. [To obtain more information or in case of an emergency call (800) 521-2525.]

Environmental Hazards

This product is toxic to aquatic organisms, including fish and invertebrates. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. 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 visiting the treatment area.

To the extent consistent with applicable law, Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herewith.

[] Denotes alternate/optional language

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