

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



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 21, 2012

James McFadden
Wellmark International
1501 E. Woodland Rd., Suite 200W
Schaumburg, IL 60173

Subject: Amended Reregistration Label
Product Name: Elite Aloe Ear Mite Treatment for Dogs & Cats
EPA Registration Number: 2724-734
EPA Decision Numbers: 410795, 412044

Dear Dr. McFadden,

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 **not** being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label or durably marked on the container itself, and can be added by non-notification per PRN 98-10.

Please also note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated November 23, 2010
- Alternate CSF 1, dated November 23, 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. 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).

Finally, please be aware that should you wish to add/retain a reference to a website on your label, then the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, *regardless of whether a website is referenced on your product's label*, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website may be referred to the EPA's Office of Enforcement and Compliance Assurance.

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," dated February 21, 2012
Acute Toxicity Review, dated July 8, 2010
Product Chemistry Reviews, dated October 12, 2010, January 21, March 15, and
October 13, 2011*

ALTERNATE LANGUAGE appears in brackets [] and *italics*

ELITE ALOE EAR MITE TREATMENT FOR DOGS & CATS

KILLS EAR MITES ON CONTACT

[Contains Aloe to Help Soothe Irritated Skin]

[Easy to Use Applicator Tube]

[With Soothing Aloe & Lanolin][offers relief for (cats)(dogs) suffering from ear mites]

(FRONT OR BACK PANEL)

ACTIVE INGREDIENTS:

Pyrethrins.....	0.05%
Piperonyl Butoxide*.....	0.50%

OTHER INGREDIENTS:	99.45%
---------------------------------	---------------

Total.....	100.00%
------------	---------

*Butylcarbityl 6-propylpiperonyl ether and related compounds

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See Back Panel For [Ingredient Statement and] Precautionary Statements

NET CONTENTS: _____ 3 TUBES-
3 cc's 0.101 fl oz. each; 9 cc 0.303 fl oz. total.

EPA Reg. No. 2724-734
EPA Est. No.

ACCEPTED
FEB 21 2012

**Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:**

EPA. Reg. No: 2724-734

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON CATS OR DOGS.**

[Elite Aloe Ear Mite Treatment offers relief for dogs and cats suffering from ear mites. Dogs & cats that have ear mites will typically shake their heads and scratch their ears frequently. Ear Mites live in the ear canal of the animal and cause a brownish, waxy debris to be formed.][Ear mites usually induce the formation of a dry, dark brown, waxy exudate with crusts in the ears of pets.] Ear mites may be detected by placing some of the waxy debris on a dark surface and carefully watching for the movement of tiny white specks away from the debris. Inflamed, watery, or blocked ear canals indicate a more serious condition which requires the services of a veterinarian.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

HUMANS: Avoid contact with skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

ANIMALS: Do not use on puppies or kittens less than 12 weeks old. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals, or animals on medications. Avoid contact with eyes. 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.

FIRST AID	
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
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-xxx-xxxx for emergency medical treatment information.	

DIRECTIONS FOR USE

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

USE RESTRICTIONS:

The maximum application rate depends on animal weight and is 5 drops/day for animals 5-15 lbs, 10 drops/day for animals 16 - 30 lbs, and 15 drops/day for animals 30 lbs and over. Treatment can be applied daily for 7 to 10 days, then repeated 2 weeks after the last treatment, if necessary.

To Kill Ear Mites

Clean ears to remove built-up wax and dirt. While firmly holding pet, fill ear canal with labeled number of drops in each ear. Massage base of ear to insure insecticidal action penetrates ear wax. Gently dry ear with a cotton ball, soft cloth, or cotton swab. This product may be applied daily for 7 to 10 days. Repeat treatment in two weeks if necessary.

[Alternate tube directions]

- [(1) Remove one applicator tube from package and hold in an upright position.
- (2) Pull off cap. Turn the cap around and place on top of tube.
- (3) Simply press cap down to break the seal of tube and remove cap carefully.
- (4) Position the tip of the tube at the base of the pet's ear. Firmly hold pet and fill each ear canal with labeled number of drops.
- (5) Massage base of ear to insure insecticidal action penetrates ear wax.
- (6) Gently dry with a cotton ball, soft cloth or cotton swab.
- (7) After application, simply invert the cap of the tube and snap back on the tube for easy closure.]

(Alternate tube directions)

- [(1) Remove one applicator tube from package and hold in an upright position.
- (2) Hold bottom of tube with one hand. With other hand, snap cap off.
- (3) Position the tip of the tube at the base of the pet's ear. Firmly hold pet and fill each ear canal with labeled number of drops.
- (4) Massage base of ear to insure insecticidal action penetrates ear wax.
- (5) Gently dry with a cotton ball, soft cloth or cotton swab.
- (6) After application, simply invert the cap of the tube and snap back on the tube for easy closure.]

Body Weight

- 5 to 15 lbs. [**< 15 lbs.**]
- 16-30 lbs.
- 30 lbs. & over [**> 30 lbs.**]

Dosage

- 4-5 drops/day/ear
- 5-10 drops/day/ear
- 10-15 drops/day/ear

[Each tube contains 100 drops]

If conditions for which this preparation is used persist or if an irritation develops, discontinue use and consult a veterinarian.

For Use With a Swabstick:

Open packet, remove swabstick. While firmly holding pet, fill ear with liquid from packet. Massage base of ear to insure that insecticidal action penetrates ear wax. Use swabstick to remove as much waxy exudate as possible from outer ear.

This product may be applied daily for 7 to 10 days. Repeat treatment in two weeks if necessary.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in a cool, dry area away from heat or open flame.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: **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 for disposal instructions. Never place unused product down any indoor or outdoor drain.

6/7

In case of emergency or for product use information call 1-800-XXX-XXXX (distributors may elect to use their own phone numbers and hours of operation).
To learn more, visit www.adamsfleacontrol.com/www.hartz.com

To the extent consistent with applicable law, Seller makes no warranty, expressed or implied, concerning the use and handling of this product other than indicated on the label. To the extent consistent with applicable law, Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Wellmark International
1501 East Woodfield Road 200 W
Schaumburg, Illinois 60173

[ELITE ALOE EAR MITE TREATMENT SMALL TUBE COPY]:

Elite Aloe Ear Mite Treatment

Pyrethrins.....	0.05%
Piperonyl Butoxide.....	0.50%

CAUTION

See label for Precautionary Statements and Directions for Use

EPA Est. No.

EPA Reg. No. 2724-734

(contents)

Wellmark International
1501 East Woodfield Road 200 W
Schaumburg, IL 60173