



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
WASHINGTON, D.C. 20460

May 7, 2024

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

Subject: Notification per PRN 98-10 – Adding graphic of ear mite and claim “manufactured in USA from US and imported ingredients”
Product Name: Elite Aloe Mite Treatment for Dogs
EPA Registration Number: 2724-734
Application Date: April 23, 2024
Case Number: 608065

Dear Noelle Sanfilippo:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “NOTIFICATION” and placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 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) lists 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 will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, please contact Autumn Metzger at 202-566-2830 or Metzger.autumn@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Beth Fertich", followed by the word "for" written in a smaller, simpler script.

Beth Fertich, Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

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]

Graphic icons for optional use on label:



NOTIFICATION

2724-734

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

5/7/2024

(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: _____ 1/2 FL OZ (14.8 mL) or

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.

**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.

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.

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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)

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