



United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington DC 20460

Application for Pesticide:

Registration
 Amendment
 Other

OPP Identifier Number

270906

Section I

1. Company/Product Number 68688-41	2. Product Manager Mr. Marion Johnson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ELITE ALOE EAR MITE TREATMENT	PM# 10	
5. Name and Address of Applicant (include ZIP Code) SPEER PRODUCTS, INC. P. O. Box 18993 Memphis, TN 38181-0993 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

NOTIFICATION

Amendment - Explain below
 Resubmission in response to Agency letter dated 9/26/01
 Notification - Explain below.

Final printed label in response to Agency letter dated _____
 "ME TOO" Application.
 Other - explain below

OCT 18 2001

Explanation: Use additional page(s) if necessary. (For section I and Section II)

RESUBMISSION OF LABEL REMOVING THE WORD "NATURAL".
THE LABEL NOW READS "WITH SOOTHING ALOE AND LANOLIN"

Section III

1. Material in Which This Product Will Be Packaged:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes * <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water-Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted.		If "YES," Unit package wgt	No. per container	If "YES," Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed To Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section IV

1. Contact Point (Complete items directly below for identification of the individual to be contacted, if necessary, to process this application)			6. Date Application Received (Stamped)
Name Jean Butler	Title Regulatory Assistant	Telephone No. (include Area Code) 901/362-1950	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			
2. Signature 	3. Title Regulatory Assistant		
4. Typed Name Jean Butler		5. Date 10/10/01	

2 8 5

NOTIFICATION STATEMENT:

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

NOTIFICATION

OCT 18 2001

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]

ACTIVE INGREDIENTS:

Pyrethrins.....0.05%
*Piperonyl Butoxide, Technical.....0.50%
INERT INGREDIENTS:.....99.45%
100.00%

*Equivalent to 0.40% of Butylcarbityl 6-propylpiperonyl ether and 0.10% of related compound.

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NET CONTENTS: 3 TUBES, 3 cc's 0.06 fl oz. each, 9 cc 0.18 fl oz. total.

EPA Est. No. 11715 -TN-1 or [2596-NJ-1]
EPA Reg. No. 68688-41

MANUFACTURED BY:
SPEER PRODUCTS, INC.
4242 B.F. GOODRICH BLVD.
MEMPHIS, TN 38118

NOTIFICATION

OCT 18 2001

**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.

DIRECTIONS FOR USE

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

To Kill Ear Mites

Clean ears to remove built-up wax and dirt. While firmly holding pet, fill ear canal with recommended 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 recommended 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 recommended 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	Dosage
5 to 15 lbs. [<i>< 15 lbs.</i>]	4-5 drops/day/ear
16-30 lbs.	5-10 drops/day/ear
30 lbs. & over [<i>> 30 lbs.</i>]	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

3 2 5

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. Do not use on puppies or kittens less than 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals or animals on medications.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC
ANIMALS
CAUTION**

HUMANS: Harmful if swallowed. Avoid breathing vapors. Avoid contact with eyes. In case of contact, immediately flush eyes with plenty of water. Obtain medical attention if irritation persists. If swallowed, do not induce vomiting. Wash hands with soap and water after using.

ANIMALS: Avoid contact with eyes. If in eyes, flush with water. Do not use on any meat or milk producing 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.

FIRST AID

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting because of aspiration hazard.

IF ON SKIN: Wash immediately with soap and water.

IF IN EYES: Flush with plenty of water. See a physician if irritation persists.

IF INHALED: Remove victim to fresh air.

STORAGE AND DISPOSAL

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

DISPOSAL: Do not reuse empty container. Wrap and put in trash.

In case of emergency or for product use information call (901) 362-1950, Monday – Friday, 8:30 AM – 4:30 PM, CST (distributors may elect to use their own phone numbers and hours of operation).

485

***ELITE ALOE EAR MITE TREATMENT
SMALL TUBE COPY:***

Elite Aloe Ear Mite Treatment

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

CAUTION: Read label before use
USE ONLY ON CATS OR DOGS.

EPA Est. No. 11715-TN-1
EPA Reg. No. 68688-41 (contents)

SPEER PRODUCTS, INC.

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575