

2724-734 1-18-2008

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JAN 18 2008

Ms. Nancy Huebl
Product Registration
Wellmark International
1501 Woodfield Road, Suite 200W
Schaumburg, Ill 60173

SUBJECT: Application for Pesticide Notification (PRN 98-10)
Request Warning Statement Change
EPA Reg. No. 2724-734
Application Dated January 7, 2008

Dear Ms. Huebl:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 01/07/2008 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Owen F. Beeder of my staff at 703-308-8899.

Sincerely,

Linda Arrington
for Linda Arrington

Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173
847 330 5300
www.wellmarkinternational.com

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January 7, 2008

Document Processing Desk (NOTIF)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900 One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: Richard Gebken, PM 10

SUBJECT: LABEL NOTIFICATION FOR
ELITE ALOE EAR MITE TREATMENT FOR DOGS AND CATS
EPA REG. NO. 2724-734
ADD STREET ADDRESS/DELETE TUBE TEXT (NOT REQUIRED)

Dear Mr. Gebken:

Enclosed is completed EPA Form 8570-1 and 2 copies of revised labeling for the above product. A highlighted version is enclosed for your convenience in viewing the changes (red is new text, blue [strikeout] is deleted text). The change involves the addition of Wellmark's street address to the label and deleting one line of tube text that is not required text and already appears on the packaging blister card. I have enclosed a self-addressed postcard for notification confirmation.

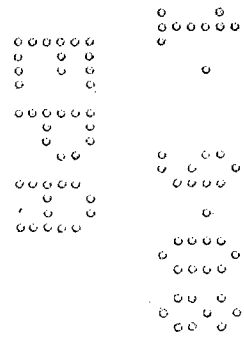
If you have any questions please, call me directly at 847-330-5376. Thank you for your assistance in this matter.

Yours sincerely,
WELLMARK INTERNATIONAL

Nancy Huebl
Senior Registration Specialist

enclosure

cc: R. Rosenwasser, Hartz Mountain





United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

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Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-734	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/Elite Aloe Ear Mite Treatment	PM # 10	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173 <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

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

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

Label notification to add street address and delete tube text that is not required to appear on tube (due to space constraints)
 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.

Section - III

1. Material This Product Will be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>printed cardboard card</u>
* Certification must be submitted	If "Yes" Unit Packaging wgt. 3 ccs	No. per container 3	If "Yes" Unit Packaging wgt. No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 3 tubes at 3 cc each	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other <u>printed cardboard card</u>	

Section - IV

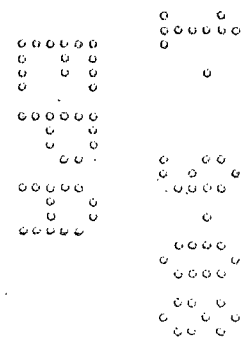
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Nancy Huebl	Title Senior Registration Specialist	Telephone No. (Include Area Code) 847-330-5376
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Nancy Huebl</i>	3. Title Senior Registration Specialist	(Stamp area with grid of dots)
4. Typed Name Nancy Huebl	5. Date 07-Jan-08	

REGULATORY LABEL DATA SHEET

File Name:	Epa notif street tube 108	Data Sheet Date:	January 2008
Product:	ELITE ALOE EAR MITE TREATMENT FOR DOGS & CATS	EPA Reg #:	2724-734 (68688-41)
Approved:	Notification submitted 1/7/08	Supersedes:	8/22/07

OVERVIEW: Label notification to add street address and modify tube artwork

Page #	Description of Major Changes
3	Added street address
4	Deleted phrase "Use only on cats or dogs". Because of small size of tubes and getting all required text on tube, and the fact that this statement already appears on packaging blister card that contains the tubes, deleted from tube text Added street address



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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, Technical* 0.50%

OTHER INGREDIENTS: 99.45%

Total..... 100.00%

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

KEEP OUT OF REACH OF CHILDREN

CAUTION

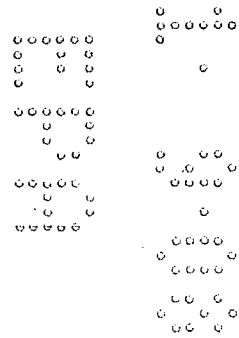
See Back Panel For [Ingredient Statement and] Precautionary Statements

NET CONTENTS: _____ 3 TUBES-

3 cc's 0.06 fl oz. each; 9 cc 0.18 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: Harmful if swallowed. Avoid breathing vapors. Avoid contact with eyes. 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.

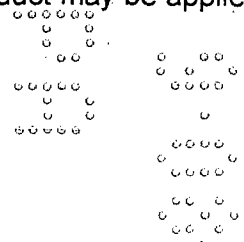
FIRST AID	
Call a poison control center or doctor immediately for treatment advice.	
IF SWALLOWED:	<ul style="list-style-type: none"> • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by 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.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
HOT LINE NUMBER	
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.

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.
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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.

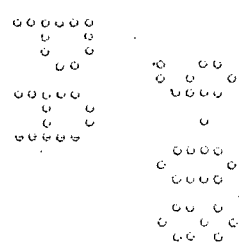
This product may be applied daily for 7 to 10 days. Repeat treatment in two weeks if necessary.

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.

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

To learn more, visit [URL]
 Wellmark International
 1501 East Woodfield Road 200 W
 Schaumburg, Illinois 60173



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[ELITE ALOE EAR MITE TREATMENT SMALL TUBE COPY]:

Elite Aloe Ear Mite Treatment

Pyrethrins 0.05%
Piperonyl Butoxide, Technical* 0.50%

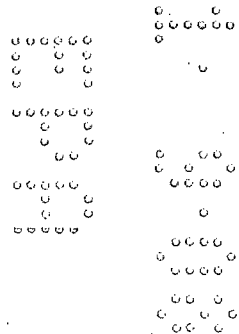
CAUTION

See label for Precautionary Statements and Directions for Use
~~USE ONLY ON CATS OR DOGS.~~

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

(contents)

Wellmark International
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Schaumburg, IL 60173



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(FRONT OR BACK PANEL)

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OTHER INGREDIENTS:..... 99.45%

Total 100.00%

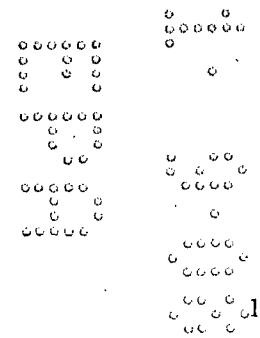
*Equivalent to 0.40% of Butylcarbityl 6-propylpiperonyl ether and 0.10% of related compounds

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

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EPA Reg. No. 2724-734
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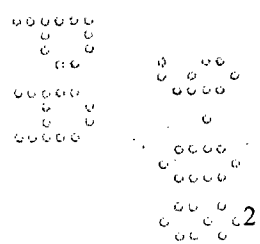
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[Alternate tube directions]

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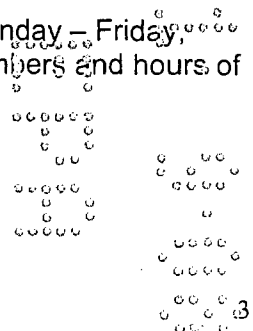
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