

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES AND PLANT
REGISTRATION DIVISION (75-767)
WASHINGTON, DC 20460

EPA REGISTRATION NO.

DATE OF ISSUANCE

656-43

MAR 9 1993

TERM OF ISSUANCE

Registration

NAME OF PESTICIDE PRODUCT

R & M Aloe Ear Mite
Treatment

NOTICE OF PESTICIDE: REGISTRATION
 REREGISTRATION

(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

R & M Regulatory Services, Inc.
5145 Forest Run Trace
Alpharetta, GA 30202-4504

160/5427311
18/1

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data or other material required for registration/reregistration of your product under FIFRA sec. 3(c)(5) or FIFRA sec. 4 when the Agency requires all registrants of similar products to submit such data.

2. Make the labeling change listed below before you release the product for shipment:

- a. Add the phrase, "EPA Registration No. 65636-43."
- b. Under "For use with a swabstick" revise as follows:
IMPORTANT: Do not use the swabstick for the ear canal (i.e. swab part should always be visible) to avoid damaging the delicate tissue of the ear.
- c. Under Precautionary Statements add: "Do not apply directly to food or contaminate food or feedstuffs with this product."

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

Robert 2-3-93

- d. Daily application of your product is excessive. Revise your application rates as follows:

"This solution applied twice monthly will reduce the possibility of ear mite infestation and the accumulation of ear wax. If no improvement is seen after 2 applications consult a veterinarian."

- e. Delete "natural soothing" adjectives preceding Aloe and Lanolin on front panel.

- f. Under Precautionary Statements add:

"Not for use on puppies, kittens, rabbits less than 7 weeks old. For external use only. Do not use for prolonged period of time."

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

A stamped copy of the label is enclosed for your records.

George T. LaRocca
Product Manager 13
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosures

PM13 65636-43

3044

**R & M ALOE EAR MITE TREATMENT
With Natural Soothing Aloe and Lanolin
FOR DOGS, CATS and RABLITS**

KILLS EAR MITES ON CONTACT

ACTIVE INGREDIENTS:

Pyrethrins	0.05%
*Piperonyl Butoxide, Technical	0.50%
INERT INGREDIENTS:.....	<u>99.45%</u>
	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 Precautionary Statements**

Manufactured by:
R & M REGULATORY SERVICES, INC.
5145 FOREST RUN TRACE, ALPHARETTA, GA 30202

EPA EST #65636-GA-1

EPA REG #65636-

Net Contents ___ oz.

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 ear exudate on a dark surface and carefully watching for the movement of tiny white specks away from the exudate. Inflamed, watery or blocked ear canals indicate a more serious condition which requires the services of a veterinarian.

DIRECTIONS FOR USE

It is 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated

MAR 9 1993

10/02/92 RM043

BEST AVAILABLE COPY

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 65636-43

4044

Body Weigh	Dosage
5 to 15 lbs.	4 to 5 drops
15 to 30 lbs.	5 to 10 drops
30 lbs. & over	10 to 15 drops

If condition for which this preparation is used persists 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 the outer ear. **IMPORTANT: Do not use the swabstick for the inner ear (i.e. Swab part should always be visible!)**

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

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.

**Precautionary Statement
Hazards to Humans and Domestic Animals
CAUTION**

Human: 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 meat or milk producing animals.

Statement of Practical Treatment

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 eyes with plenty of water. See a physician if irritation persists.

If Inhaled: Remove victim to fresh air.

