

MAY 22 1991

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Mr. Joseph C. Pavelchak
Schering-Plough Animal Health
Schering-Plough Corporation
P.O. Box 529
Kenilworth, NJ 07033

Dear Mr. Pavelchak:

Subject: Diocetyl Sodium Sulfosuccinate (DDS) from Active to Inert
Ingredient
Aurimite
EPA Registration No. 45860-1
Your Letter Dated April 15, 1991

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided that you make the labeling changes indicated below prior to release for shipment of product bearing the amended labeling.

- 1. Under the Directions for Use, add the following instructions for clarification to aid the customer's proper use of the product:

Shake well before using. Cleanse ear thoroughly. Apply the recommended drops into ears twice daily for 7 to 10 days. Repeat treatment in two weeks if necessary.

Body Weight	Dosage
5 to 15 lbs	4 to 5 drops
15 to 30 lbs	5 to 10 drops
30 lbs or over	10 to 15 drops

DIAGNOSIS: Ear mites usually induce the formation of a dry, dark brown, waxy exudate with crusts in the ears of Dogs and Cats. 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 with requires the services of a veterinarian.

CONCURRENCES							
SYMBOL	CGA						
SURNAME							
DATE							

2. Add the following precautionary statement under Hazards to Humans and Domestic Animals, "Avoid contact with eyes. Flush eyes with plenty of water. Get medical attention if irritation persists.", after the statement, "Avoid contact with skin."
3. The product is used for the control of ear mites (*otodectes cynotis*). Thus change the front label panel statement to read:

"For use as an aid in controlling ear mites in the ears of dogs and cats.

Submit five copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

This letter also acknowledges the removal the Dioctyl Sodium Sulfosuccinate (DDS) from active ingredient to inert ingredient. However, since the product formulation has changed significantly from when it was first registered, you must submit a complete set of product chemistry data. Please submit a revised Confidential Statement of Formula including the certified limits in column 14.

Sincerely,

George T. LaRocca
Product Manager 15
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure

cc Denise Greenway
SRRD

Silk Screened label for the 16 oz. Bottle

NDC-0061-0733-03



Aurimite.

For use as an aid in controlling ticks and mites in the ears of dogs and cats.

Active Ingredients: ~~1.952% diethyl sodium sulfocarbamate,~~
0.04% pyrethrins, 0.49% piperonyl butoxide technical*

Inert Ingredients: ~~95.556%~~ 99.47

*Equivalent to 0.392% of Butylcarbitol (6-propylpiperonyl ether) and 0.099% of related compounds.

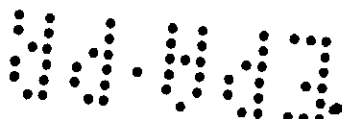
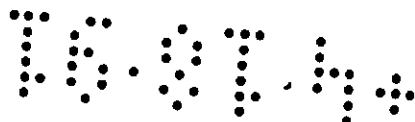
**KEEP OUT OF REACH OF CHILDREN
CAUTION**
See rear panel for additional precautions

EPA Est. 29809-CA-1

EPA Reg. No. 45860-1

16 FL. OZ. (1 PT.)

SCHERING CORPORATION U.S.A.



DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Shake well before using. Apply 10 drops into ears twice daily until ticks and mites are eliminated.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid inhalation of vapors. Avoid contact with skin. Wash contaminated skin promptly with soap and water. Avoid contamination of food and water.

STORAGE AND DISPOSAL: Store in original bottle in locked storage areas. Do not reuse bottle. Rinse thoroughly before discarding in trash.

Discontinue use and consult a veterinarian if infection persists.

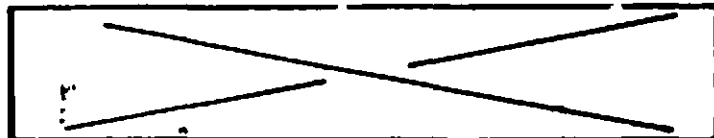
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ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 22 1991

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 45860-