

PM 13 45860-1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 31 1994

~~316-44627~~
17/5

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

Dear Mr. Pavelchak:

Subject: Amendment - Revised Labeling and Confidential Statement
of Formula
Aurimite
EPA Registration No. 45860-1
Your Letters Dated August 10 and November 3, 1993

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. Since the product is limited to use by veterinarians, you do not have to add the paragraph on "Diagnosis" in paragraph 1 of our May 22, 1991 letter.

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.

The Confidential Statement of Formula (CSF) dated August 10, 1993 will not meet the label claim for the nominal concentration for the active ingredients. The upper and lower certified limits are based on the pure active ingredient rather than the technical or concentrate. Refer the PR Notice 91-2 and 40 CFR 158.175 for guidance and revised the CSF and the labeling ingredient statement to reflect the nominal concentration of the pure active ingredient.

Sincerely yours,

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

CONCURRENCES

SYMBOL	Enclosure						
SURNAME	2/1/94						
DATE	1/6/94						

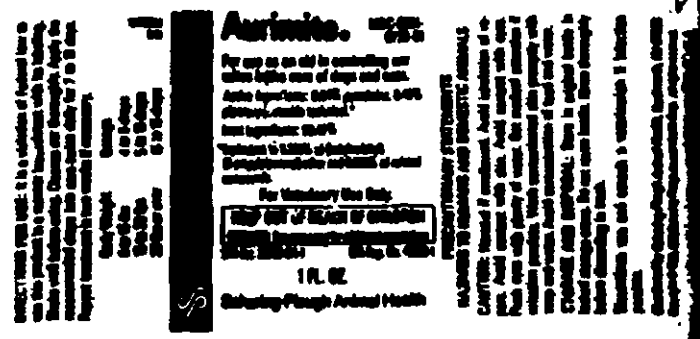
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ACCEPTED
with COMMENTS
in EPA Letter Dated

JAN 31 1994

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg

15860-1



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. 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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid inhalation of vapors. Avoid contact with skin. Avoid contact with eyes. Flush eyes with plenty of water. Get medical attention if irritation persists. 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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NDC-0061-0733-03

Aurimite®

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

Active Ingredients: 0.04% pyrethrins, 0.49% piperonyl butoxide technical.*

Inert Ingredients: 99.47%

*Equivalent to 0.392% of (butylcarbityl) (6-propylpiperonyl) ether and 0.098% of related compounds.

For Veterinary Use Only.

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

EPA Est. 29909-CA-1

EPA Reg. No. 45860-1

16 FL. OZ. (1 PT.)



Schering-Plough Animal Health