



000773-00087-060799

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Systems Integration Group, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 7, 1999

Mr. Joseph C. Pavelchak
Schering Plough Animal Health
1095 Morris Avenue
Union, New Jersey 07083

Subject: Label Revisions per PR Notice 96-6
Aurimite Insecticide
EPA Reg. No. 773-87
Your Letter Submitted February 10, 1999

Dear Mr. Pavelchak:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

- 1) Please remove the term "Precautionary Statement" from your "Hazards to Humans and Domestic Animals" section, and simply start the paragraph with "Sensitivities may occur...". Using the term "Precautionary Statement" in your Precautionary Statements section is confusing.
- 2) Based on your estimated tox categories, you must have a "First Aid" Statement. It should be located under your "Precautionary Statements" and state the following:

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

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

3) Please include your complete address (including the street) on the label.

If you have any questions regarding this action, please contact Tracy Keigwin of my team at (703) 305-6605.

Sincerely,

Tracy Lynn Keigwin

for
George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

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 2 weeks if necessary.

Body Weight	Dosage
5 to 12 lbs	4 to 5 drops
15 to 30 lbs	5 to 10 drops
30 lbs or over	10 to 15 drops

13508933 Rev. 4/97

Aurimite® 0061-0733-03

For use as an aid in controlling ear mites in the ears of dogs and cats. Contains: 0.04% pyrethrins, 0.49% piperonyl butoxide technical.*

Use Only On Dogs and Cats.

KEEP OUT OF REACH OF CHILDREN

EPA Est. 29909-CA-1 EPA Reg. No. 773-87

1 FL OZ.

Schering-Plough Animal Health

DO NOT REMOVE CONTAINER FROM CARTON EXCEPT FOR IMMEDIATE USE.

CAUTION: Refer to shell carton for Caution and Precaution information. Distributed by Schering-Plough Animal Health Corp., Union, NJ 07083. Copyright © 1985, 1991, 1997, Schering-Plough Animal Health. All rights reserved.

ACCEPTED with COMMENTS in EPA Letter Dated

JUN 7 1999

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 773-87

Silk Screened Bottles

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 2 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

Do not reapply product for 2 weeks. Do not use on dogs or cats under 12 weeks of age. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing animals, or animals on medication.

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.

PRECAUTIONARY STATEMENT: 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.

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 infestation persists.

EMERGENCY: Contact Rocky Mountain Poison Center (303) 595-4869. Distributed by Schering-Plough Animal Health Corp., Union, NJ 07083. Copyright © 1985, 1991, 1997, Schering-Plough Animal Health. All rights reserved. 13508933 Rev. 4/97

0061-0733-03

Aurimite®

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

Contains: 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.

Read Entire Label Before Each Use. Use Only On Dogs and Cats.

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

EPA Est. 29909-CA-1 EPA Reg. No. 773-87

16 FL. OZ. (1 PT.)



Schering-Plough Animal Health

ACCEPTED
with COMMENTS
in EPA Letter Dated

DIE2055

JUN 7 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
773-87

0061-0733-01

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

EPA Est. 29909-CA-1

EPA Reg. No. 773-87

12-1 FL OZ. BOTTLES



Schering-Plough Animal Health

Aurimite[®]**Aurimite[®]**

EMERGENCY: Contact Rocky Mountain Poison Center
(303) 595-4869.

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

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