

Reg # 45087-21

PM-10

194

APR 29 1991

Mr. Hal K. Bowman
Zema Corporation
P.O. Box 12803
Research Triangle Park, NC 27709

Dear Mr. Bowman:

Subject: Zema Ear Miticide for Dogs and Cats
EPA Registration No. 45087-21
Your Application Dated November 13, 1990

The proposed amendment to the registration of the product cited above under the Federal Insecticide, Fungicide, and Rodenticide Act changing the declaration of mineral oil from active to inert and changing the percentage of mineral oil and lanolin is acceptable. The Confidential Statement of Formula (CSF) dated November 13, 1990 is acceptable subject to the comment listed below. It has been made a part of the file.

- The pH is listed as 4.7 on the CSF and 4.8 in the chemistry data. Explain the discrepancy.

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CONCURRENCES

| | | | | | | | |
|---------|---------|--|--|--|--|--|--|
| SYMBOL | H75052 | | | | | | |
| SURNAME | Tavano | | | | | | |
| DATE | 4/24/91 | | | | | | |

The draft label enclosed with your application is acceptable subject to the comment listed below. A stamped copy is enclosed for your records.

- Add a physical hazard statement to read:

Physical Hazard

Do not use or store near heat or open flame.

Sincerely yours,



Richard F. Mountfort
Product Manager (10)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosures

The proposed label for the registration of the product listed above under the Federal Insecticide, Fungicide, and Rodenticide Act requires the declaration of physical hazard data to be placed on the label. The data listed on the label is as follows:

- The pH is listed as 1.7 on the label and 2.5 in the chemistry data. Explain the discrepancy.

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DRAFT LABEL

ZEMA EAR MITICIDE FOR DOGS (CATS)

CONTAINS LANOLIN

FRONT PANEL:

ACTIVE INGREDIENTS:

| | |
|--------------------------------|--------|
| Pyrethrins | 00.05% |
| *Piperonyl Butoxide, technical | 00.50% |

INERT INGREDIENTS:

99.45%

100.00%

ACCEPTED
with COMMENTS
in EPA Letter Dated
APR 29 1991
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
#5887-251

KEEP OUT OF REACH OF CHILDREN

CAUTION

Additional precautions on back panel

*Equivalent to 0.4% (butylcarbityl) (6-propylpiperonyl) ether and 0.1% related compounds.

Net Contents: 1 fl. oz.

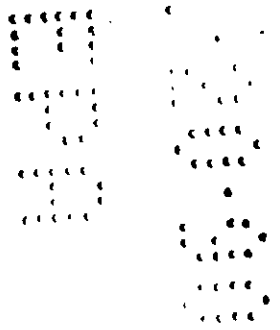
BACK PANEL:

PRECAUTIONARY STATEMENTS

Hazards to Humans and Animals

CAUTION: Not for human use. Harmful if swallowed or absorbed through skin. Avoid breathing vapors. Avoid contact either skin and eyes. If ingested, vomiting should not be induced. consult physician. In case of contact, flush eyes or skin with plenty of water. See physician if irritation persists.

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BACK PANEL CONTINUED

Draft Label for Zema Ear Miticide for Dogs (Cats)

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Remove excess dirt and wax. Place recommended dose in each ear. Repeat daily for 7 to 10 days. Repeat treatment as necessary.

BODY WEIGHT

DOSE

1 to 15 lbs.

3 to 5 drops

15 to 30 lbs.

5 to 10 drops

30 lbs. or over

10 to 15 drops

STORAGE AND DISPOSAL DIRECTIONS

Storage: Store in original container in locked storage area.

Disposal: Securely wrap original container in several layers of newspaper and discard in trash. Do not reuse bottle. Rinse thoroughly before discarding in trash.

EPA Reg. No. 45087-21

EPA Est. No. 45087-NC-1

Manufactured by: ZEMA CORPORATION
P.O. Box 12803
Research Triangle Park, NC 27709

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