

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 26 1993

3455427389
175

Mr. Hal Bowman
Zema Corporation
6514 Chapel Hill Road
Raleigh, NC 27607

Dear Mr. Bowman:

Subject: Revised Labeling and Revised Confidential Statement of
Formula
Zema Ear Miticide For Dogs and Cats
EPA Registration No. 45087-21
Your Application Dated September 24, 1992

The labeling 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 listed below before you release the product for shipment bearing the amended labeling:

- 1. Under Directions for Use add the following:

INDICATIONS: Ear mites normally cause a dry, dark brown waxy exudate with crusts in the ears of dogs and cats. Mites are easily observed by placing some of the ear wax on a dark surface and watching closely for moving white specks. Do not injure the delicate tissue of the ear. Inflamed, watery or blocked ear canals indicate a more serious condition which requires services of a veterinarian.

- 2. Under Precautionary Statements revise as follows:

For animals, discontinue use and consult veterinarian if irritation develops.

Your Confidential Statement of Formula dated September 24, 1992 will meet the label claim for the active ingredient and is acceptable. The change from Mineral Oil to Sesame Oil is acceptable. However, please provide the chemical identity of all components, the percentage composition, CAS Registry Number, and Material Safety Data Sheet (two copies) for Lipovol Ses (sesame seed oil). The supplier may contact EPA directly referencing the EPA Registration Number in the response.

SYMBOL							
SURNAME	Helmut						
DATE	1-26-93						

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.

Sincerely,

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

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%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautions on back panel

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

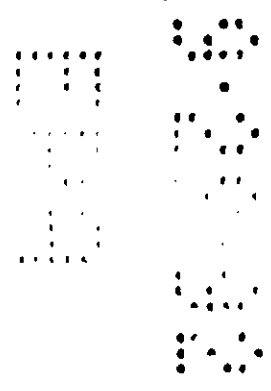
Net Contents: 1 fl. oz.

ACCEPTED
with COMMENTS
in EPA Letter Dated

JAN 26 1993

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

45087-21



Zema Ear Miticide for Dogs (Cats) Continued

BACK PANEL:

PRECAUTIONARY STATEMENTS Hazards to Humans and Animals

CAUTION: Not for human use. Harmful if swallowed or absorbed through skin. Avoid breathing vapors. 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.

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 seven to ten days. Repeat treatment as necessary.

<u>BODY WEIGHT</u>	<u>DOSE</u>
01 TO 15 LBS.	03 TO 05 DROPS
15 TO 30 LBS.	05 TO 10 DROPS
30 LBS. OR OVER	10 TO 15 DROPS

PHYSICAL HAZARD

Do not use or store near heat or open flame.

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
Research Triangle Park, NC 27709

