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SEP 25 1986

Mr. Donald A. Buss
Coopers Animal Health, Inc.
2000 South 11th Street
Kansas City, KS 66103-1438

Dear Mr. Buss:

Subject: Amendment - Revised Label
Skin Sensitization In Dogs
EPA Accession Number 260908
Dermaton III
EPA Registration No. 59-203
Your Letter Dated December 17, 1985

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

1. The submitted efficacy study does not satisfy Agency requirements for domestic animal safety data regarding the potential for the subject product to be a dermal sensitizer on dogs. The submitted study did not provide for reapplication, an essential factor in a sensitization study. As a result you must either submit a study acceptable to the Agency, or until such time as a study is submitted and accepted a statement should be added to the Hazards to Domestic Animals section indicating that the product is a potential sensitizer and that use should be immediately discontinued at the first sign of a sensitizing reaction. For future reference, this study has been assigned the EPA Accession Number 260908.
2. The Note to Physician should be revised to read:

Note to Physician: Solvent may present aspiration hazard. Gastric lavage may be indicated if product was taken internally. This product is a cholinesterase inhibitor. If symptoms of cholinesterase inhibition are present,

86260:Shell:LR-15:KENCO:10/28/86:11/6/86:N.e.Cee:VO

CONCURRENCES

SYMBOL ▶								
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atropine sulfate by injection is antidotal.
2-PAM is also antidotal and may be administered,
but only in conjunction with atropine.

3. The product performance information submitted is acceptable.
For future reference, please note that 24-hour counts are normally
required for flea control claims rather than 3 days.

Submit five (5) 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 yours,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

Enclosure

**PRECAUTIONARY STATEMENTS
WARNING**

Hazards To Humans: May be fatal if swallowed, inhaled or absorbed through the skin. Do not breathe spray mist. Causes eye irritation. Do not get in eyes, on skin or on clothing. Children should not be allowed to handle or apply this product. Data indicate this product to be contact allergenic. Hypersensitive individuals should avoid exposure.

Hazards To Domestic Animals: DO NOT USE ON CATS. Do not use at concentrations greater than recommended. Do not allow dogs to drink dip solution.

STATEMENT OF PRACTICAL TREATMENT

If Swallowed: CONSULT A PHYSICIAN OR POISON CONTROL CENTER IMMEDIATELY. NOTE: ATROPINE IS ANTIDOTAL. If swallowed, gastric lavage is indicated. DO NOT INDUCE VOMITING, unless under medical supervision. Vomiting petroleum distillates may produce aspiration pneumonia. If vomiting occurs spontaneously DO NOT let victim lie down. DO NOT allow any material to enter the airway.

If Inhaled: Remove victim to fresh air. Artificial respiration or administration of oxygen may be lifesaving.

If On Skin: Remove contaminated clothing and immediately wash skin thoroughly with soap and water.

If In Eyes: Immediately flush eyes with running water for at least 10 minutes. Get medical attention if irritation persists.

Note To Physician: 2-chloro-1-(2,4-dichlorophenyl) vinyl diethyl phosphate is a cholinesterase inhibitor and treatment of poisoning should include atropine.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds and other wildlife. Birds feeding on treated areas may be killed. Do not apply directly to water. Do not apply when weather conditions favor drift from areas treated. Do not contaminate water by cleaning of equipment or disposal of wastes.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

Dermaton 3

**Kills Ticks and Fleas
An emulsifiable concentrate
for dogs only**

Active Ingredient

2-chloro-1-(2,4-dichlorophenyl)

vinyl diethyl phosphate

Inert Ingredients

This product contains methylene chloride.

**KEEP OUT OF REACH OF CHILDREN
WARNING
SEE SIDE PANELS FOR ADDITIONAL
PRECAUTIONARY STATEMENTS**

THIS PRODUCT IS FOR USE BY OR UNDER THE DIRECT SUPERVISION OF A LICENSED VETERINARIAN.

Net contents one U.S. gallon (3.785 L)

EPA Est.
EPA Reg.



Coopers Animal Health Inc.
Kansas City, MO 64108 U.S.A.
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ACCEPTED
with conditions
EPA Letter Da

SEP 25 198

Under the Federal
Fungicide and Rodenticide
Act amended by the
registered under EPA R
59-20

DIRECTIONS FOR USE

Use only on surfaces that are not painted or otherwise treated. Consistent with its use.

For use on walls, ceilings, and other vertical surfaces: Apply with a brush or roller. Repeat treatment if necessary. Do not use on painted or otherwise treated surfaces. Wear protective clothing and eye protection.

For use on floors, walls, and other horizontal surfaces: Apply with a brush or roller. Repeat treatment if necessary. Do not use on painted or otherwise treated surfaces. Wear protective clothing and eye protection.

STORAGE AND DISPOSAL

Store in a cool, dry place. Do not store in a container that has been used for other purposes. Do not use if the container is damaged or the contents are not as labeled. For proper disposal of this product, contact your local health department or the hazardous waste representative in your area. For more information, contact your local health department or the hazardous waste representative in your area. For more information, contact your local health department or the hazardous waste representative in your area.