US EPA ARCHIVE DOCUMENT

Memorandum

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Date: October 2, 1980

Subject: EPA Reg. No. 2382-38 MANGEX [redacted]
Caswell #82, 741

From: B. T. Backus
IRB/TSS

To: Mr. George LaRocca
Product Manager 15

Registrant: Carson Chemicals Inc.
P.O. Box 466
New Castle, IN 47362

Active Ingredients:
Benzyl benzoate.....30.0%
Soap (anhydrous).....7.5%
Inert Ingredients:.....62.5%

Background:

The label specifies that this product is to be sold only by "graduate" veterinarians. Product is registered for use as an application to no more than 1/3rd of a dog's body area (surface?) at one time to control sarcoptic and demodectic mange. The registrant has submitted acute oral LD50, dermal LD50, skin and eye irritation studies to show that the product's toxicity is such that it will not require childproof packaging.

Comments and Recommendations:

1. The acute dermal LD50, skin and eye irritation studies are adequate and acceptable.

2. The oral LD50 study has been classificd as supplementary data since it was not determined whether or not the oral LD50 is below or above 5 gm/kg. However, the study does indicate the product has an oral LD50 greater than 1.5 gm/kg.

3. On the basis of the submitted studies, this product does not require childproof packaging. It must be emphasized that the Agency is not issuing a exemption from the requirement of childproof packaging for this product, but rather that the potential hazards of exposure to this product are such that childproof packaging is not required.

4. The data indicate that this product is in toxicity category II on the basis of potential eye exposure hazards. The appropriate signal word for this product is therefore WARNING rather than CAUTION.

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Manufacturing Process Information is not Included

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Review:

The following studies were conducted on the registered product at Biosearch, Inc. P.O. Box 8598, Philadelphia, PA 19101. The studies were received at EPA on 8/9/80 and are in Acc. 243100.

1. Acute Oral Toxicity - Rats

   Procedure: 5M, 5F Sherman-Wistar rats, 200-300 gms, received an oral dosage of 1.5 gm/kg, with subsequent 14-day observation.

   Results: No mortalities. Animals appeared ruffled and slightly depressed 1-2 hrs after dosage, but appeared normal at 24 hrs and thereafter. Gross pathology at 14 days was unremarkable.

   Study Classification: Core Supplementary Data (only level tested was 1.5 gms/kg).

2. Acute Dermal Toxicity - Rabbits

   Procedure: 5M, 5F rabbits, 2.0-3.0 kgs, with abraded skin received 24-hr occluded dermal exposure to a dosage level of 2.0 gm/kg of test material, with subsequent 14-day observation.

   Results: No mortalities. Dermal LD50 above 2 gm/kg. No unusual behavioral noted. Gross pathologies were unremarkable

   Study Classification: Core Minimum Data

   Product Classification: Tox. Cat. III

3. Primary Skin Irritation - Rabbits

   Procedure: 0.5 mls was applied to both an intact and abraded skin site on each of 6 rabbits, with 24-hr occluded exposure.

   Results: No irritation. All scores zero. PDIS = 0.

   Study Classification: Core Minimum Data (only 2 application sites on each subject).

   Product Classification: Tox. Cat. IV

4. Primary Eye Irritation - Rabbits

   Procedure: 0.1 mls was instilled into one eye of each of 9 rabbits. Three rabbits had the treated eye flushed with water starting 30 seconds after product instillation.

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Results: Corneal opacity noted in 3/6 unwashed, 0/3 washed eyes. One unwashed eye still had corneal opacity on day 7, but all other eyes had cleared by this time. The eye with corneal opacity on day 7 had cleared by day 14.

Study Classification: Core Guidelines Data

Product Classification: Tox. Cat. II

Byron T Backus 10/02/80

Byron T. Backus
IRB/TSS

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DIRECTIONS: Apply to the moist skin with swab or brush following a soap bath and rinse. Bathe the animal twenty-four hours later.

In sarcoptic mange and demodectic mange repeat after a week, if necessary. Since demodectic mange is difficult to diagnose and often requires prolonged treatment and may involve other factors such as diet, treatment should be done by or under veterinary directions.

NOTE: Mangex is more effective if parasitized areas are clipped before treatment is applied.

CAUTION: Never apply this product to more than the equivalent of 1/3 the body area at one time. When necessary, treat extensive areas on alternate days. Do not use on cats.

CAUTION: Wash hands thoroughly with soap and warm water after handling. Avoid contamination of feed and foods. Avoid contact with eyes. Excessive use may cause nausea and depression. If such occurs, discontinue use. Harmful if swallowed. Irritating to eyes.

DISPOSAL: Do not reuse empty container. Wrap container and put in trash collection.

EPA Reg. No. 2382-38
EPA EST. 2382-IN-1
Lot No.

GREASELESS TREATMENT **MANGEX**

A NON-STAINING, GREASELESS TREATMENT FOR SARCOPTIC MANGE AND DEMODECTIC MANGE IN DOGS.

Active Ingredients:	w/w
Benzyl benzoate	30.0 %
Soap (anhydrous)	7.5 %
Inert Ingredients	62.5 %
Total	100.00%

Sold Only By Graduate Veterinarians

CAUTION

KEEP OUT OF REACH OF CHILDREN
SEE BACK PANEL FOR ADDITIONAL CAUTIONS

8 fl. oz.

CARSON CHEMICALS, INC.
New Castle, Indiana 47362
Made in U.S.A.

ACCEPTED
MAY 7 1979
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 2382-38

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