006147

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

APR 30 1986

MEMORANDUM

SUBJECT: EPA Registration Number 9993-2
Sanafoam Vaporooter

FROM: Deloris F. Graham DFG 5/7/86 E 5/7/86
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

TO: Robert Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Applicant: Airrigation Engineering Co.
Box H
Carmel Valley, CA 93924

Active Ingredients:
Sodium Methyldithiocarbamate(anhydrous) 24.25%
Dichlobenil (2,6-dichlorobenzonitrile) 1.77%
Inert Ingredients: 73.98%

Background:

Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation, and Skin Irritation Studies. Studies conducted by Stauffer Chemical Company's Western Research Center. Data under Accession Number 260166. Method of support not indicated.

Recommendations:

1. FHB/TSS finds the Primary Skin Irritation and Eye Irritation Studies acceptable to support conditional registration of this product.

2. The Acute Oral and Acute Dermal Studies are unacceptable because at least five animals per sex per dose must be used; LD_{50} and 95% confidence limits for males and females individually must be submitted.

3. The Acute Inhalation Study was not acceptable because the results were not submitted in the report.

4. A Dermal Sensitization Study was not submitted and one must be submitted or data to support waiver.

5. Based on Skin Irritation Study appropriate signal word is DANGER.

Label:

Labeling comments reserved until acceptable Acute Oral, Acute Dermal, Acute Inhalation, and Dermal Sensitization Studies are submitted.

Review:

(1) Acute Oral Toxicity Study: Western Research Center; Lab. Report T-4059-1; November 1, 1972.

Procedure:

Three groups consisting of five male rats each were dosed with one of the following dosages orally: 1000, 2150, or 4640 mg/kg. Observations made for 14 days postdosing. Necropsy performed on all animals.

Results:

At 2150 mg/kg, 1/5 M died; at 4640 mg/kg, 5/5 M died. Toxic signs reported included depression, salivation, lacrimation, and narcosis at higher dose levels. Necropsy report indicated congestion of the heart, lungs, liver, kidneys, adrenal glands and gastrointestinal tract in animals that died during study, and no abnormalities noted in survivors.

Study Classification:

Core Supplementary Data. At least five animals per sex per dose must be used. LD_{50} for males and females individually must be submitted.

(2) Skin Irritation Study: Western Research Center; Lab. Report T-4059-1; November 1, 1972.

Procedure:

"The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances."

Results:

At 4 hours, 6/6 had well-defined to severe erythema (scores of 2, 3, 4) and slight to severe edema (scores of 1, 2, 3, and 4) at intact and abraded skin sites. At 24 hours, 6/6 well-defined to severe erythema (scores of 2 and 4) and slight to severe edema (scores of 1, 2, 3, and 4) at abraded and intact sites. At 48 hours, 6/6 had severe erythema (scores of 4) at abraded and intact sites and 4/6 slight to severe edema (scores of 1, 2, and 4) at intact and abraded sites. Primary Irritation Score reported to be 5.67.

Study Classification:

Core Minimum Data. Assuming the Draize procedure was followed. Observations must be made for at least 72 hours.

Toxicity Category: I - DANGER.

(3) Eye Irritation Study: Western Research Center; Lab. Report T-4059-1; November 1, 1972.

Procedure:

Six rabbits received 0.1 ml of the test material in one eye each. Observations made for 72 hours posttreatment.

Results:

Conjunctival edema, erythema and discharge in 6/6 animals and corneal opacity in 3/6 animals reported. Irritation reported to have cleared by day 7. However, individual scoring for each animal was not submitted.

Study Classification:

Core Minimumn Data. Individual score for each animal in regard to corneal opacity, iris irritation, conjunctival redness, chemosis, and discharge must be submitted.

Toxicity Category: III - CAUTION.

(4) Acute Dermal Toxicity Study: Western Research Center; Lab. Report T-4059-1; November 1, 1972.

Procedure:

Four groups consisting of four rabbits with intact skin sites each were treated with one of the following doses: 464, 1000, 2150, or 4640 mg/kg of the test material under occlusive

wrap for 24-hour exposure. Observations made for 14 days.
Results:

At 1000 mg/kg, 3/4 animals died; at 2150 and 4640 mg/kg, 4/4 animals per dose died. Toxic signs reported included depression, cyanosis and narcosis.

Study Classification:

Core Supplementary Data. At least five animals per sex per dose must be used. LD_{50} and 95% confidence for males and females individually must be submitted.

(5) Acute Inhalation Toxicity Study: Western Research Center; Lab. Report T-4059-1; November 1, 1972.

Procedure:

Five males and five females were exposed for 1 hour to test concentration. Observations made for 14 days postexposure. Necropsy performed on all animals.

Results: Results not submitted in report.

Study Classification:

Core Supplementary Data. See Subdivision F - Hazard Evaluation: Humans and Domestic Animals; Section 81-3 for appropriate testing and reporting procedures.