3-13-80
707-160

707-160

DATE: February 29, 1980

SUBJECT: Captan 50-W
EPA File Symbol: 707-RAN (160)
Caswell #159

FROM: Sherell A. Sterling
FHB/TSS

TO: Henry Jacoby
Product Manager (21)

Applicant: Rohm and Haas Company
Independence Mall West
Philadelphia, PA 19105

| Active Ingredient | |
|---|---|
| Captan ..... | 50% |
| Inert Ingredients ..... | 50% |

Background: The data in Accession No. 241538 were submitted in support of the conditional registration of this product. Included in the data were Acute Oral, Acute Dermal, Acute Inhalation, Eye and Skin Irritation studies. The studies were conducted at the Warf Institute, Inc. of Madison, Wisconsin. The method of support is "alternate." The test material (Merpan 50 WP) is identical to EPA No. 707-RAN.

Recommendations:

1. Based on the Eye Irritation study, the appropriate signal word is "DANGER."

2. The Acute Oral, Acute Dermal, Acute Inhalation, Eye and Skin Irritation studies are adequate and acceptable for the conditional registration of this product.

3. While the studies are acceptable for this registration, testing procedures have been improved since these studies were conducted. A copy of the Proposed Guidelines for Human Health Evaluation are enclosed for the registrant's future reference.

4. FHB/TSS has no objection, based on the human and domestic animal hazard data, to the conditional registration of this product provided that the following labeling revisions are made.

Labeling Recommendations:

1. The signal word must be changed to "DANGER" on both the front and side panels.

2. The following or similar statements must appear under the HAZARDS TO HUMANS AND DOMESTIC ANIMALS section of the labeling, following the signal word:

> "Corrosive. Causes eye damage. Do not get in eyes, on skin or clothing. Wear goggles or face shield when handling. Harmful if swallowed. Avoid breathing dust."

Review:

1. Acute Oral Toxicity; Warf Inst. No. 6051095; July 22, 1976.

   Procedure: Groups of 10 M, 10 F Sprague-Dawley rats (150-250g) received oral dosages of 2.0, 5.0, 7.5 and 10.0 g/kg of Merpan 50 WP. The animals were observed for 14 days post-treatment.

   Results: No mortalities at 2 g/kg. At 5 g/kg, 4/10 M and 5/10 F died. At 7.5 g/kg, 9/10 M and 2/10 F died. At 10 g/kg, 10/10 M and 9/10 F died. LD50 for males was 5.4 g/kg with a 95% confidence range of 4.29-6.80 g/kg. LD50 for females was 5.5 g/kg with a 95% confidence range of 4.37-6.93 g/kg.

   Study Classification. Core Minimum Data. No body weight data submitted. No record of observations for toxic effects was submitted.

   Toxicity Category: IV-CAUTION

2. Acute Dermal Toxicity; Warf Inst. No. 6051095; July 22, 1976.

   Procedure: 4 M (2.826-3.122 kg) rabbits received an application of 8 g/kg of Merpan 50 WP. Exposure was for 24 hours under occlusive wrap. Animals were observed for 14 days post-treatment.

   Results: No mortalities. Terminal body weights were higher than initial body weights. LD50 was greater than 2 g/kg.

Study Classification: Core Minimum Data. Only M subjects tested; however, since M and F Oral LD50 were similar, F Acute Dermal LD50 should not differ significantly from M Acute Dermal LD50. Test substance was not slightly moistened.

Toxicity Category: III-CAUTION

3. Acute Inhalation Test; Warf Inst. No. 6051095; July 22, 1976.

Procedure: One group 5 M, 5 F rats were exposed to an aerosolized dust of Merpan 50 WP for one hour. The air flow to the chamber was maintained at 1013.9 l/hour. A Wright's dust feeder was used to deliver the material into the air stream. The concentration was determined gravimetrically to be 18.73 mg/l. Animals were observed for 14 days post-treatment. At termination of study, animals were sacrificed and submitted to necropsies.

Results: No physical effects observed during exposure. No mortalities. At necropsy, 1/10 showed abscesses in left lobe of lung; 9/10 exhibited normal viscera.

Study Classification: Core Minimum Data. Acute Inhalation studies should show range of dosages or that LC50 is greater than 5 mg/l for 4 hours.

Toxicity Category: III-CAUTION. Study shows that product is no worse than toxicity category III.

4. Eye Irritation; Warf Inst. No. 6051095; July 22, 1976.

Procedure: 0.1 g of Merpan 50 WP was instilled into one eye of each of six New Zealand albino rabbits. Scoring at 24, 48, 72 hours, 7 and 14 days.

Results: At 24 hours, no corneal opacity observed; no iris irritation; 6/6 showed conjunctival redness (6/6=2); chemosis in 6/6 (6/6=2) and discharge from 6/6 eyes (1/6=1, 5/6=2). At 48 hours, 1/6 showed corneal opacity (1/6=20); no iris irritation; 6/6 with conjunctival redness (6/6=2); 6/6 with chemosis (3/6=1, 3/6=2); discharge from 3/6 eyes (3/6=1). At 7 days 2/6 with corneal opacity (1/6=20, 1/6=40); no iris irritation; 5/6 with redness (3/6=1, 2/6=2); 5/6 with chemosis (4/6=1, 1/6=2); 2/6 exhibited discharge (2/6=1). On day 14, only irritation observed was corneal opacity in 2/6 animals.

Study Classification: Core Minimum Data. One group (minimum of 3 rabbits) should have been treated with eyewash after instillation.

Toxicity Category: I-Danger. Corneal opacity observed in 2/6 through day 14.

5. Primary Skin Irritation: Warf Inst. No. 6051095; July 22, 1976.

Procedure: 0.5 g of Merpan 50 WP was applied to each of 2 sites (1 abraded, 1 intact) on each of 6 rabbits. Exposure was for 24 hours under occlusive wrap. Scoring at 24 and 72 hours.

Results: All scores were zero.

Study Classification: Core Minimum Data. Four sites per animal (2 abraded, 2 intact) should be tested.

Toxicity Category: IV-CAUTION