12-6-82

MEMORANDUM

Date: December 6, 1982

004664

Subject: EPA File Symbol: 476-EERU
Sutan + A 6-E

From: Deloris F. Graham DFG 12/13/82
FHB/TSS E 12/14/82

To: Robert Taylor
Product Manager (25)

Applicant: Stauffer Chemical Company
1200 South 47th Street
Richmond, California 94804

Caution

Active Ingredients:
S-ethyl diisobutylthiocarbamate.....74.2%
Inert Ingredients.....25.8%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Skin Irritation Studies. Studies conducted by Stauffer Chemical Company. Data under accession number 248815. Combined cite-all and alternate method of support.

Recommendation:

1. FHB/TSS finds these data acceptable to support conditional registration of this product. However, for future submissions please note:

   a. In the Eye Irritation Study, individual scoring for corneal opacity, iritis and conjunctive redness, chemosis and discharge for each animal must be sumitted.

2. An Acute Inhalation Study was not submitted, but one must be submitted and/or cited.

3. The appropriate signal word is CAUTION.

Label:

1. No labeling comments.

1 of 5

Review

1. Acute Oral Toxicity Study: Stauffer Chemical Co.; Report #T-10693; May 11, 1982.

   Procedure: 5 groups consisting of 10 M rats each received one of the following doses: 1585, 1778, 1995, 2239 and 3162 mg/kg. Observations made for 14 days after treatment. Necropsy performed on all animals. Forty male rats were exposed to deionized water and serve as the controls.

   Results: At 1585 mg/kg, 6/10 M rats died; at 1778 mg/kg, 4/10 M rats died; at 1995 mg/kg 9/10 M rats; at 2239 m/kg, 10/10 M rats; at 3162 mg/kg, 10/10 M rats. Clinical signs observed included depression, prostration, ataxia, salivation, lacrimation, dyspnea, chromoacyarrhea, exophthalmus, general debilitation and weakness, diuresis, diarrhea, red muzzle stains, yellow ano-genital stains, pale ears, piloerection and ptosis. Necropsy revealed red lungs, black edged liver lobes, dark and/or rough spleens, mottled livers, yellow fluid within the intestines, bloated, gaseous, reddened GI tracts, purple receded testes, dark fluid in the urinary bladder, red fluid in the peritoneal cavity, swelling of glands attached to the bladder and pale tan spots on the kidney. LD_{50}(M) 1667 mg/kg with confidence limits from 1496 to 1858 mg/kg. No abnormalities noted among controls.

   Study Classification: Core Guideline Data.

   Toxicity Category: III - CAUTION

2. Acute Oral Toxicity Study: Stauffer Chemical Company; Report #T-10693; May 11, 1982.

   Procedure: 5 groups consisting of 10 F rats each received one of the following doses: 1000; 1259, 1585, 1995 and 2239 mg/kg. Observations made for 14 days after treatment. Necropsy performed on all animals. Forty female rats were treated with deionized water and served as vehicle control.

   Results: At 1000 mg/kg, 1/10 F died; at 1259 mg/kg, 2/10 F died; at 1585 mg/kg, 8/10 F died; at 1995 mg/kg 10/10 F died; at 2239 mg/kg, 10/10 F died. Clinical signs observed included moderate to severe depression, prostration, chronic convulsions, ataxia, diuresis, diarrhea, dyspnea, red stains at muzzles, chromodacryarrhea, salivation, ptosis, and piloerection, moribundity, tremors, hypersensitivity, lacrimation, yellow ano-genital staining. Necropsy revealed pale tan livers with black edged lobes, black spleens, gaseous intestines filled with black material and black intestinal mueosa. LD_{50}(F) 1383 mg/kg with confidence limits from 1212 to 1579 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

3. Acute Dermal Toxicity Study: Stauffer Chemical Company; Report #T-10693; May 11, 1982.

Procedure: 5 M and 5 F rabbits received a single dermal application of 2000 mg/kg of the test material under occlusive wrap for a 24-hour exposure period. The skin was abraded on one half the animals and left intact on the others. After the 24-hour exposure period, the binder material was removed, the skin inspected for irritation and rewrapped in gauze binder. Three days later, this gauze was removed. Observations made for 14 days following the initial treatment. Necropsy performed on all animals. Two male and 2 female rabbits were sham-treated and served as controls.

Results: No mortalities. Mild to moderate erythema and edema. No abnormalities at necropsy. LD_{50} greater than 2000 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

4. Eye Irritation Study: Stauffer Chemical Company; Report #T-10693; May 11, 1982.

Procedure: Nine rabbits received 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were rinsed with water 20-30 seconds after treatment. Observations made at 24, 48, 72 hours and 4 and 7 days. Irritation present at 7 days, additional observations were made every 3-4 days until injury subsided or was found to be irreversible.

Results: At 24 hours, the average total score was 8.8, at 72 hours 5.6, and at 7 days 0.0. The three washed eyes showed mild conjunctal redness; 2/6 of the unwashed group showed mild corneal opacity; 1/6 showed mild iritis; 4/6 animals showed mild to moderate conjunctival redness and/or discharge and 1/6 showed moderate to severe redness and discharge. All irritation subsided by day 7.

Study Classification: Core Minimum Data

Individual scoring for corneal opacity, iritis, and conjunctive redness, chemosis and discharge for each animal must be submitted.

Toxicity Category: III - CAUTION

5. Skin Irritation Study: Stauffer Chemical Company; Report #T-10693; May 11, 1982.

Procedure: Six rabbits received 0.5 ml of the test material at abraded and intact skin sites per rabbit under occlusive wrap for 24 hour exposure. Observations made at 24 and 72 hours after treatment.

Results: At 24 hours, 6/6 animals had slight to well defined erythema (5/6 = 1, 1/6 = 2) and edema (5/6 = 1, 1/6 = 2). At 72 hours, 4/6 slight erythema (4/6 = 1) and no edema. Primary irritation score was 1.5.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

Butylate toxicology review

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