10-16-87

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

~~SEP 28 1987~~

SUBJECT: EPA File Symbol 7501-REA
Gustafson TSX Apron

FROM: Mary L. Waller
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

10/15/87
E 10/16/87

TO: Lois A. Rossi, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: Gustafson, Inc.
P.O. Box 660065
Dallas, TX 75266-0065

ACTIVE INGREDIENTS:

PCNB: Pentachloronitrobenzene	25.00%
Metalaxyl: N-(2,6-dimethylphenyl)-N-methoxyacetyl) aniline methyl ester	6.25%
INERT INGREDIENTS:	78.75%

BACKGROUND:

The applicant has submitted an acute oral, acute dermal, acute inhalation, primary eye irritation, primary skin irritation and dermal sensitization studies. The studies were conducted by Stillmeadow, Inc. The MRID Numbers are 402726-01 thru -06. The method of support is owner submission.

RECOMMENDATION:

FHB/TSS finds the studies acceptable to support registration of 7501-REA. The signal word is "CAUTION."

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LABELING:

1. Add the following Statement of Practical Treatment for oral exposure:

If Swallowed:	Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

2. Revise first sentence of Precautionary Statements as follows: " Harmful if swallowed, absorbed through skin or inhaled."

REVIEW:

(1) Acute Oral Toxicity Study: Stillmeadow, Inc.; Project Number 4748-87; MRID No. 402726-01; 6-25-87.

PROCEDURE:

Five male and five female albino rats each received a single dose by oral intubation of 5050 mg/kg of test material administered as a 25.0% w/v concentration in 0.5% w/v aqueous carboxymethyl cellulose. Three additional groups of 5 females each were dosed with 3000, 4000, and 6000 mg/kg. Animals were observed at least 3 times on day of dosing and once daily thereafter for 14 days. Body weights were recorded prior to dosing and at 7 and 14. All animals were necropsied at study conclusion or upon discovery of death.

RESULTS:

No females died at 3000 mg/kg. At 4000 mg/kg, 1/5 females died. At 5050 mg/kg, 3/5 females died. At 6000 mg/kg, 4/5 females died. The LD_{50} for males was reported to be > 5050 mg/kg. The LD_{50} for females was reported to be 4870 (4170-5690) mg/kg.

Toxic symptoms observed were activity decrease, ataxia, body tremors, constricted pupils, convulsions, dilated pupils, lacrimation, muscle tremors, brown oral discharge, piloerection, polyuria, ptosis, salivation, and sensitivity to touch. Gross necropsy revealed discolored contents in the gastrointestinal tract, or empty intestinal tract.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Category III - CAUTION.

(2) Acute Dermal Toxicity Study: Stillmeadow, Inc.; Project Number 4749-87; MRID No. 402726-02; 5-27-87.

PROCEDURE:

Five male and five female New Zealand white rabbits were clipped free of fur on the dorsal surface of the trunk. Each animal was administered 2010 mg/kg of test material (moistened with 9% saline) which was applied topically to the shaven area and covered with occlusive wrap for 24 hours of exposure. After exposure, the wrap and residual test material were removed. Animals were observed at 1/2, 3 and 6 hours after treatment and at least once daily thereafter for 14 days. Body weights were recorded on days 0, 7 and 14. Animals were necropsied at study conclusion.

RESULTS:

No deaths occurred. The LD_{50} was reported to be > 2010 mg/kg of test material. Animals exhibited decreased urination and diarrhea. No abnormalities were noted at necropsy.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Category III - CAUTION

(3) Acute Inhalation Toxicity Study: Stillmeadow, Inc.; Project Number 4753-87; MRID No. 402726-03; 5-22-87.

PROCEDURE:

Five male and five female Sprague-Dawley rats were exposed for 4 hours in a 200 L dynamic flow inhalation chamber to an aerosol generated from test material. The mean concentration in the test chamber was 5.06 mg/L of test material. Animals were observed during exposure, after exposure and at least once daily for 14 days. Body weights were recorded prior to exposure and at 7 and 14 days. Animals were necropsied at study conclusion.

RESULTS:

No deaths occurred. Tne LC_{50} was reported to be > 5.06 mg/L. Observations included activity decrease, gasping, lacrimation, nasal discharge, piloerection, ptosis and salivation. Gross necropsy revealed discolored lungs.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Category IV - CAUTION

(4) Primary Eye Irritation Study: Stillmeadow, Inc.; Project Number 4750-87; MRID No. 402726-04; 5-4-87.

PROCEDURE:

Nine New Zealand white rabbits were each administered 100 mg of test material that was placed in the right eye of each animal. The treated eye was held shut for one second after instillation of test material. Thirty seconds after treatment, the treated eyes of 3/9 animals were rinsed with deionized water for one minute. The untreated left eye of each animal served as a control Eye irritation was scored at 1, 24, 48 and 72 hours and at 4 and 7 days.

RESULTS:

Eye irritation in the unwashed group was scored as follows: at 24 hours, iris irritation (4/6 = 5), conjunctivae redness (6/6 = 1), chemosis (2/6 = 2, 4/6 = 1) and discharge (1/6 = 2, 5/6 = 1); and at 7 days, all irritation had cleared.

Eye irritation in the washed group was scored as follows: at 24 hours, conjunctivae redness (3/3 = 1), chemosis (2/3 = 1) and discharge (3/3 = 1); and at 7 days, all irritation had cleared.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Category III - CAUTION

(5) Primary Skin Irritation Study: Stillmeadow, Inc.; Project Number 4751-87; MRID No. 402726-05; 5-1-87.

PROCEDURE:

Six New Zealand white rabbits were clipped free of fur on the dorsal surface of the trunk. Approximately 24 hours later, each animal was administered a topical application of 0.5 g of test material moistened with 0.5 ml of 0.9% saline. The moistened test material was applied to the shaven skin and covered with occlusive wrap for 4 hours. After exposure, the wrap and residual test material were removed. Skin irritation was scored at 1, 24, 48 and 72 hours.

RESULTS:

At one hour, 6/6 animals exhibited very slight erythema and 5/6 animals exhibited very slight edema. At 72 hours, no irritation was present. Four out of six animals displayed gray discoloration of test site hairs.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Category IV - CAUTION

(6) Dermal Sensitization Study: Stillmeadow, Inc.; Project Number 4752-87; MRID No. 402726-06; 6-19-87.

PROCEDURE:

Two groups of ten albino guinea pigs received induction treatments which were administered on days 1, 3, 6, 8, 10, 13, 15, 17, 20, and 22 to a previously shaven test site located on the back of each animal. The test group received induction treatments which consisted of 500 mg of test material moistened with 0.5 ml of deionized water, and the positive control group received induction treatments which consisted of 0.5 ml of a 0.05% w/v solution of 2,4-dinitrochlorobenzene in ethanol. After administration of each induction treatment, the test site was covered with occlusive wrap, and the animal was placed in a restrainer during the six-hour exposure period. After each exposure, the wrap and residual test material were removed. Skin irritation was scored at 24 hours after each treatment. Two weeks after the last induction treatment, each group was challenged in a manner identical to an induction treatment. Each group was challenged at the previously treated site and at a virgin site. Skin irritation was scored at 24 and 48 hours after challenge treatment.

RESULTS:

The positive control group exhibited very slight to well-defined erythema and very slight edema after the second induction treatment. Irritation increased in number of animals and severity so that by the last induction treatment animals exhibited well-defined to severe erythema and very slight to moderate edema. After challenge, animals exhibited very slight to well-defined erythema and very slight to slight edema.

The test group exhibited very slight erythema and very slight edema after the next to last induction treatment. At challenge, one animal exhibited very slight erythema and very slight edema.

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STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Nonsensitizer

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METALAXYL

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