

US EPA ARCHIVE DOCUMENT



006409

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA File Symbol 1812-GER
Trilin DF Herbicide

AS IS
AUG 13 1987

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

MW 9/9/87
E 9/9/87

TO: Richard F. Mountfort, PM 23
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: Griffin Corporation
P.O. Box 1847
Valdosta, GA 31603-1847

ACTIVE INGREDIENT:

Trifluralin 80.0%
INERT INGREDIENTS: 20.0%

BACKGROUND:

The applicant has submitted an acute oral, acute dermal, acute inhalation, primary skin irritation, primary eye irritation and dermal sensitization studies. The studies were conducted by Springborn Institute for Bioresearch, Inc. The MRID number is 402384-02. The method of support was not indicated.

RECOMMENDATION:

FHB/TSS finds the data acceptable to support registration of 1812-GER. The signal word is CAUTION.

The Product Manager should inform the registrant that page 22 of 39 in the Dermal Sensitization study was missing and the individual eye irritation scores for animal number 249-87M in the primary eye irritation study were missing. The registrant

should make certain that future data packages are complete. Fortunately, with the information provided, the review of these studies could be completed.

LABELING:

1. Change the signal word to CAUTION on the front and side panel.
2. The precautionary statements should read as follows:

Causes eye injury. Harmful if inhaled or absorbed through skin. Avoid contact with skin, eyes or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.
3. Instructions on reentry and protective clothing should be placed under the directions for use.

REVIEW:

- (1) Dermal Sensitization Study: Springborn Institute for Bioresearch; SIB study number 3159.6.6; 4-24-87.

PROCEDURE:

A group of ten guinea pigs were clipped free of hair on the back and each animal received induction treatments once a week for three weeks. Each induction treatment consisted of 0.4 ml of 50% test material in distilled water that was applied to a patch and placed on each animals' clipped back under occlusive wrap for 6 hours of exposure. Animals were restrained during exposure. After exposure, the wrap and residual material were removed. Two weeks after the last induction treatment, the test group and a control group of 10 guinea pigs were challenged at a previously untreated shaven site using 25% test material in distilled water. Skin irritation was scored at 24 and 48 hours after challenge.

RESULTS:

At challenge, ~~8/10~~ 8/10 animals in the test group exhibited irritation ranging from slight patchy erythema to moderate erythema. The mean score at 48 hours was 1.0 (slight erythema). The control group did not exhibit irritation in response to the challenge.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Sensitizer

(2) Acute Dermal Toxicity Study: Springborn Institute for Bioresearch, Inc.; SIB study number 3159.2; 3-31-87.

PROCEDURE:

Five male and five female New Zealand white rabbits were clipped free of fur on the dorsal trunk area. Approximately 24 hours later, each animal received 2 g/kg of test material that was applied to the shaven area on each animal. Moistened gauze and occlusive wrap was placed over each test site. Animals were restrained during the 24 hour exposure period. After exposure, the wrap and residual test material were removed. Animals were observed three times on the day of dosing and once daily thereafter for 14 days. Body weights were recorded on days 1, 8 and 15. Animals were necropsied at study conclusion.

RESULTS:

No deaths occurred. The LD₅₀ was reported to be > 2 g/kg. Animals exhibited soft stools, fecal stains and few feces. No abnormalities were noted at necropsy.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Category III - CAUTION

(3) Primary Eye Irritation Study: Springborn Institute for Bioresearch; SIB study number 3159.6.5; 3-29-87.

PROCEDURE:

Nine New Zealand white rabbits each received 35 mg (0.1 ml) of test material that was placed in the right eye of each animal. Thirty seconds after test material instillation, the treated eyes of 3/9 animals were rinsed with physiological saline. The untreated eye of each animal served as a control. Eye irritation was scored at 1, 24, 48 and 72 hours.

RESULTS:

No irritation was observed in the washed group. Eye irritation in the unwashed group was scored as follows: at 1 hour, conjunctivae redness (5/6 = 2, 1/6 = 1), chemosis (5/6 = 1) and discharge (4/6 = 1); at 24 hours, conjunctivae redness (1/6 = 2, 3/6 = 1), and discharge (1/6 = 1), and at 72 hours, all irritation had cleared.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Category III - CAUTION

- (4) Acute Oral Toxicity Study: Springborn Institute for Bioresearch, Inc.; SIB study number 3159.6.1; 4-2-87.

PROCEDURE:

Five male and five female Sprague-Dawley rats were administered a single oral dose by gavage of 5 g/kg of 50% test material in distilled water. Animals were observed three times on the day of dosing and once daily thereafter for 15 days. Body weights were recorded on days, 1, 8 and 15. Animals were necropsied at study conclusion.

RESULTS:

No deaths occurred. The LD₅₀ was reported to be > 5 g/kg. Animals exhibited dark material around eyes, nose and/or mouth, fecal stain and yellowish red or red urine. No abnormalities were noted at necropsy.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Category IV - CAUTION

- (5) Acute Inhalation Toxicity Study: Springborn Institute for Bioresearch, Inc.; SIB study number 3159.6.3; 4-1-87.

PROCEDURE:

Five male and five female Sprague-Dawley rats were exposed for 4 hours in an inhalation chamber to a average gravimetric concentration of 1.0 mg/L (maximum attainable concentration) of particulate aerosol generated from the test material. Animals were observed daily for 15 days. Body weights were recorded on days 1, 8 and 15. Animals were necropsied at study conclusion.

RESULTS:

No deaths occurred. The LC₅₀ was reported to be > 1.0 mg/L. Animals exhibited lacrimation, dark material around the nose, eyes and/or mouth, periorbital swelling, and alopecia. Gross necropsy revealed multiple yellow foci on the lungs and white to yellow gelatinous material in the small intestines.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Category III - CAUTION

(6) Primary Dermal Irritation Study: Springborn Institute for Bioresearch, Inc.; SIB study number 3159.6.4; 3-28-87.

PROCEDURE:

Six New Zealand white rabbits were clipped free of fur on the dorsal area of the trunk. Twenty-four hours later, each animal was administered 0.5 g of test material that was applied to the shaven area and covered with moistened gauze and occlusive wrap. After 4 hours of exposure, the wrap and residual test material were removed. Skin irritation was scored at 24, 48 and 72 hours.

RESULTS:

One hour after patch removal, 2/6 animals exhibited very slight erythema. All irritation had subsided by 24 hours.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Category IV - CAUTION

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