6-11-86

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

JUN 11 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration Number 241-243
Prowl Herbicide

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

MW E 6/26/86

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

APPLICANT: American Cyanamid Company
Agricultural Division
P.O. Box 400
Princeton, NJ 08540

ACTIVE INGREDIENT:
Pendimethalin (N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine) 42.3%
INERT INGREDIENTS: 57.7%

BACKGROUND:

The registrant has submitted a dermal sensitization study. The study was conducted by Food & Drug Research Laboratories, Inc. The data Accession Number is 261505. The method of support was not indicated.

RECOMMENDATION:

FHB/TSS finds the study acceptable to support registration and the product is classified as a nonsensitizer.

LABELING: No additional labeling is necessary.

1

REVIEW:

Dermal Sensitization Study: Food & Drug Research Laboratories, Inc.; FDRL Study No. 8100; November 16, 1984.

PROCEDURE:

Two groups of male albino guinea pigs each received topical applications which were applied to a gauze pad and placed on a previously shaven test site on each animal's back. Induction treatments for the test group consisted of 0.4 ml of 30% (v/v) solution of test material in 0.9% sterile saline. Induction treatments for the positive control group consisted of 0.4 ml of 0.15 (w/v) solution of 1-chloro-2,4-dinitrobenzene (DNCB) in 80% ethanol. Induction treatments were made once a week for 3 weeks for 6 hours of exposure under occlusive wrap. After each 6 hour exposure, the wrap was removed. Two weeks later, the challenge dose was administered. The test group and a naive control group of 10 animals received a challenge dose identical to an induction treatment applied to a virgin test site. The positive control group received 0.4 ml of DNCB (0.15% w/v) in acetone. Animals were observed daily, and skin irritation was scored at 24 and 48 hours after each induction and challenge dose. Body weights were recorded on days 1, 8, 15, 22, 29, and 33. Animals which died during the study were subjected to gross necropsy.

RESULTS:

One animal in the test group was found dead on day 30. After the second induction treatment, 3/10 animals exhibited very slight erythema. After the challenge dose, 2/10 animals exhibited very slight erythema. After the first induction treatment, the positive control group exhibited erythema ranging from very slight to well-defined. Irritation in the positive control group increased in severity with each subsequent treatment. After the challenge dose, the positive control group exhibited erythema ranging from well-defined to severe. After the challenge dose, 1/10 animals in the naive control group exhibited very slight erythema.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: NONSENSITIZER.

2