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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration Number 12020-1
Diuron Technical

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

mw
E 4/25/86

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

APPLICANT: Staveley Chemicals Limited
c/o Griffin Corp.
P.O. Box 1847
Valdosta, GA 31603

ACTIVE INGREDIENT:
Diuron (3-(3,4-Dichlorophenyl)-1,1-dymethylurea 97%
INERT INGREDIENTS: 3%

BACKGROUND:

The registrant has submitted a Dermal Sensitization Study in response to the Diuron Reregistration Standard. The study was conducted by Intox Laboratories. The data Accession Number is 258553. The method of support was not indicated.

RECOMMENDATION:

FHB/TSS finds the study acceptable and classifies the product as a nonsensitizer.

LABELING: No labeling changes are necessary.

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REVIEW:

Dermal Sensitization Study: Intox Laboratories; Project No. GRF-AT-009; June 25, 1985.

PROCEDURE:

Fifteen female guinea pigs (10 treated, 5 vehicle control) were clipped and depilated laterally across the shoulders 2 days prior to the first treatment and 1 day before each subsequent treatment. The first insult treatment consisted of three pairs of symmetrical 0.1 ml intradermal injections to the shoulder (one on each side of the spinal column) as follows: the first pair of injections consisted of 1:1 emulsion of Freund's Complete Adjuvant in sterile physiological saline (control and treated group); the second pair of injections consisted of test material suspended in sterile physiological saline (20 mg/ml) (treated group) or sterile physiological saline (control group); and the third pair of injections consisted of 1:1 emulsion of test material suspended in sterile physiological saline (20 mg/ml) and Freund's Complete Adjuvant (treated group) or a 1:1 emulsion of adjuvant and sterile physiological saline (control group). Six days later, a mixture of sodium lauryl sulfate in petroleum was massaged into the exposure sites for both the treated and control groups. Twenty-four hours later, the treated group received a second insult treatment of 250 mg of test material applied topically to the test site under occlusive wrap and the control group received a patch of filter paper saturated with sterile physiological saline applied topically over the exposure site under occlusive wrap. Exposure lasted 48 hours. Two weeks later, a challenge dose, identical to each group's second insult treatment, was administered to new depilated exposure sites on the right flank of each animal under occlusive wrap. After 24 hours, the wrap was removed.

Observations to score erythema and edema were made on day 6, day 23, and day 24. Animals were checked twice daily for morbidity/mortality. Animals were weighed at study initiation and conclusion.

RESULTS:

Skin irritation after the first insult treatment was scored as follows: at site 1 where Freund's and saline were injected into both control and treated groups, all animals except one animal in each group exhibited erythema and edema ranging from very slight to severe; at site 2 where saline was injected into the control group and saline and the test material were injected into the treated group, no irritation

occurred in either group; and at site 3 where Freund's and saline were injected into the control group and Freund's, saline, and the test material were injected into the treated group, all animals except one animal in each group exhibited erythema and edema ranging from very slight to severe. No irritation was observed in either group after challenge treatment. All animals gained weight throughout the study.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Nonsensitizer.

DIURON SCIENTIFIC REVIEWS

Page 4 is not included in this copy.

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

✓ A draft product label

___ The product confidential statement of formula

___ Information about a pending registration action

___ FIFRA registration data

___ The document is a duplicate of page(s) _____

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