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

006201

MAR 27 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration Number 464-589
Esteron BK Weed and Brush Killer

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

E 9/15/86

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

Applicant: The Dow Chemical Company
P.O. Box 1706
Midland, MI 48640

BACKGROUND:

The registrant has submitted a dermal sensitization study and additional data to support an acute inhalation toxicity study which was reviewed by TSS on June 3, 1985 (review is located in registration jacket 464-554). The data Accession Number for the dermal sensitization study is 261359 and the data Accession Number for the acute inhalation toxicity study is 254305. The method of support was not indicated.

RECOMMENDATION:

1. FHB/TSS finds the dermal sensitization study acceptable and the product is classified as a sensitizer.

2. FHB/TSS is upgrading the acute inhalation toxicity study on 464-589 to core guideline data. This study was classified as supplementary in the FHB/TSS review dated June 3, 1985. FHB/TSS's decision to upgrade the study is based on the registrant's statement in a July 26th letter that the study was conducted at the maximum attainable air concentration.

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LABELING:

1. Add the following sentence to the Precautionary Statements:

   This product may cause allergic skin reactions.

2. Remove the following sentence from the Statements of Practical Treatment and place it under the Precautionary Statements:

   Remove and wash contaminated clothing before reuse.

REVIEW:

(1) Acute Inhalation Study: Dow Chemical U.S.A.; Lab Report Number HETM-004715-001; October 27, 1983.

PROCEDURE:

Groups of five male and five female rats were exposed to 0 and 5.1 mg/L of test material under appropriate laboratory conditions. Rats were restrained in wire mesh tubing during the exposure. The particle size of the test material during exposure was calculated. All rats were weighed prior to exposure, the day after and weekly thereafter. All animals were observed at least once daily for 2 weeks after exposure. Rats that died during exposure or the next day were not necropsied. Necropsy was performed on all other animals.

RESULTS:

2/5 male rats died. There were no deaths among the females. At 18 hours, all animals looked normal. At 27 hours, 4/5 male rats were breathing through the mouth and had dark exudate around the nares but otherwise appeared normal. Two male rats returned to normal, two male rats died, and one male rat showed occasional labored breathing throughout the postexposure observation period.

Initially after exposure, both male and female rats lost weight. At termination of the study 2/5 males and 5/5 females had reached 88 percent of the control group's weight. One male continued to lose weight throughout the study. The mass median aerodynamic diameter of the test material was 2.8 micrometers. The LC_{50} was reported to be > 5.1 mg/L for female rats and approximately 5 mg/L for male rats.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

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(2) Dermal Sensitization Study: Dow Mammalian and Environmental Toxicology Research Laboratory; July 22, 1985.

PROCEDURE:

Twenty male Hartley Albino guinea pigs were shaved on the back and 24 hours later, 10 animals per group were treated once a day for 4 days with either 0.1 ml of undiluted test material or DER 331 epoxy resin (a known sensitizer) as a 10 percent solution in DOWANOL DPM/TWEEN 80. Each insult treatment was applied to a patch which was placed on the test site on the animal's back. The first and second insult treatments were kept under occlusive wrap for 24 hours. The third and fourth insult treatments were kept under occlusive wrap for 48 hours. At the third treatment, each animal also received a total of 0.2 ml of Freunds Complete Adjuvant injected intradermally adjacent to the test site. After 2 weeks, the animals' flanks were shaved and challenged. Skin irritation was scored during insult and challenge phase.

RESULTS:

No edema or hyperemia (erythema) was observed in either the test or positive control group. At 24 and 48 hours after challenge treatment, both the test group and the control group exhibited slight to marked hyperemia.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Sensitizer.

Page _____ is not included in this copy.

Pages 4 through 6 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 quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

X 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) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.