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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: Garlon 4 Herbicide
EPA Registration Number 464-554
Esteron BK Brush Killer
EPA Registration Number 464-589

FROM: Mary L. Waller

TO: Robert Taylor
Product Manager (25)

Applicant: The Dow Chemical Company
P.O. Box 1706, 9008 Building
Midland, MI 48460

Active Ingredients:

Product Number 464-554

Triclopyr (3,5,6-trichloro-2-pyridinyloxyacetic acid), butoxyethyl ester	61.6%
Inert Ingredients	38.4%

Product Number 464-589

Butoxy ethyl ester of (2,4-dichlorophenyl) acetic acid	34.4%
Butoxy ethyl ester of (3,5,6-trichloro-2-pyridinyloxy) acetic acid	16.5%
Inert Ingredients	49.1%

Background:

The applicant has submitted an acute inhalation study and a dermal sensitization study. These studies, which were conducted by Dow Chemical USA, were submitted to fulfill an Agency

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requirement as noted in the August 17, 1984, Agency review of the following: acute oral, acute dermal, eye irritation and skin irritation studies. The data accession numbers are 254304 and 254307. The method of support was not indicated.

Recommendation:

FHB/TSS finds the dermal sensitization study acceptable to support registration of the product tested. However, the registrant will have to identify the product tested (464-589 or 464-554) and will have to submit a dermal sensitization study on the other product since the two products are substantially dissimilar. In addition, the registrant must submit an acute inhalation study for product No. 464-554, and FHB/TSS finds the acute inhalation study unacceptable to support registration of product number 464-589. The registrant can either reconduct the acute inhalation study testing three dose levels on a minimum of 4, preferably 5 animals per sex per dose, or use the data on the females provided in the study (Accession Number 254305) and conduct a range test on males to determine their LC_{50}.

The registrant should be informed that for future studies the relative humiditiy should be maintained between 40 to 60 percent unless the nature of the test material or the generating procedures precludes this. In addition, when conducting the dermal sensitization study, the test material should be diluted with physiological saline solution when possible.

Label: Additional labeling may be necessary upon submission of the acute inhalation studies and the dermal sensitization study.

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.

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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:

Supplementary - Data can be upgraded; see comments noted under recommendation.

(2) Dermal Sensitization Study: Hazelton Laboratories, Europe LTD; Laboratory Report Number 3865-50/255; April 1984.

Procedure:

(Screening Study) The test material was applied to two male and two female guinea pigs at four concentration levels (undiluted, 50%, 25% and 10% v/v) to four shaven test sites on the back of each of the four guinea pigs. The sites were examined 24 hours after treatment and the highest nonirritating concentration was used for the main study.

(Main Study) A lint pad with 0.5 ml of the undiluted test material was applied under occlusive wrap for 6 hours to the shaven left flank of five male and five female guinea pigs. The treatment was repeated on the same test site 7 and 14 days after the initial exposure. Two weeks after the induction phase, the test animals and the negative control animals received a challenge dose of the test material under occlusive wrap. After six hours, the patches were removed and the challenge sites were treated with a dipilatory cream, rinsed thoroughly and dried. Observations were made 3 hours after dipilation and later at 24 and 48 hours.

Results:

(Screening Study) Exposure to the test material at 25 percent v/v and 10 percent v/v produced slight redness in some of the test

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animals. Exposure to the test material at the 50 percent v/v and undiluted produced no irritation.

(Main Study) No skin irritation was noted in either the test group or the negative control group at both the 24- and 48-hour observation times. One male animal in the control group was found dead on day 11, however, the animal's death was reported as being unrelated to the treatment.

Study Classification: Core Guideline Data

Toxicity Category: Non-sensitizing