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

006139

JUL 30 1986

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration No. 50534-188
Bravo 720

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

TO: Henry M. Jacoby, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: SDS Biotech Corporation
7528 Auburn Road
P.O. Box 348
Painesville, OH 44077

ACTIVE INGREDIENT:
Chlorothalonil (tetrachloroisophthalonitrile) 54.0%
INERT INGREDIENTS: 46.0%

BACKGROUND:

The registrant has submitted a primary eye irritation study and an acute dermal toxicity study to support an amendment that would change the current signal word "DANGER" to "WARNING." The studies were conducted by WIL Research Laboratories. The Data Accession Number is 262554. The Method of Support was not indicated.

RECOMMENDATION:

FHB/TSS finds the studies acceptable to support a change in the signal word from "DANGER" to "WARNING" only if the current signal word "DANGER" was based on the primary eye irritation study. FHB/TSS cannot be certain that the change in signal words is acceptable since the acute toxicity studies

to TSS

referenced to support this registration were not submitted and there was no indication in the registration jacket that these studies had ever been reviewed by the Agency.

REVIEW:

(1) Primary Eye Irritation Study: WIL Research Laboratories; Report No. WIL-11006; January 23, 1986.

PROCEDURE:

Six male and three female New Zealand White rabbits each received 0.1 ml of test material placed in the conjunctival sac of the right eye. Approximately 30 seconds after administration, the treated eyes of three males were flushed with approximately 100 ml of tap water. The untreated eye of each animal served as a control. Eye irritation was scored at 1, 24, 48, and 72 hours and on days 4, 7, 10, 14, and 21. Eyes were examined using sodium fluorescein dye at 72 hours and on days 7, 14, and 21.

RESULTS:

Eye irritation in the unwashed group was scored as follows: at 24 hours, corneal opacity (1/6 = 10), iris irritation (2/6 = 5), conjunctiva redness (6/6 = 3), chemosis (3/6 = 4, 2/6 = 3, 1/6 = 2), and discharge (3/6 = 2, 3/6 = 1); at day 7, conjunctiva redness (1/6 = 3, 2/6 = 2, 3/6 = 1), chemosis (4/6 = 1) and discharge (1/6 = 2, 1/6 = 1); at day 14, conjunctiva redness (1/6 = 1) and discharge (2/6 = 1); and at day 21, all irritation had cleared. Animals also displayed purulent and/or clear discharge, petite hemorrhaging, and blanching all of which cleared by day 21.

Eye irritation in the washed group was scored as follows: at 24 hours, conjunctiva redness (2/3 = 3), chemosis (1/3 = 2, 1/3 = 1) and discharge (1/3 = 1); at day 7, conjunctiva redness (1/3 = 1); and at day 10, all irritation had cleared. One animal displayed purulent discharge which subsided by 48 hours.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category II - WARNING.

(2) Acute Dermal Toxicity Study: WIL Research Laboratories; Report No. WIL-11005; January 27, 1986.

PROCEDURE:

Five male and five female New Zealand White rabbits each received 2000 mg/kg of test material which was applied to a previously shaven test site on the back of each animal. Each test site was kept under occlusive wrap for 24 hours. Animals were placed in restraint collars during exposure. After exposure, the collars and bandages were removed, and the test sites were washed with wet paper towels. Animals were observed at 1, 4, and 6 hours on day of dosing and twice daily thereafter for 14 days. Skin irritation was scored 30 minutes after removal of wrap and on days 3, 7, 10, and 14. Body weights were recorded on day of dosing and on days 3, 7, and 14. All animals were submitted for gross necropsy.

RESULTS:

No deaths occurred. The LD_{50} was reported to be > 2000 mg/kg. Toxic symptoms observed were diarrhea, soft stool, decreased defecation, urogenital and/or anogenital staining and matting, ocular discharge, very slight to severe erythema and edema, desquamation, fissuring, and weight loss. Gross necropsy revealed enlarged mesentaric lymph nodes, reddened kidneys, white areas on the liver, and hypoplastic testes. Excluding skin irritation, these toxic symptoms were reported not to be related to the test material.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

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