6-18-84

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

Date: June 11, 1984

Subject: EPA File Symbol: 100-AUR
Banner Fungicide

From: Deloris F. Graham
FHB/TSS

To: Henry Jacoby
Product Manager (21)

Applicant: Ciba-Geigy Corporation
Agricultural Division
P.O. Box 18300
Greenboro, NC 27419

Active Ingredients:
1-[2-(2,4-dichlorophenyl)-4-propyl
-1,3-dioxolan-2yl]methyl-1H-1,2,
4-triazole. 14.3%
Inert Ingredients 85.7%

Background: Submitted Eye Irritation, Primary Skin Irritation and Dermal Sensitization Studies. Studies conducted by Stillmeadow, Inc. Studies under accession number 251241. Method of support not indicated.

Recommendation:
(1) FHB/TSS finds these data acceptable to support conditional registration of this product.

Label:

(1) No additional labeling comments. Labeling acceptable as submitted.
~~with the previously requested amendments included.~~

Review:

(1) Eye Irritation Study: Stillmeadow, Inc.; Project No. 2727-82; September 13, 1982.

Procedure: Nine rabbits received 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed with deionized water for one minute, 30 seconds after treatment. Observations were made at 1, 24, 48 and 72 hours, and at 4, 7, 10, and 13 days after treatment.

Results: At 24 hours, 6/6 in the unwashed group had corneal opacity (6/6=5) and 2/3 corneal opacity in washed group (2/3=5); 6/6 + 1/3 iris irritation (6/6=5) (1/3=5); 6/6 + 3/3 conjunctive redness (6/6=2) (3/3=2), chemosis (2/6=2, 4/6=3) (2/3=2, 1/3=3) and discharge (2/6=2, 4/6=3) (2/3=1, 1/3=2). At 7 days, 3/6 + 2/3 redness (3/6=1) (2/3=1). 4/6 + 1/3 chemosis (4/6=1) (1/3=1); hair loss around the eye. At day 10, all irritation cleared.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

(2) Primary Skin Irritation Study: Stillmeadow, Inc.; Project No. 2779-82; November 8, 1982.

Procedure: Six rabbits with two abraded and two intact skin sites each received 0.5 ml of the test matter under occlusive wrap for 24 hour exposure. Observations made at 24 and 72 hours after treatment.

Results: At 24 hours, 6/6 slight to well defined erythema (scores of 1 and 2) and slight to moderate edema (scores of 1, 2, 3, 4). At 72 hours, 6/6 slight to well defined erythema (scores 1 and 2) and slight to moderate edema. Primary Irritation Score reported to be 4.77. According to method of scoring product considered moderately irritating. Eschar, shallow lateral fissuring, focal areas of pustules and sloughing of skin of various thickness. Sloughing of skin continued through the 14-day observation period.

Study Classification: Core Guideline Data.

Toxicity Category: II WARNING.

(3) Dermal Sensitization Study: Stillmeadow, Inc.; Project No. 2780-82; December 2, 1982.

Procedure: Ten male guinea pigs per each of two treatment groups. Group I guinea pigs were treated with a 0.05 of w/v solution of 2,4-dinitrochlorobenzene in ethanol as a positive control group. Group II guinea pigs were treated with a 1.00% v/v solution of the test material in deionized water. The animals were treated on days 0, 2, 5, 7, 9, 12, 14, 16, 19, 21 and 35. The animals were treated with 0.5 ml of the appropriate material on each of the first ten treatments, initial treatments. On day 35 animals were treated with 0.5 ml of the appropriate

material, challenge treatment. Observations were made 24 hours after each treatment. "A marked increase in positive skin reactions after day 35 treatment (challenge treatment) above those observed after day 0 treatment (initial treatment) was indicative of a sensitizing reaction".

Results: Group I (positive control) average skin reaction for day 0 was 0.0 and 3.1 for virgin challenge an 5.0 for day 35 (challenge treatment). Therefore product considered to have produced a sensitizing reaction in guinea pigs.

Group II (test group) average skin reaction for day 0 was 0.0 and for virgin challenge and day 35 (Challenge treatment) was 0.0. Therefore it was stated that this product did not produce a sensitizing reaction in guinea pigs.

Study Classification: Core Guideline Data.

Toxicity Category: Non-sensitizing.