UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

8-10-81
215B

DATE: August 10, 1981

SUBJECT: EPA Registration No. 677-313
Bravo 5000

FROM: EPA Registration No. 677-315
Daconil 2787 Flowable Fungicide

002037

TO: Deloris F. Graham EFG 8/14/81
FHB/TSS
E 8/14/81

Henry Jacoby
Product Manager (21)

Applicant: Diamond Shamrock Corporation
Agricultural Chemicals
1100 Superior Avenue
Cleveland, Ohio 44114

Active Ingredients:
Chlorothalonil (Tetrachloroisophthalonitrite) . . 40.4%
Inert Ingredient: 59.6%

Background: Submitted two Eye Irritation Studies, one using monkeys and the other using rabbits, to be evaluated using the new criteria set forth in policy and criteria notice effective March 1981. Based on the re-evaluaton of these studies, the company feels the signal word will change from DANGER to WARNING. Cite-All method of support used. Data under accession numbers 245574 and 245399.

Recommendation:

(1) FHB/TSS finds these eye studies acceptable to support conditional registration of this product.

(2) The signal word for both eye studies was WARNING.

(3) Child Resistant Packaging (CRP) is not based on signal, therefore if the signal word changes from DANGER to WARNING, as in this case, it doesn't mean CRP is not necessary. Please see 40 CFR 162.16(c)92).

Label:

(1) The proposed labeling is acceptable.

Review:

(1) Eye Irritation Study: Bio/dynamics; Project No. 6436-80; March 17, 1981.

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Procedure: Nine monkeys received 0.1 ml of test substance into the right eye. Six of the treated monkey eyes remained unwashed while the remaining three of the treated monkey eyes were washed. Observations made at 24, 48 and 72 hours, 4,7 and 14 days.

Results: At 24 hours, 6/6 animals of the unwashed group had corneal opacity (1/6=10, 4/6=20, 1/6=40); nc iris irritation; 6/6 redness (1/6=1). 4/6=2, 1/6=3), 4/16 chemosis (3/6=1, 1/6=2), 5/6 discharge (5/6=1). At day 7, 4/6 corneal opacity (1/6=1, 2/6=15, 1/6=20); 6/6 redness (4/6=1, 2/6=2). At day 14, 2/6 corneal opacity (1/6=5, 1/6=10) and 1/6 redness (1/6=1). At day 21, no corneal opacity or any other irritation. At 24 hours, no corneal opacity in 2/3 washed group, or iris irritation; 3/3 redness (1/3=1, 2/3=2), 2/3 discharge (2/3=1). At day 7, 1/3 redness (1/3=1). No other irritation present. At day 14, 1/3 redness (1/3=1). At day 21 redness had cleared.

Study Classification: Core Guideline Data:

Toxicity Category: II-WARNING

(2) Eye Irritation Study: Bio/dynamics; Project no. 6504-80; March 17, 1981.

Procedure: Nine rabbits received 0.1 ml of test substance into the right eye. Six of the treated rabbit eyes remained unwashed while the remaining three of the treated rabbit eyes were washed. Observations made at 24, 48 and 72 hours, 4, 7 and 14 days.

Results: At 24 hours, 6/6 animals of the unwashed group had corneal opacity (2/6=10, 4/6=20); 6/6 iris irritation (6/6=5); 6/6 redness (1/3=1. 2/3=2), chemosis (4/6=2, 2/6=3), discharge (6/6=3). At day 7, 1/6 iris irritation (1/6=5); 4/6 redness (4/6=1), 1/6 chemosis (1/6=1). At day 14, all irritation had cleared.

At 24 hours, no corneal opacity in 3/3 animals of washed group; 1/3 iris irritation (1/3=5); 3/3 redness (1/3=1, 2/3=2), 2/3 chemosis (1/3=1), 1/3=2); 2/3 discharge (2/3=2). At day 7, all irritation had cleared.

Study Classification: Core Guideline Data

Toxicity Category: II - WARNING

Page_____ is not included in this copy.

Pages 3 through 16 are not included.

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.

✓ 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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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.