

US EPA ARCHIVE DOCUMENT

001068

DATE: January 10, 1980

SUBJECT: Review of Toxicity Data - EPA #677-326, Chlorothalonil 2.88 and 677-331, Chlorothalonil Flowable 3; Request to Change Signal Word and Precautionary Statement. Caswell # 215B

FROM: D. Ritter, Toxicologist
Toxicology Branch, Review Section #1 3.12 1/14/80

TO: D. Ierley, Team #21
HF3/RD TS-767

Action Proposed: Upgrade Signal Word from "Warning" to "Danger" and upgrade Precautionary Statement. Studies to apply to both formulations since they are virtually identical.

Conclusions:

1. The submitted Eye Irritation studies by Industrial Biotech (IBT) have not been validated and certified; hence we are unable to use them for regulatory purposes. However, Tox. Br. notes that the data produced in these studies suggest that toxicity to eyes borders on Tox Cat 1.
2. The Eye Irritation studies performed at International Research and Development Corp. (IRDC) do not support a change in Signal Word or Precautionary Labeling.
3. Submit the percentages of inert ingredient and a.i. for [REDACTED]
4. Studies apply to both formulation (3.0 & 2.88F).

Since the IRDC studies contain data that support only a Tox Category II, Signal Word "Warning", we conclude that the label should remain unchanged without studies to unequivocally place the test material in Tox Cat I.

Review of Data

1. Rabbit Eye Irritation Study IBT # 601-03816, 9/7/73.

Material Tests: Brave 2.88 Flowable (=677-326)

Methods

0.1 ml of four different lots of the undiluted product were instilled into the right eye of NZW rabbits. Examinations and scoring were made at hr; and 1, 2, 3, 7 and 14 days according to Draize, J. Pharm. & Exp. Ther. 92:377 (1944).

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

Results

Overall Draize Score by batch:

7948-79-1 - 48.5/110	Moderately irritating
2 - 27.6/110	" "
3 - 25.9/110	" "
4 - 108.7/110	Extremely irritating

Corneal vascularization, pannus and conjunctival swelling at 14 days.

Classification: CORE: minimum data

Tox Category: 1

Signal Word: Danger

2. Rabbit Eye Irritation test IRDC # 293-025, 10/30/73
Material tested: Daconil 2.88F (7948-79-2)

Methods:

0.1 ml test material instilled into right of 3 male and 3 female NZW rabbits. Examination at 2, 24, 48 and 72 hours, and at 7 and 14 days. Fluorescein and UV examinations at inception, 72 hours, and 14 days.

Scoring after method of Draize (AFDO, 1959, revised 1964, p. 51).

Results:

Conjunctival redness, chemosis and discharge at 14 days.

Classification: CORE Minimum data

Tox Category: II

Signal Word: WARNING

3. Eye Irritation Test IBT # 601 - 03816, 10/28/74.
Test Material: Bravo 2.88F (7448-79-2)
Note: This study is a duplicate to the IRB study reviewed above.
Only the date has been changed.

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