10-16-87

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SEP 29 1987

SUBJECT: EPA File Symbol 100-ATE
Apron T69 Fungicide

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

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TO: Lois A. Rossi, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: Ciba-Geigy Corporation
Agricultural Division
P.O. Box 18300
Greensboro, NC 27419

ACTIVE INGREDIENT:
Metalaxyl: N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester 45.0%
Thiabendazole: 2-(4-thiazolyl) benzimidazole . . . 24.0%
INERT INGREDIENTS: 31.0%

BACKGROUND:

The registrant has submitted a primary eye irritation study. This action is in response to the Agency SOP on inerts. The registrant has deleted an inert of concern and has run another primary eye irritation study on the revised formulation to determine if the current toxicity category (I) assigned to the primary eye irritation study (see TSS review dated 4-9-87) can be lowered.

The study was conducted by Stillmeadow, Inc. The MRID Number is 402939-01. The method of support was not indicated.

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RECOMMENDATION:

FHB/TSS finds the eye study acceptable to support registration of the revised formulation. The signal word is "WARNING."

In addition, the registrant must supply an acute oral, acute dermal, primary skin irritation, acute inhalation and dermal sensitization studies on the new revised formulation. The registrant has stated that the remainder of the acute toxicity studies on the revised formulation were not conducted since the studies were all toxicity category III and IV. TSS is requesting these additional studies because of the fact that, in addition to deleting the inert of concern, the registrant has increased the amount of the active ingredient (metalaxyl) per the confidential statements of formula (CSF). (See first CSF dated 12-22-86 submitted with first TSS review of 4-9-87 and second CSF dated 6-15-87 submitted with primary eye irritation study.)

LABELING:

Comments reserved until outstanding data is submitted.

REVIEW:

Primary Eye Irritation Study: Stillmeadow, Inc.; Study Number 4876-87; 7-15-87.

PROCEDURE:

Nine New Zealand white rabbits were each administered 100 mg of test material which was placed in the right eye of each animal. The treated eye was held shut for one second. Thirty seconds after treatment, the treated eye of 3/9 animals was washed with deionized water for one minute. The untreated left eye served as a control. Eye irritation was scored at 1, 24, 48 and 72 hours and at 4, 7, 10, 14 and 17 days after treatment.

RESULTS:

Eye irritation in the unwashed group was scored as follows: at 24 hours, iris irritation (2/6 = 10, 2/6 = 5), conjunctivae redness (6/6 = 2), chemosis (2/6 = 3, 3/6 = 2, 1/6 = 1), and discharge (2/6 = 2, 4/6 = 1); at 7 days, conjunctivae redness (1/6 = 2, 2/6 = 1), chemosis (4/6 = 1), fluorescein staining (1/6); and at 14 days, all irritation had cleared.

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Eye irritation in the washed group was scored as follows: at 24 hours, iris irritation (2/3 = 5), florescein staining (2/3), conjunctivae redness (2/3 = 2, 1/3 = 1), chemosis (1/3 = 3, 2/3 = 1) and discharge (2/3 = 2, 1/3 = 1); at 7 days, chemosis (1/3 = 1); and at 14 days, all irritation had cleared.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Category II - WARNING

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THIABENDAZOLE 060101

Page_____ is not included in this copy.

Pages 4 through 8 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.

X 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) _____.

____ The document is not responsive to the request.

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.