3-23-88

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAR 18 1988

MEMORANDUM

SUBJECT: EPA File Symbol 773-LL
Clinafarm EC

FROM: Mary L. Waller
Technical Support Section 3/23/88
Fungicide-Herbicide Branch
Registration Division (TS-767C) E 3/23/88

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

APPLICANT: Pitman-Moore, Inc.
ATTN: Regulatory Affairs
P.O. Box 344
Washington Crossing, NJ 08560

ACTIVE INGREDIENT:
Imazalil: 1-(2-(2,4-dichlorophenyl)-2-
(2-propenyloxy)ethyl)-1H-imidazole 13.76%
INERT INGREDIENT: 86.24%

BACKGROUND:

The applicant has submitted a primary eye irritation study. The study was conducted by Janssen Pharmaceutica Research Laboratories. The MRID number is 401521-02. The method of support was not indicated.

RECOMMENDATION:

FHB/TSS finds the study unacceptable and classifies it as supplementary. The registrant must submit an acute oral toxicity study, acute dermal toxicity study, acute inhalation toxicity study, a primary eye irritation study, a primary skin irritation study and a dermal sensitization study.

When conducting future primary eye irritation studies, the end-use product must be tested to support registration of the end use product. Studies conducted on dilutions of the end-use product are unacceptable.

LABELING: Comments reserved until data is submitted.

REVIEW:

Primary Eye Irritation Study: Janssen Pharmaceutica Research Laboratories; No. 1675; 5-12-85.

PROCEDURE:

Nine New Zealand white rabbits were each administered 0.1 ml of a 1:100 dilution of test material in water which was placed in lower conjunctival sac of the left eye of each animal. The treated eye was held shut for one second. The right eye of each animal served as a control. Thirty seconds after treatment, the treated eye of 3/9 animals was rinsed with water. Eye irritation was scored at 1, 2, 3, 4, 7, 10, 14 and 21 days.

RESULTS:

Twenty-four hours after treatment, 1/6 animals in the unwashed group exhibited conjunctive redness (1/6=1) and 5/6 exhibited discharge (5/6=1). All irritation in the unwashed group had cleared by day 3.

Forty-eight hours after treatment, one animal in the washed group exhibited discharge (1/3=1). Irritation had cleared by day 3.

STUDY CLASSIFICATION:

Supplementary - See comments under Recommendation.