

US EPA ARCHIVE DOCUMENT



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

006371

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

JAN 13 1987

SUBJECT: Rally 60 DF Fungicide
EPA File Symbol 707-EUP-RRG

FROM: Deloris F. Graham *D.F.G. 1/20/87*
Technical Support Section *E. 1/20/87*
Fungicide-Herbicide Branch
Registration Division (TS-767C)

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

Applicant: Rohm & Haas Company
Independence Mall West
Philadelphia, PA 19105

ACTIVE INGREDIENT:

70% α -butyl- α -(4-chlorophenyl)-1H-1,2,4-triazole-1-
propanenitrile 60%
INERT INGREDIENTS: 40%

BACKGROUND:

Submitted Acute Oral, Acute Dermal, and Eye Irritation Studies and discussion in lieu of Acute Inhalation, Primary Dermal and Dermal Sensitization Studies. Data under Accession Number 265789. Studies conducted by Rohm & Haas Company. Method of Support not indicated.

RECOMMENDATION:

1. FHB/TSS finds the acute oral, acute dermal, and eye irritation studies submitted acceptable to support conditional registration of the product.

104

2. According to data submitted particle size is in the range of 200 to 500 microns. If 85% or more of the product falls in this range then an acute inhalation study is not required. *The percent of particles between 200 and 500 microns should be verified before study is carried.*
3. Primary dermal and dermal sensitization studies must be submitted or acceptable data to support waiver. Information submitted for this review is not sufficient.
4. Based on the eye study the appropriate signal word is "WARNING."

LABEL:

Additional precautionary labeling may be necessary upon submission of the primary dermal and dermal sensitization studies.

REVIEW:

- (1) Acute Oral Study on Male Rats (Report No. 86R 089A) and Female Rats (86R 089B): Rohm & Haas; August 14, 1986.

PROCEDURE:

Six groups consisting of ten male and ten female rats each were dosed with one of the following concentrations: 0.0, 500, 734, 1077, 1581, or 2321 mg/kg. Observations made for 14 days postdosing. Necropsy performed on all animals.

RESULTS:

At 734 mg/kg, 2/10 M and 2/10 F died; at 1077 mg/kg, 9/10 M; 5/10 F; at 1581 mg/kg, 8/10 M and 7/10 F died; at 2321 mg/kg, 8/9 M and 8/10 F died. At 2321 mg/kg, 1 hour postdosing one animal reported found dead due to thoracic cavity filled with white fluid, so only nine male animals at this dose level. Toxic signs reported included passiveness, prostration, moribund, ataxia, convulsion, salivation, abdominal breathing, gasping, cool to touch, diarrhea, red-stained eyes, red or tan-stained muzzle, anogenital area brown or yellow stained, and lacrimation. Necropsy report revealed tan or red stained muzzle; yellow or brown stained anogenital area; liver darkened; spleen darkened and pale; stomach filled with tan or white fluid; stomach mucosa reddened or filled with clear fluid; intestines reddened and/or filled with white fluid; kidneys pale. LD₅₀ for males reported to be 98 mg/kg. LD₅₀ for females reported to be 1235 mg/kg with confidence limits between 960 and 1634 mg/kg.

STUDY CLASSIFICATION:

Core Guideline Data when Report Nos. 86R 089A and 86R 089B are used in conjunction with each other.

006371

2

TOXICITY CATEGORY: III - CAUTION.

- (2) Acute Dermal Toxicity Study on Male Rats (Report No. 86R 089A) and Female Rats (Report No. 86R 089B): Rohm & Haas; August 14, 1986.

PROCEDURE:

Six male and six female rats with intact skin sites each were treated with a single 5.0 g/kg dose of test material. Treated sites were placed under occlusive wrap for 24-hour exposure period. Observations were made for 14 days posttreatment. Necropsy performed on all animals.

RESULTS:

No mortalities or abnormalities at necropsy reported. Red stained eyes only toxic sign reported. LD₅₀ reported to be greater than 5.0 g/kg for males and females.

STUDY CLASSIFICATION:

Core Guideline Data when Report Nos. 86R 089A and 86R 089B are used in conjunction with each other.

TOXICITY CATEGORY: IV - CAUTION.

- (3) Eye Irritation Study: Rohm & Haas; Report No. 86R 089A; August 14, 1986.

PROCEDURE:

Nine rabbits received 0.1 g of the test material in one eye each. The treated eyes of three of the rabbits were washed with water for 60 seconds beginning 20 to 30 seconds after dosing. Observations made for 21 days postdosing.

RESULTS:

At 24 hours postdosing, 6/6 rabbits of the unwashed group and 0/3 of the washed group had corneal opacity (1/6 = 10, 5/6 = 20); 5/6 iris irritation (5/6 = 2.5); 6/6 + 3/3 conjunctive irritation (2/6 = 6, 1/6 = 8, 2/6 = 10, 1/6 = 12, cumulative scores for redness, chemosis and discharge) (2/3 = 2, 1/3 = 4, cumulative scores); one animal had blanching of the nictitating membrane. At day 7, 2/6 animals had streaky haze through center of cornea after treatment with 2.0% sodium fluorescein; no other irritation noted. Irritation had cleared by day 21.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: II - WARNING.

006371

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Pages _____ through _____ 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) _____.
 - The document is not responsive to the request.
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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.
