

US EPA ARCHIVE DOCUMENT



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

4-14-87

006263

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

~~APR - 8 1987~~

MEMORANDUM

SUBJECT: EPA Registration No. 7501-42
Gustafson Apron Fl Treatment Fungicide

FROM: Deloris F. Graham *4/14/87*
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

E 4/14/87

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

APPLICANT: Gustafson, Inc.
P.O. Box 660065
Dallas, TX 75266

ACTIVE INGREDIENT:
Metalaxyl 28.35%
INERT INGREDIENTS: 71.65%

BACKGROUND:

Submitted Eye Irritation Study on formulation containing an emulsifier (July 9, 1986) less severe in potential than emulsifier in product submitted originally on June 23, 1986. Study conducted by Food and Drug Research Laboratories, Inc. Data under Accession Number 266162. Method of support not indicated.

RECOMMENDATION:

FHB/TSS finds study acceptable to support conditional registration on product which was tested. However, the Confidential Statements of Formula in question (ones submitted in June 23 and July 9, 1986) do not indicate an emulsifier. Therefore, the question of the emulsifier should be clarified from a product chemistry standpoint.

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LABEL:

In regard to product tested the eye statement must be similar to following "May cause eye irritation. If in eye flush with plenty of water and get medical attention if irritation persists."

REVIEW:

- (1) Eye Irritation Study: Food & Drug Research Laboratories; FDRL Study No. 9184B; August 25, 1986.

PROCEDURE:

Nine rabbits received 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed 30 seconds after treatment. Observations made for 7 days posttreatment.

RESULTS:

At 24 hours posttreatment, 4/6 rabbits of the unwashed group had corneal opacity (1/6 = 5, 3/6 = 10); 6/6 of the unwashed group and 3/3 of the washed group had conjunctive redness (6/6 = 2) (3/3 = 1); 6/6 chemosis (6/6 = 1) and 5/6 discharge (5/6 = 1). Irritation and opacity had cleared by day 7 in unwashed group. Redness in washed group had cleared in 72 hours.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

METALAXYL

Page 3 is not included in this copy.

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.
