

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

4-14-87

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PESTICIDES AND TOXIC SUBSTANCES

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APR - 8 1997

MEMORANDUM

SUBJECT: EPA Registration No. 7501-42

Gustafson Apron Fl Treatment Fungicide

4/14/87

PROM: Deloris F. Graham

Technical Support S cion Fungicide-Herbicide Branch

Registration Division (TS-767C)

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:

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.

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Identity of product inert ingredients.	
Identity of product impurities.	
Description of the product manufacturing proce	ess.
Description of quality control procedures.	
Identity of the source of product ingredients.	
Sales or other commercial/financial information	on.
A draft product label.	
The product confidential statement of formula.	•
Information about a pending registration action	on.
FIFRA registration data.	
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