003540

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

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MEMORANDUM

DATE: March 2, 1981

SUBJECT: Acme Vegetation Killer
EPA Reg. No. 33955-454

FROM: Sherell A. Sterling
FEB/TSS

TO: Richard Mountfort
Product Manager (23)

BEST AVAILABLE COPY

Applicant: Acme Division
PBI/Gordon Corporation
300 South Third Street
P.O. Box 2276
[redacted], Kansas 66110

Active Ingredients:
Prometon [redacted] 3.6%
2,4-Dichlo[redacted]etic acid 1.0%
Aromatic pet[redacted] distillates 76.4%
Inert Ingredients 19.0%

Background: A Dermal Sensitization test was submitted in response to a request made when other acute data were reviewed (see Sterling 3/28 /80). The other acute exposure data were considered adequate for conditional registration purposes.

The Dermal Sensitization study was conducted by Stillmeadow, Inc. of Houston, Texas. It is under Accession Number 244288.

Recommendations:

1. The Dermal Sensitization study is considered adequate and acceptable for conditional registration purposes.

Labeling Recommendations:

1. The statement "May cause allergic skin reaction" must be added to the "Hazards to Humans and Domestic Animals" section.

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2. Under "Directions for Use" please note the following:

   (a) The statement " It is a violation of federal law to use this product in a manner inconsistent with its labeling" must appear on the label. The appropriate place is directly below the "Directions for Use" heading.

   (b) The statement "Read Cautions First" is inappropriate and must be deleted. An alternative statement would be "Read Precautionary Statements first."

Review:

1. Guinea Pig Sensitization: Stillmeadow Project #1942-80; January 6, 1981; Acc. No. 244288

   Procedure: Twenty male Hartley-albino guinea pigs were treated with 0.5 ml of a substance under occlusive wrap at days 0,3,5,7,10,12,14,17,19 and 21. In 10 of the animals, the test substance was 10% v/v solution of Acme Vegetation Killer in dionized water which was the highest non-irritating level. The remaining animals acted as a positive control with 0.05%w/v solution of 2,4-dinitrochlorobenzene in ethanol. On day 35, the animals were challenged with 0.5 ml of their respective test substances at each of two sites.

   Results: [redacted] hours, the positive controls showed no erythema [redacted]. The test substance showed erythema at 4/10 [redacted]. At Day 35, the positive controls showed [redacted] 17/10 = 1, 3/20 = 2 and edema in 10/20 = 1; the test [redacted] showed erythema in 18/20 = 1, 1/20 = 2 and 10/20 = 1 for edema. The test substance was found to be a dermal sensitizing agent.

   Study Classification: Core Minimum Data. The dosage levels should be: 0.05 ml initially, 0.1 ml 3 times per week for three weeks (total = 10), wait 2 weeks and challenge. Sites should be rotated.

   Toxicity Category: Dermal sensitizer

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RIN-0334-94 PROMETON REVIEWS (080804)

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.

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.
