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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 006046
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAY 27 1987

MEMORANDUM

SUBJECT: EPA File Symbol 538-ERI
Lawn Weed Control Plus Fertilizer

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

TO: Richard F. Mountfort, PM 23
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: O.M. Scott and Sons Company
14310 Scottslawn Road
Marysville, OH 43041

LOW RANGE

ACTIVE INGREDIENTS:	
2-methyl-4-chlorophenoxyacetic acid	0.66%
2-(2-methyl-4-chlorophenoxy)propionic acid	0.66%
INERT INGREDIENTS:	96.68%

HIGH RANGE

ACTIVE INGREDIENTS:	
2-methyl-4-chlorophenoxyacetic acid	1.37%
2-(2-methyl-4-chlorophenoxy)propionic acid	1.37%
INERT INGREDIENTS:	97.26%

BACKGROUND:

The applicant has submitted a dermal sensitization study. The study was conducted by Hazelton Laboratories America, Inc. The data are not accessioned. The method of support was not indicated.

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RECOMMENDATION:

FHB/TSS finds the study acceptable and classifies the product as a nonsensitizer; however, the applicant must identify, in writing, the product tested and must specify whether the high- or low-range formulation was tested. If the applicant tested the high-range formulation, then the dermal sensitization study can be used to support both the high- and low-range formulation. If the applicant tested the low-range formulation, then the applicant must conduct a dermal sensitization study on the high-range formulation.

LABELING:

1. The Statements of Practical Treatment should be separated from the Precautionary Statements. Move the second and third sentences from under the Precautionary Statements and place them under the "Statements of Practical Treatment" heading.

2. The Product Manager should note that the ingredient statement on the low-range formulation is either incorrect or misleading because 0.66% + 0.66% + 96.68% does not equal 100%.

REVIEW:

Dermal Sensitization Study: Hazelton Laboratories America, Inc.; Lab Sample No. 61005148; December 15, 1986.

PROCEDURE:

Two groups of guinea pigs (test group - 10 animals and positive control group - 4 animals) were clipped free of hair on the back prior to each treatment. Each group received induction treatments on the left flank for 6 hours of exposure under occlusive wrap once a week for 3 weeks as follows: test group received 0.2 g of test material moistened with 0.9% saline and the positive control group received 0.4 ml of a 0.3% w/v solution of 2,4-dinitrochlorobenzene (DNCB) in 80% ethanol/deionized water. Two weeks after the last induction treatment, the test group and a naive control group of 10 guinea pigs received the challenge dose on the right flank identical to an induction treatment. The positive control group received a challenge dose on the right flank of 0.4 ml of 0.1% (w/v) DNCB in 80% ethanol/deionized water. Skin irritation was scored at 24 and 48 hours after each treatment.

RESULTS:

The test group did not exhibit any irritation during the induction treatment. Both the test group and the naive control group did not exhibit irritation following challenge treatment. The positive control group exhibited very slight erythema after the first induction treatment and irritation increased with subsequent treatments to moderate to strong erythema with subcutaneous hemorrhaging and necrotic areas. After the challenge dose, positive control animals exhibited very slight erythema.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Nonsensitizer.

MCPP Toxicology review

Page _____ is not included in this copy.

Pages 4 through 7 are not included in this copy.

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 product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

X 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.