

US EPA ARCHIVE DOCUMENT



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

DATE: October 8, 1980

SUBJECT: EPA File Symbol 2749-UIO
Aceto Linuron Technical Herbicide: Caswell # _____

FROM: Deloris F. Graham *DEL 10/12/80*
FHB/TSS *E-11/3/80*

TO: Robert Taylor
Product Manager (25)

#528

Applicant: Aceto Agricultural Chemical Corp.
126-02 Northern Boulevard
Flushing, New York 11368

Active Ingredients:

LINURON: 3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea 96%
Inert Ingredients 4%

Background:

Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation and Skin Irritation studies in support of the conditional registration of this product. Data not accessioned. Method of Support not indicated. Acute Oral, and Acute Dermal studies were conducted by Consultox Laboratories, London. The Acute Inhalation, Eye Irritation and Dermal Irritation studies were conducted by Hazleton Laboratories America, Inc.

Recommendation:

1. The Acute Oral, Acute Dermal and Skin Irritation studies are acceptable to support the conditional registration of this product. However, for future submissions, please note:
 - a. In the Acute Oral Study individual symptomology and necropsy reports for each animal must be submitted.
 - b. In the Acute Dermal Study individual symptomology and necropsy reports for each animal must be submitted. Also treated sites must be wiped clean, not washed, of excess material after exposure period.
 - c. In the Skin Irritation Study 4 sites (2 abraded and 2 intact) per animal must be used.

-2-

2. The Acute Inhalation Study is not acceptable to support the conditional registration of this product.
 - a. Chamber design and operation, including type of chamber, its dimensions, the source of makeup air and its conditioning (heating and cooling) for use in the chamber, the treatment of exhausted air, the housing and maintenance of the animals in the chamber and similar related information must be submitted.
 - b. Actual concentration value and the calculations for determining this value must be submitted.
 - c. Median particle sizes and their geometric standard deviations must be submitted.
 - d. Tabulation of response data must be submitted.
 - e. LC₅₀ and 95% confidence limits and specification of method used for LC₅₀ calculation must be submitted.

Please see section 163.81-3 of the "Proposed Guidelines".
A copy is enclosed for your convenience.

3. The Eye Irritation Study is not acceptable to support the conditional registration of this product.
 - a. Must use 100 mg dose for solid or 0.1 ml dose for liquids.
4. FHB/TSS objects to the conditional registration of this product until acceptable Acute Inhalation and Eye Irritation studies are submitted.

Label:

1. Labeling comments reserved until acceptable Acute Inhalation and Eye Irritation studies are submitted.

Note to PM:

1. Neither the Certification statement nor Offer-to-Pay statement is enclosed.

2

Review:

1. Acute Oral Toxicity Study: Consultox Lab., Ltd., April, 1974.

Procedure: 4 groups each consisting of 2 rats received one of the following doses: 5,000; 1,000; 500; 100 mg/kg. Since 2/2 animals died at 5,000 and 0/2 at 1,000, another assay was run using 5 groups, each consisting of 10 (5M and 5F) rats, that received one of the following doses: 1,000; 2,000; 3,000; 4,000; and 5,000 mg/kg. Observations were made for 14 days.

Results: No mortalities at 1,000 mg/kg dose; 2/10 animals at 2,000 mg/kg dose; 7/10 animals died at 3,000 mg/kg; 9/10 animals died at 4,000 mg/kg dose and 10/10 animals died at 5,000 mg/kg dose. Symptoms observed included lethargy, disoriented locomotion, excessive salivation, chromadacryorrhea and coma. LD₅₀ was 2,600 (2122-3185) mg/kg.

Study Classification: Core Minimum Data. Individual symptomology and necropsy reports for each animal must be submitted.

Toxicity Category: III-CAUTION

2. Acute Dermal Toxicity Study: Consultox Lab., Ltd.

Procedure: A group of 10 (5M and 5F) rats received a 2,000 mg/kg dose. The test material was applied to the shaved area of each rat and treated area was placed under occlusive wrap for 24 hours. At the end of the 24 hour exposure period the wrap was removed and the area thoroughly washed with detergent and water. Animals were observed for 14 days.

Results: No mortalities. Symptoms observed included slight chromadacryorrhea. LD₅₀ greater than 2,000 mg/kg.

Study Classification: Core Minimum Data. Individual symptomology and necropsy reports for each animal must be submitted. Also treated sites must be wiped clean, not washed, of excess material after exposure period.

Toxicity Category: III-CAUTION



3. Acute Inhalation Study: Hazleton Laboratories, April 10, 1975; Project No. M 915-103.

-4-

Procedure: One group of 10 male white rats weighing between 221-281 grams were exposed under dynamic conditions in a 38-liter glass inhalation chamber for one hour to a nominal concentration of 200 mg/l of the test material. All animals were observed for pharmacotoxic signs and mortality during each exposure and during the 14 day post-exposure observation period.

Results: 170 grams of Linuron technical was generated into the exposure chamber during the one hour period during which 780 liters of air was passed through the chamber. The nominal concentration was thus 218 mg/l of air. No mortalities. All animals exhibited slight hyperactivity and discharge around the mouth and eyes throughout the exposure period. All animals exhibited normal appearance and behavior during the 14 day observation period.

Study Classification: Core Supplementary Data. Chamber design and operation, including type of chamber, its dimensions, the source of makeup air and its conditioning (heating and cooling) for use in the chamber, the treatment of exhausted air, the housing and maintenance of the animals in the chamber and similar related information must be submitted.

data upgraded to min. see Cokerly file #482

Actual concentration value and the calculations for determining this value must be submitted.

Median particle size, LD₅₀ and 95% confidence limits must be submitted.

4. Eye Irritation Study: Hazleton Laboratories; April 1, 1975.

Procedure: 6 New Zealand white rabbits received a 46 mg dose of the test material in conjunctival sac of the left eye of each rabbit. Observations were made at 24, 48 and 72 hours.

Results: 3/6 at 24 hour slight redness (3/6=1), but had cleared by 48 hours. No corneal opacity or iris irritation.

Study Classification: Core Supplementary Data. For solids a 100 mg dose or for liquids 0.1 ml dose must be used.

5. Dermal Irritation Study: Hazleton Laboratories, April 1, 1975.

4

-5-

Procedure: 6 New Zealand white rabbits received a 0.5 g dose at one abraded and one intact site per animal. The treated sites were under occlude wrap for a 24 hour exposure period. Observations were made at 24 and 72 hours post application.

Results: No signs of toxicity observed throughout the 72 hour test period. Primary irritation score was zero.

Study Classification: Core Minimum Data. Four sites (2 abraded and 2 intact) must be used.

Toxicity Category: IV-CAUTION

Page ___ is not included in this copy.

Pages 6 through 7 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.
