UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

2,4-D/TOX

000458

(43)

DATE: January 28, 1981

SUBJECT: EPA File Symbol: 464-LAG
LONTREL 205 Herbicide: Caswell # 323H (315)

FROM: Deloris F. Graham DFG 2/2/81
FHB/TSS E 2/3/81

Releasable

TO: Richard Mountfort
Product Manager (23)

Applicant: Dow Chemical U.S.A.
Agricultural Products Division
P.O. Box 1706
Midland, Michigan
Attention: Robert F. Bischoff

Active Ingredients:

3,6-Dichloropicolinic Acid.....5.3
(DOWCO 290)

2,4-Dichlorophenoxyacetic Acid.....21.1
(2,4-D Acid)

Inert Ingredients.....73.6

Background: Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation and Skin Irritation studies. These studies were conducted by DOW. "Cite-All" method of support. These data are under accession number 243804.

Recommendations:

(1) FHB/TSS finds the Acute Oral, Acute Dermal, Eye Irritation and Skin Irritation studies are acceptable to support the conditional registration of this product. However, for future submissions, please note:

(a) In the Acute Dermal study, 5M and 5F animals per dose must be used.

(b) In the Eye Irritation study; 9 animals, 6 animals with treated unwashed eyes and 3 animals with treated washed eyes, must be used.

(c) In the Dermal Irritation study, individual 24 and 72 hours readings after a single dose application must be taken.

(2) The Acute Inhalation study was not acceptable. An actual concentration of 5 mg/l must be used.

(3) These data are acceptable for the formulation submitted however the label is not acceptable because it doesn't reflect the formulation used.

(4) A label reflecting formulation used must be submitted.

Label:

(1) The appropriate signal word is DANGER for this fo

(2) Further labeling revision will be r
the appropriate label is submitte

Review:

(1) Acute Oral Toxicity Study: DOW; October 3, 1974.

Procedure: 5 groups, each group consisting of 5M
the following doses: 252, 500, 1000, 2000 or 3980
were recorded. Observations were made periodicall

Results: At 252 mg/kg 1/5M died, but this death w
the treatment; at 200 mg/kg, 1F died; at 3980 mg/k
Other signs of toxicity include lethargy and incre
around the nose and eye in some animals. The Acut
was determined to be 3730 mg/kg with 95% confidenc
mg/kg. The Acute Oral LD50 for females was 2830 m
confidence limits of 1930-4150 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

(2) Acute Dermal Toxicity Study: DOW; October 3, 1974

Procedure: 2M and 2F rabbits received a 3980 mg/k
material. The treated areas were placed under occ
exposure. Animals were observed frequently during
weeks after exposure.

Results: No mortalities. Slight to moderate eryt
to slight edema. Diarrhea present in one animal f
Majority of animals gained weight. The Acute Derm
females was determined to be greater than 3980 mg/

Study Classification: Core Minimum Data. 5M and
must be used.

Toxicity Category: III - CAUTION

(3) Acute Inhalation Toxicity Study: DOW; October 3,

Procedure: 5M and 5F rats were exposed to an aero
diluted 1 part to 8 parts with water for 1 hour in
under dynamic conditions. The aerosol was delive

entering the chamber. Airflow was maintained at a constant 25 liters per minute. The nominal aerosol concentration was calculated. Aerosol particle size distribution was determined using a ROYCO particle analyzer. Observations were made for two weeks after exposure. Necropsies were performed on all animals.

Results: No mortalities. No signs of toxicity or irritation. The nominal aerosol concentration achieved during exposure was 5.03 mg/1. The number length mean diameter of aerosol particles was 2.4u with over 99.9% of the aerosol particles 7.0u or smaller in number length mean diameter.

Study Classification: Core Supplementary Data. An actual concentration of 5 mg/1 must be used.

Eye Irritation Study: DOW; October 3, 1974.

Procedure: Six rabbits received a 0.1 ml of the formulation into the conjunctival sac of the right eye of each rabbit. After 30 seconds the eye was washed for 2 minutes under a stream of tepid water. Then 0.1 ml of the formulation was instilled into the left eye, but this eye was not washed. Observations were made at 24, 48, 72 hours and 7 days after instillation.

Results: Corneal opacity in the washed and unwashed eyes of all six rabbits (6/6 = 20); iris irritation (6/6 = 20); conjunctive irritation with scores ranging from 3-5. Corneal opacity and all other irritation persisted thru day 7.

Study Classification: Core Minimum Data. 9 animals, 6 animals with treated unwashed eyes and 3 animals with treated washed eyes, must be used.

Toxicity Category: I - DANGER

Dermal Irritation Study: DOW; October 3, 1974.

Procedure: Six rabbits were applied 0.5 ml dose each day for three days to intact and abdominal skin sites. Observations were made for 3 days.

Results: At 24 hours after first application no reaction to slight erythema at all sites. After repeated exposure slight edema and slight to moderate necrosis.

Study Classification: Core Minimum Data. Individual 24 and 72 hour readings must be submitted.

Toxicity Category: III - CAUTION

2,4-D

Page 4 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.

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.