4-6-84 RE-12/4 TXR-5477

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

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MEMORANDUM

DATE: April 6, 1984

SUBJECT: EPA File Symbol: 46574-R
Rout GS

FROM: Deloris F. Graham
FHB/TSS

TO: Richard Mountfort
Product Manager (23)

Applicant: Sierra Chemical Company
1001 Yosemite Drive
Milpitas, CA 95035

Active Ingredient:

Oxyfluorfen: 2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4(trifluoromethyl)benzene 2.00%

Oryzalin: 3,5-dinitro-N^4,N^4- dipropylsulfanilamide 1.00%

Inert Ingredients 97.00%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Skin Irritation studies. Studies conducted by Northview Pacific Laboratories, Inc. An Acute Inhalation Study conducted by Temple University was also submitted. Data under accession number 252260.

Recommendations:

(1) FHB/TSS finds these data acceptable to support conditional registration of this product.

(2) A Dermal Sensitization Study was not submitted.

(3) The appropriate signal word is CAUTION.

1 of 1

Label:

(1) The statement "Keep out of reach of children" must precede the signal word.

(2) Additional labeling may be necessary upon submission of Dermal Sensitization data.

Review:

(1) Acute Oral Toxicity Study: Northview Pacific Laboratories, Inc.; NVP# X3J011; October 31, 1983.

Procedure: One group consisting of 5M and 5F Sprague-Dawley rats received two 2500 mg/kg doses of the test orally per rat to equal a 5000 mg/kg dose. Due to the thickness of the test material the single 5000 mg/kg dose was broken down into two 2500 mg/kg doses per animal in order to administer the test compound orally. A group consisting of one male and one female rat served as vehicle control. Observations made for 14 days after treatment. Necropsy performed on all animals.

Results: No mortalities or toxic symptoms reported. Necropsy report included few red spots on the lungs, clear red fluid present in the peritoneal cavity of one animal, abnormal spleens and intestines and one control animal had an inflamed intestine.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

(2) Acute Dermal Toxicity Study: Northview Pacific Laboratories, Inc.; NVP# X3J011; October 31, 1983.

Procedure: Five male and five female rabbits with intact skin received 2000 mg/kg of the test material under occlusive wrap for 24 hour exposure. Observations made for 14 days post treatment. Necropsy performed on all animals.

Results: No mortalities reported. Toxic signs reported included diarrhea and loss of appetite. All animals gained weight except one male, and one female did not gain weight from day 7 to day 14. Necropsy report revealed blood vessels on stomach walls appeared enlarged, pale colored kidneys, reddish colored lungs, rough textured spleen and livers.

Study Classification: Core Guidance Data

Toxicity Category: III - CAUTION

(3) Primary Skin Irritation Study: Northview Pacific Laboratories, Inc.; NVP# X3J011; October 31, 1983.

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Procedure: Six rabbits received 0.5 gm of the test material at intact skin sites under occlusive wrap for 4-hour exposure period. Observations made at 24, 48 and 72 hours after exposure.

Results: No erythema or edema reported.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

(4) Eye Irritation Study: Northview Pacific Laboratories, Inc.; NVP# X3J011; October 31, 1983.

Procedure: Nine rabbits received 100 mg of the test material in one eye each. The treated eyes of three of the rabbits were washed twenty seconds after treatment. Observations were made at 1, 24, 48 and 72 hours after treatment.

Results: At 24 hours, 2/6 animals of the unwashed group had corneal opacity (2/6=5) and 3/3 of washed had no corneal opacity (3/3=0); no iris irritation; 6/6 conjunctive redness (1/6=1, 3/6=2, 2/6=3) and chemosis (2/6=1, 3/6=2, 1/6=3). All corneal opacity and conjunctive irritation had cleared by 72 hours.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

(5) Acute Inhalation Toxicity Study: Temple University; November 8, 1983.

Procedure: Five male and five female rats weighing between 125 and 150 grams were exposed for one hour to a gravimetrically determined concentration of 7.18 ± 0.23 mg/l. Temperature ranged from 23°C to 25°C and relative humidity from 40% to 60%. Observations made every 10 minutes during exposure, then for 14 days after exposure. Necropsy performed on all survivors.

Results: No mortalities or toxic signs reported.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

Oxyfluorfen toxicology review

Page _____ is not included in this copy.

Pages 4 through 11 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.