00-1166
TXR-2789

DATE: March 31, 1982

SUBJECT: EPA Registration Number: 7969-56 002789
Poast

FROM: Deloris F. Graham 4/5/82
FHB/TSS

TO: Robert Taylor
Product Manager (25)

Applicant: BASF Wyandotte Corporation
Agricultural Chemicals Division
100 Cherry Hill Road
Parsippany, New Jersey 07054

Active Ingredients:
2-[1-(ethoxylmino)butyl]-5-[2-(ethylthio)
propyl]-3-hydroxy-2-cyclohexen-1-one.....50.0%
Inert Ingredients.....50.0%

Background: Submitted an Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation and Primary Dermal Irritation Studies. Studies conducted by NISSO Institute for Life Science, Japan. Data under Accession Number 246930. Method of support not indicated.

Recommendation:

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

(2) The appropriate signal word is CAUTION.

Label:

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

(2) The precautionary statements must be revised to include "Harmful if absorbed through skin."

(3) The appropriate storage and disposal statements must appear on the label. See the enclosed copy of the storage and disposal statements.

Review:

(1) Acute Oral Toxicity Study: NISSO Institute for Life Sciencie, September 3, 1981.

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Procedure: 13 groups of 10 rats each (6 groups of males only and 7 groups of females only). The respective doses for each group were 4000, 4520, 5108, 5772, 6522, and 7370 mg/kg for males and 3000, 3500, 3955, 4469, 5050, 5707, and 6449 mg/kg for females. Observations made for 14 days post treatment. Necropsy performed on all animals.

Results: At 4000 mg/kg, 2/10 M died; at 4520 mg/kg, 6/10 M died; at 5108 mg/kg, 6/10 M died; at 5722 mg/kg, 4/10 M died; at 6522 mg/kg, 9/10 M died; at 7370 mg/kg, 10/10 M died. At 3000 mg/kg, 1/10 F died; at 3500, 3955, and 4469 mg/kg, 6/10 F died; at 5050 and 5707 mg/kg, 5/10 F died; at 6449 mg/kg, 10/10 F died.

Toxic signs included hyperactivity, hypotonia, ventral position, lacrimation, salivation, ataxia, incontinence of urine, ptosis, loss of body temperature.

Necropsy revealed hemorrhages on stomach, intestines, bladder mucosa in rats that died during the study. No abnormalities at necropsy in the surviving rats.

$LC_{50}$ for males was 4844 mg/kg with confidence limits between 4376 and 5046 mg/kg. $LD_{50}$ for females was 4087 mg/kg with confidence units between 3550 and 4178 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III-CAUTION

(2) Acute Dermal Toxicity Study: NISSO Institute for Life Science; Study #0044; July 21, 1981.

Procedure: Two groups (10 M and 10 F rabbits each) received one of the following doses at abraded skin sites under occlusive wrap for 24-hour exposure: 2000 and 5000 mg/kg. Observations made for 14 days post treatment. Necropsy performed on all animals.

Results: No mortalities. No toxic signs or pathological changes on necropsy. $LD_{50}$ greater than 5000 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III-CAUTION

(3) Acute Inhalation Toxicity Study: NISSO Institute for Life Sciences; Study #0048; August 7, 1981.

Procedure: 2 groups (10 M and 10 F rats each); 1 group was exposed to a 5.21 mg/l actual concentration of the test material for 4 hours under adequate

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chamber conditions and the other group was used as a negative control. The nominal concentration was 26.54 mg/l. The particle size was 3.238 u with a standard derivation of 3.267 u. Chamber temperature was 23.44 ± 0.34°C and relative humidity was 58.5% and decreased to 49.0% at end of study. Observations were made for 14 days post-exposure. Necropsy performed on all animals.

Results: No mortalities. Toxic signs included lacrimation, salivaton, ataxia, ptosis and incontinence of urine. Ptosis and incontinence of urine seen only in female rats. No abnormalities at necropsy. $LC_{50}$ greater than 5.21 mg/l for four hours.

Study Classification: Core Guideline Data.

Toxicity Category: IV-CAUTION

(4) Eye Irritation Study: NISSO Institute for Life Science; Study #0047; July 30, 1981.

Procedure: One tenth milliliter of the test material was instilled in one eye each of nine rabbits. The eyes of three of the rabbits were washed with lukewarm water, 20 to 30 seconds post-treatment. Observations were made at 24, 98, 72, 96 hours and at 7 days.

Results: One out of six animals of the unwashed group had redness (1/6 = 1) on day 1, but had cleared up by day 2.

Study Classification: Core Guideline Data.

Toxicity Category: IV-CAUTION

(5) Primary Dermal Irritation Study: NISSO Institute for Life Science; Study #0046; Jul. 30, 1981.

Procedure: A 0.5 ml aliquot of the test material was applied to two intact and two abraded skin sites per each of six rabbits under occlusive wrap for 24-hour exposure. Observations were made at 24, 48, 72, 96 and 120 hours.

Results: At 24 hours; slight to well defined erythema in 6/6 animals (2/6 = 1, 4/6 = 2) and slight edema in 3/6 animals (3/6 = 1). At 72 hours slight erythema in 2/6 animals (2/6 = 1) and no edema. All irritation was clear at 120 hours (5 days). Primary Irritation Score was 0.9.

Stuidy Classification: Core Guideline Data.

Toxicity Category: IV-CAUTION.

Sethoxydim scientific review

Page 4 is not included in this copy.

Pages _____ through _____ 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.