

MEMORANDUM

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DATE: March 29, 1984
SUBJECT: EPA Registration Number: 239-2381
Triox Vegetation Killer

FROM: Deloris F. Graham *DFG 4/9/84*
FHB/TSS *E 4/10/84*

TO: Robert Taylor
Product Manager (25)

Applicant: Chevron Chemical Company
Ortho Consumer Products Division
940 Hensley Street
Richmond, California 94804-0036

Active Ingredient:

Prometon (2-methoxy-4,6-bis
(isopropylamino)-s-triazine).....1.86%
Inert Ingredients.....98.14%

Background: Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation and Skin Irritation Studies to support change in signal word from WARNING to CAUTION. Studies conducted by Chevron. Data under Accession Number 251591. Method of support not indicated.

Recommendations:

(1) THB/TSS finds all studies except the Acute Inhalation Study acceptable to support ~~change in signal word~~ *conditional registration for this product*

a. In the Acute Inhalation Study, LC₅₀ for males and females, using actual concentrations, must be submitted. Particle size and chamber conditions (temperature, humidity, etc.) must also be submitted.

How. etc. (Skin Irritation study)
(2) Based on data submitted, the appropriate signal word is ~~WARNING~~ *WARNING*

BEST AVAILABLE COPY

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Label:

(1) The statement "Keep children and animals away from treated areas until these areas are dry. Do not contaminate food or feed" must be deleted from precautionary statements and placed under the heading "Directions For Use."

(2) See enclosed copy for appropriate labeling format.

(3) *Cautionary statement must be revised to include: In case of emergency, wash with plenty of soap and water for 15 minutes.*

Review:

(1) Acute Oral Toxicity Study: Chevron Chemical Company; Socal 1260/81:148; September 6, 1978.

Procedure: Six groups consisting of five male and five female rats each received one of the following doses: 1.0, 1.5, 2.2, 3.3, 5.0, or 8.0 g/kg of the test material. Observations made for 14 days after treatment. Necropsy performed on all animals.

Results: At 5.0 g/kg 2/5 M and 3/5 F; at 8.0 g/kg, 3/5 M and 5/5 F died. Toxic signs reported included depression, diarrhea, salivation, collapse, discharge from the eyes and nose. Most animals had normal weight gain, except for 2 surviving males at highest dose. No pathological changes at necropsy reported. LD₅₀ reported to be 6.6 g/kg with 95% confidence limits between 2.0 and 23.5 g/kg for males and for females 4.4 g/kg with 95% confidence limits between 0.6 and 11.2 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

(2) Acute Dermal Toxicity Study: Chevron Chemical Company; Socal 1261/96:148; September 6, 1978.

Procedure: Six rabbits received 5 g/kg of the test material under occlusive wrap for 24-hour exposure period. One-half the animals had abraded skin and the other half intact skin. Observations made for 14 days after treatment. Necropsy performed on all animals.

Results: No mortalities reported, however severe skin irritation was reported. Necropsy report revealed dry flaky skin and one animal had small body fat, no other pathological changes reported.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

(3) Eye Irritation Study: Chevron Chemical Company; Socal 1542/39:104; February 27, 1980

Procedure: Nine rabbits received 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed thirty seconds after treatment. Observations were made at one hour and at 1, 2, 3, 4 and 7 days after treatment.

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Results: At day 1, 3/6 animals of the unwashed group had corneal opacity (3/6 = 10); 2/6 iris irritation (2/6 = 5); 6/6 conjunctive redness (3/6 = 1, 3/6 = 2); 2/6 chemosis (2/6 = 1) and 4/6 discharge (3/6 = 1, 1/6 = 2). Corneal opacity and conjunctive irritation had cleared by day 4.

At day 1, 3/3 animals of the washed group had conjunctive redness (3/3 = 1). Redness had cleared by day 2.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

(4) Skin Irritation Study: Chevron Chemical Company; Socal 1541/39:103; February 11, 1980

Procedure: Six rabbits received 0.5 ml of the test material at two abraded and two intact skin sites per animal under occlusive wrap for 24-hour exposure period. Observations made at 24, 48 and 72 hours and at 7 days after treatment.

Results: At 24 hours, 6/6 had well defined erythema (scores of 2) and slight to moderate edema (scores of 1, 2, and 3). At 72 hours, 6/6 slight to moderate erythema (scores of 1, 2, and 3) and slight to moderate edema (scores of 1, 2, and 3). Primary Irritation Score was reported to 3.7. Irritation had cleared by day 7.

Study Classification: Core Guideline Data

Toxicity Category: ~~III - CAUTION~~ II - CAUTION

(5) Acute Inhalation Toxicity: Chevron Chemical Company; Socal 1264/36:46; September 7, 1978

Procedure: Two groups consisting of five male and five female rats received one of the following exposures: Group I - one-hour exposure to 7.6 g vapor concentration of the test material; Group II - one-hour exposure 37.3 g aerosol concentration of diluted test material. Observations were made for 14 days after exposure. Necropsy performed on all animals.

Results: No mortalities reported at either exposure. No toxic signs or pathological changes reported at either exposure.

Study Classification: Core Supplementary Data. LC50 for males and females using actual concentrations must be submitted. Particle size and chamber conditions (temperature, humidity, etc.) must also be submitted.

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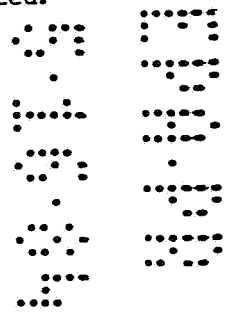
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Recommendations:

- (1) THE/TSS finds all studies except the Acute Inhalation Study acceptable to support ~~the appropriate signal word~~. *Conditional registration of this product.*
 - a. In the Acute Inhalation Study, LC50 for males and females, using actual concentrations, must be submitted. Particle size and chamber conditions (temperature, humidity, etc.) must also be submitted. *However the signal word WARNING is appropriate.*
- (2) Based on data submitted, the appropriate signal word is ~~WARNING~~.
WARNING



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Label:

- (1) The statement "Keep children and animals away from treated areas until these areas are dry. Do not contaminate food or feed" must be deleted from precautionary statements and placed under the heading "Directions For Use."
- (2) See enclosed copy for appropriate labeling format.

Review:

- (1) Acute Oral Toxicity Study: Chevron Chemical Company; Socal 1260/81:148; September 6, 1978.

Procedure: Six groups consisting of five male and five female rats each received one of the following doses: 1.0, 1.5, 2.2, 3.3, 5.0, or 8.0 g/kg of the test material. Observations made for 14 days after treatment. Necropsy performed on all animals.

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Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

- (2) Acute Dermal Toxicity Study: Chevron Chemical Company; Socal 1261/96:148; September 6, 1978.

Procedure: Six rabbits received 5 g/kg of the test material under occlusive wrap for 24-hour exposure period. One-half the animals had abraded skin and the other half intact skin. Observations made for 14 days after treatment. Necropsy performed on all animals.

Results: No mortalities reported, however severe skin irritation was reported. Necropsy report revealed dry flaky skin and one animal had small body fat, no other pathological changes reported.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

- (3) Eye Irritation Study: Chevron Chemical Company; Socal 1542/39:10; February 27, 1980

Procedure: Nine rabbits received 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed thirty seconds after treatment. Observations were made at one hour and at 1, 2, 3, 4 and 7 days after treatment.

Results: At day 1, 3/6 animals of the unwashed group had corneal opacity (3/6 = 10); 2/6 iris irritation (2/6 = 5); 6/6 conjunctive redness (3/6 = 1, 3/6 = 2); 2/6 chemosis (2/6 = 1) and 4/6 discharge (3/6 = 1, 1/6 = 2). Corneal opacity and conjunctive irritation had cleared by day 4.

At day 1, 3/3 animals of the washed group had conjunctive redness (3/3 = 1). Redness had cleared by day 2.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

(4) Skin Irritation Study: Chevron Chemical Company; Socal 1541/39:103; February 11, 1980

Procedure: Six rabbits received 0.5 ml of the test material at two abraded and two intact skin sites per animal under occlusive wrap for 24-hour exposure period. Observations made at 24, 48 and 72 hours and at 7 days after treatment.

Results: At 24 hours, 6/6 had well defined erythema (scores of 2) and slight to moderate edema (scores of 1, 2, and 3). At 72 hours, 6/6 slight to moderate erythema (scores of 1, 2, and 3) and slight to moderate edema (scores of 1, 2, and 3). Primary Irritation Score was reported to 3.7. Irritation had cleared by day 7.

Study Classification: Core Guideline Data

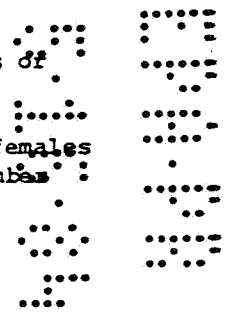
Toxicity Category: ~~III - CAUTION~~ II - WARNING

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Procedure: Two groups consisting of five male and five female rats received one of the following exposures: Group I - one-hour exposure to 7.6 g vapor concentration of the test material; Group II - one-hour exposure 37.3 g aerosol concentration of diluted test material. Observations were made for 14 days after exposure. Necropsy performed on all animals.

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Study Classification: Core Supplementary Data. LC50 for males and females using actual concentrations must be submitted. Particle size and chamber conditions (temperature, humidity, etc.) must also be submitted.



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RIN-0334-94 PROMETON REVIEWS (088804)

Page 7 is not included in this copy.

Pages _____ through _____ are not included.

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- 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.
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