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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: January 25, 1984

SUBJECT: EPA Registration Number 239-2186
Ortho Paraquat CL

FROM: Deloris F. Graham 1/31/84
FHB/TSS
E 1/31/84

TO: Robert Taylor
Product Manager (25)

Applicant: Chevron Chemical Company
Ortho Agricultural Chemicals Division
940 Hensley Street
Richmond, CA 94804-0036

Active Ingredient:

Paraquat dichloride (1,1'-dimethyl
-4,4'bipyridinium dichloride).....29.1%

Inert Ingredients.....70.9%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation Skin Irritation and Acute Inhalation Studies. Studies conducted by Chevron. Data under accession number 252110. Method of support not indicated.

Recommendation:

(1) FHB/TSS finds all studies except Acute Dermal and Acute Inhalation acceptable to support conditional registration of this product.

(a) In the Acute Dermal Study at least 5 animals per sex per dose must be used.

(b) In the Acute Inhalation Study, actual concentrations must be used. Chamber conditions (temperature, humidity, etc.) must be submitted.

(2) A Dermal Sensitization Study was not submitted.

(3) Appropriate signal word is DANGER based on Eye Irritation Study.

Label:

(1) Labeling comments reserved until acceptable Acute Dermal, Acute Inhalation and Dermal Sensitization data are submitted.

Review:

(1) Acute Oral Toxicity Study: Chevron; S-1009; October 26, 1976.

Procedure: Five groups consisting of 5 female rats each received one of the following doses orally: 160, 240, 370, 550, 830 and 1250 mg/kg. Five groups consisting of 5 male rats each received one of the following doses orally: 370, 550, 830 and 1250 mg/kg. At dose level 370 mg/kg 10 female rats instead of 5 were used. One group consisting of 5 male and 10 female rats were not treated and served as control group of animals. Observations made for 14 days posttreatment. Necropsy performed on surviving animals.

Results: At 240 mg/kg, 1/5 F died; at 370 mg/kg 1/5 M + 10/10 F died; at 550 mg/kg. 4/5 M + 5/5 F died; at 830 mg/kg, 4/5 M and 5/5 F died; at 1250 mg/kg, 5/5 M + 5/5 F died. Toxic signs reported included slight depression, reduced food intake, weakness. Necropsy report indicated less than normal amounts of body fat in one male at 370 mg/kg and one male at 550 mg/kg treatments of test material. No other abnormalities reported. LD50 and 95% confidence limits as reported were 482 (1671394) mg/kg for male rats and 284 (151-532) mg/kg for female rats.

Study Classification: Core Guideline Data.

Toxicity Category: II - WARNING

(2) Acute Dermal Toxicity Study: Chevron; S-1010; October 26, 1976.

Procedure: Six groups consisting of six male New Zealand rabbits each received one of the following doses dermally under occlusive wrap for 24 hour exposure: 100, 250, 750, 1500 and 3500 mg/kg. One-half the animals in each group was abraded. Observations made for 14 days posttreatment. Necropsy performed on all animals.

Results: At 250 mg/kg, 1/6 M died; at 750 mg/kg, 4/6 M died; at 1500 mg/kg, 6/6 M died; at 3500 mg/kg, 6/6 M died. Toxic signs reported included phonation, diarrhea, bloody urine, diaphragmatic respiration, cyanosis, convulsion and collapse. Moderate erythema and edema also reported. Necropsy report indicated liver-like, hemorrhagic edematous lungs and discolored grainy livers, areas of necrotic tissue in lungs, less than normal amounts of of body fat. Skin in treated area reported as thickened and escharatic. LD50 and 95% confidence limits as reported for males was 526 (188-1496) mg/kg.

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Study Classification: Core Supplementary Data. At least 5 animals per sex per dose must be used.

(3) Eye Irritation Study: Chevron; S-1011; October 26, 1976.

Procedure: Six male New Zealand rabbits received 0.1 ml of the test material in one eye each. Observations made at 1 hour, 1, 2, 3, 7, 10 and 14 days after treatment.

Results: At day 1, 6/6 had moderate to severe redness (1/6=2, 5/6=3), discharge (1/6=5, 5/6=3) and 5/6 slight chemosis (5/6=1). At day 2 & 3 conjunctual tissue sloughage.

At day 7, 2/6 had corneal opacity (1/6=5, 1/6=10) and pannus; 6/6 redness (3/6=2, 3/6=3 and discharge (1/6=1, 5/6=2); 3/6 chemosis (2/6=1, 1/6=2).

At day 14, 2/6 had corneal opacity (1/6=5, 1/6=10) and pannus; 6/6 redness (3/6=2, 3/6=3) and discharge (4/6=1, 5/6=2); 3/6 chemosis (2/6=1, 1/6=2).

Study Classification: Core Minimum Data. Observations must be made for 21 days or until all irritation subsides which ever comes first.

Toxicity Category: I - DANGER.

(4) Skin Irritation Study: Chevron, S-1012; October 26, 1976

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

Results: At 24 hours, 6/6 had slight to moderate erythema (Scores of 1, 2 and 3) and 4/6 slight edema (score of 1 and 2). At 72 hours, 6/6 had slight to moderate erythema (scores of 1, 2 and 3) and 5/6 slight to moderate edema (scores of 1, 2 and 3). Primary Irritation Score was 3.5. Irritation persisted through 7 days.

Study Classification: Core Guideline Data

Toxicity Category: II - ~~CAUTION~~ WARNING

(5) Acute Inhalation Toxicity Study: Chevron; S-1013; October 26, 1976.

Procedure: One group of five male and five female Sprague-Dawley rats were exposed for one hour to vapor of the test material. Total amount of test material generated during the hour reported to be 0.5 grams. Another group of 5M and 5F rats were treated in a simialr fashion except no test material was used, these animals served as controls. Observations made for 14 days post exposure. Necropsy performed on all animals.

Results: No deaths or signs of toxicity reported. No reports of abnormalities at necropsy.

Study Classification: Core Supplementary Data. Actual concentrations must be used. Chamber conditions (temperature, humidity, etc.) must be submitted.