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

006218

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

APR 17 1987

SUBJECT: EPA File Symbol 10182-RRI  
Trooper Herbicide

FROM: Deloris F. Graham *DFG*  
Technical Support Section  
Fungicide-Herbicide Branch  
Registration Division (TS-767C)

TO: Robert J. Taylor, PM 25  
Fungicide-Herbicide Branch  
Registration Division (TS-767C)

E 4/27/87

APPLICANT: ICI Americas, Inc.  
Agricultural Chemicals Division  
Concord Pike & New Murphy Road  
Wilmington, DE 19897

ACTIVE INGREDIENTS:

Paraquat dichloride (1,1'-dimethyl-4,4-bipyridinium dichloride)	11.96%
Simazine	34.67%
INERT INGREDIENTS:	53.37%

BACKGROUND:

Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation, Skin Irritation, and Dermal Sensitization Studies and an Eye Irritation Study using a 1 to 10 dilution of test material. Studies conducted by ICI Central Toxicology Laboratory and Food and Drug Research Lab. Method of support not indicated. Data under EPA MRID Nos.: 400627-01, -02, -03, -04, -05, -06, and -07.

RECOMMENDATIONS:

FHB/TSS finds all studies except the two eye studies acceptable to support conditional registration of this product.

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- (a) In the eye studies the formulation as intended to be marketed, not dilutions of it, must be tested. However, since it is indicated that the toxicity category for both dilutions is DANGER, the undiluted form would probably be at least DANGER; therefore, additional testing is not required.
2. Based on the Acute Inhalation, Eye Irritation, and Skin Irritation Studies the appropriate signal word is DANGER.

LABEL:

Precautionary statements such as "Do not get on skin, eyes, or clothing; do not inhale spray mist; wear full face shield, rubber gloves, and apron, and waterproof footwear" must appear under the heading "Hazards to Humans and Domestic Animals," subheading "Precautionary Statements" and precede the directions for use.

REVIEW:

- (1) Acute Oral Toxicity Study: ICI Central Toxicology Lab.;  
Project ID: CTL/P/1690; January 9, 1987; EPA MRID No.  
400627-01.

PROCEDURE:

Three groups consisting of five male and five female rats each were dosed with one of the following doses: 60, 80, or 120 mg/kg. Observations made for 15 days. Necropsy performed on all animals.

RESULTS:

At 60 mg/kg, 2/5 F died; at 80 mg/kg, 1/5 F died; at 120 mg/kg, 5/5 M and 5/5 F died. Toxic signs reported included activity decrease, diarrhea, chromodacryorrhea, piloerection, sides pinched in, stained around mouth and nose, urinary incontinence, upward curvature of spine, dehydrated, pale, ungroomed, breathing irregular, gasping and whistling. Necropsy report indicated mottled lungs and air-filled enlarged stomach in one female at 60 mg/kg dose but no other abnormalities reported. LD<sub>50</sub> for males reported to be 98.0 mg/kg and 78.3 mg/kg for females.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: II - WARNING.

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- (2) Acute Dermal Toxicity Study: Food and Drug Research Lab.; FDRL Study No. 9328C; January 17, 1987; EPA MRID No. 400627-02.

PROCEDURE:

Five groups consisting of five male and five female rabbits each were treated with one of the following doses: 200, 260, 339, 442, or 575 mg/kg. Treated sites placed under occlusive wrap for 24-hour exposure period. Necropsy performed on all animals.

RESULTS:

At 260 mg/kg, 4/5 M and 1/5 F died; at 339 mg/kg, 5/5 M and 2/5 F died; at 442 mg/kg, 5/5 M and 4/5 F died; at 575 mg/kg, 5/5 M and 5/5 F died. Toxic signs reported include anorexia, ataxia, blood in litter tray, cyanosis, dark material around mouth and nose, decreased activity, lacrimation, loss of muscle control in hindquarters, nose discharge, respiratory irregularity, salivation, tremors. Necropsy report revealed kidneys - blanched areas, multiple cortical cysts, dark red areas; liver - mottled/blanched; lungs - bright red, red/black areas. LD<sub>50</sub> for males reported to be 251 mg/kg with 95% confidence limits between 208 and 293 mg/kg. LD<sub>50</sub> for females reported to be 344 mg/kg with 95% confidence limits between 274 and 413 mg/kg. LD<sub>50</sub> for males and females combined reported to be 305 mg/kg with 95% confidence limits between 260 and 351 mg/kg.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: II - WARNING.

- (3) Acute Inhalation Toxicity Study: ICI Central Toxicology Lab.; Project Nos: CTL/P/1748 and CTL/P/1748A; January 5, 1987; EPA MRID No. 400627-03.

PROCEDURE:

Three groups consisting of five male and five female rats each were exposed for 4 hours to one of the following nominal concentrations: 3.70, 5.65, or 10.60 ug/L. Particle size reported to range between 0.9 and 3.1 um. Temperature ranged from 19.0 to 20.4 °C with relative humidity from 44.0 to 56.0%. Observations made for 15 days. Necropsy performed on all animals.

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RESULTS:

At 10.60 ug/L nominal concentration, 4/5 M and 4/5 F died. Clinical signs reported included diarrhea, piloerection, red stain around nose, stains around nose, wet fur, chromodacryorrhea, hindlimb damage, red stain around nose, hunched, sides pinched in, subdued, fighting wounds both cheeks. Necropsy report indicated thymus - red spots, both lobes, lymph node enlarged; kidney - slight pelvic dilatation; ovaries - both with a cystic bursa; lungs - dark red, not fully deflated - blothy, pale; trachea - froth exuded when trachea cut. The median lethal concentration of paraquat ion concentration was reported to be 0.66 ug/L in males and females. Through extrapolation of this value a median lethal concentration for the paraquat/simazine formulation was reported to be 007.78 ug/L (.00778 mg/L) in males and females.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: I - DANGER.

(4) Eye Irritation Study: ICI Central Toxicology Lab.;  
Lab ID: CTL/P/1736; January 9, 1987; EPA MRID No.  
400627-04.

PROCEDURE:

Six rabbits received 0.1 ml of a 1 in 10 dilution of the test material in one eye each. Observations made 22 days.

RESULTS:

At 24 hours posttreatment, 6/6 rabbits had conjunctive redness (1/6 = 2, 5/6 = 3), chemosis (6/6 = 2) and discharge (6/6 = 3). At day 7, 3/6 had redness (2/6 = 1, 1/6 = 2); 1/6 chemosis (1/6 = 1) and 5/6 discharge (1/6 = 1, 2/6 = 2, 2/6 = 3). At day 22, 4/6 had discharge (3/6 = 1, 1/6 = 2).

STUDY CLASSIFICATION:

Core Guideline Data. See (1)(a) in RECOMMENDATIONS.

TOXICITY CATEGORY: I - DANGER.

(5) Skin Irritation Study: ICI Central Toxicology Lab.;  
Lab ID: CTL/P/1722; January 6, 1987; EPA MRID No.  
400627-05.

PROCEDURE:

Six rabbits with intact skin sites each received 0.5 ml of the test material. Treated sites were placed under occlusive

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wrap for a 4-hour exposure period. Observations made for 35 days posttreatment.

RESULTS:

At 24 hours posttreatment, 6/6 rabbits had moderate to severe erythema (4/6 = 3, 2/6 = 4) and severe erythema (6/6 = 4). At day 3, 6/6 moderate to severe erythema (3/6 = 3, 3/6 = 4) and severe edema (6/6 = 4). Irritation persisted up to 14 days. Desquamation, thickening, hardening, cracking, and scabbing also reported and were indicated to have persisted through the 35-day observation period.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: I - DANGER.

(6) Skin Sensitization Study: ICI Central Toxicology Lab.;  
Lab ID: CTL/P/1747; January 9, 1987; EPA MRID No.  
400627-06.

PROCEDURE:

A group of 20 guinea pigs received three 0.4 ml applications of the following concentration: 30% (w/v) of test formulation in deionized water. A group of 10 guinea pigs were treated in a similar manner as the previous group except only deionized water was used. Two weeks after final induction phase application a challenge dose was applied. At challenge the following concentrations were used: 3, 1, and 0.3% (w/v) suspension of test material in deionized water. A rechallenge application using a 10% (w/v) suspension of test material in deionized water was made. Observations made at 24 and 48 hours after each application.

RESULTS:

Slight erythema and slight or moderate desquamation noted in test group; 9 days following final induction application, four animals reported to have scratched and bleeding application sites. These animals were sacrificed for humane reasons. At challenge with 3% solution no erythema reported in test group, but moderate redness in 1 out of 10 control group animals. At challenge with 1% no erythema reported in test or control animals. At challenge with 0.3% no erythema reported. At rechallenge with 10% suspension 13/16 test group animals and 8/10 control group animals had mild to moderate redness. It was concluded that only an irritant response was produced.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Nonsensitizing Agent.

(7) Eye Irritation Study: Safepharm Laboratories Limited;  
Project No.: 6/203; December 10, 1986; EPA MRID No.  
400627-07.

PROCEDURE:

Six rabbits each received 0.1 ml of a 1:10 dilution of the test material in one eye each. Observations made for 21 days posttreatment.

RESULTS:

At 24 hours posttreatment, 6/6 rabbits had conjunctive redness (1/6 = 1, 4/6 = 2, 1/6 = 3), chemosis (1/6 = 1, 5/6 = 2) and 5/6 discharge (2/6 = 2, 3/6 = 3). At 7 days, 6/6 had redness (2/6 = 1, 4/6 = 2), chemosis (4/6 = 1, 2/6 = 2) and 5/6 discharge (2/6 = 1, 1/6 = 2, 2/6 = 3). At 21 days, 2/6 discharge (1/6 = 2, 1/6 = 3).

STUDY CLASSIFICATION:

Core Guideline Data. See (1)(a) under RECOMMENDATIONS.

TOXICITY CATEGORY: I - DANGER.

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## SIMAZINE

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Pages 7 through 8 are not included.

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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.
  - ☒ A draft product label.
  - \_\_\_\_\_ The product confidential statement of formula.
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