

US EPA ARCHIVE DOCUMENT

Date: May 20, 1983

005472

Subject: EPA Registration Number: 707-149(1)
Blazer 2L Herbicide

EPA Registration Number: 707-150(2)
Blazer 2S Herbicide

From: Deloris F. Graham *DGH 5/25/83*
FHB/TSS *E 5/25/83*

To: Richard Mountfort
Product Manager (23)

Applicant: Rohm and Haas Company
Independence Mall West
Philadelphia, PA 19105

Active Ingredient: (1)
Sodium salt of acifluorfen
Sodium 5-[2-chloro-4-(trifluoromethyl)
phenoxy]-2-nitrobenzoate 20.1%
Inert Ingredients 79.9%

Active Ingredient: (2)
Sodium salt of acifluorfen
Sodium 5-[4-chloro-4-(trifluoromethyl)
phenoxy]-2-nitrobenzoate 21.4%
Inert Ingredient 78.6%

Background: Submitted Acute Oral, Acute Dermal, Skin Irritation and Eye Irritation studies. Studies conducted by Rohm and Haas. Data under Accession Number 249794. Method of support indicated as not submitted.

Recommendation:

1. FHB/TSS finds all studies except for one Skin Irritation Study (# 81R D186) acceptable to support conditional registration of this product.
 - a. In the previously mentioned Skin Study dosage must be given.
2. An Acute Inhalation Study was not submitted and one must be submitted and/or cited or justification as to why this study is not necessary.
3. The appropriate signal word is DANGER.

Label:

1. Labeling acceptable as submitted.

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Review:

1. Acute Oral Toxicity Study: Rohm and Haas Company; May 12, 1982; Report #80R 0200.

Procedure: Four groups consisting of 10 rats (male and female) and one group consisting of 9 rats (male and female) received one of the following doses: 3.46, 3.98, 4.58, 5.27 and 6.07 g/kg. Observations made for 14 days. Necropsy performed on animals which died during the study.

Results: At 3.46 g/kg, 1/10 animals died; at 3.98 g/kg, 5/9 died; at 4.58 g/kg, 4/10 died; at 5.27 g/kg, 7/10 died; at 6.07 g/kg, 9/10 died. Clinical signs observed included passiveness, apparent weight loss, brown stained anogenital area, scant droppings, alopecia, ataxia, red stained muzzle, salivation, stained muzzle, ptosis, red stained eyes, respiratory noise, yellow stained anogenital area and mucus on dropsheet. Necropsy revealed red fluid in intestines, lungs and slight to marked redness, red foci on wall and enlarged stomach, amber fluid in intestines, red stained muzzle and eyes, yellow and red stained anogenital area, red gastric gland mucosa carcass cannabilized and semisolid material in stomach. LD₅₀ for males was 4.83 g/kg (4.02 - 6.41 g/kg, confidence limits). LD₅₀ for females 4.13 g/kg (2.73 - 4.88 g/kg, confidence limits).

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

2. Acute Dermal Toxicity Study: Rohm and Haas Company; May 11, 1982; Report # 80R 0200.

Procedure: Two groups consisting of six male New Zealand rabbits received one of the following doses: 3.55 or 5.00 g/kg. Observations were made for 14 days. Necropsy performed on all animals.

Results: No mortalities at either dose. Clinical signs observed included passiveness, apparent weight loss, diarrhea, scant droppings, salivation, stained muzzle, lacrimation, hematuria, red stained anogenital area, yellow stained anogenital area, red urine on drop sheet, mucus on dropsheet and vocalized at cuff removal. Necropsy revealed lungs moderately red, modules on liver lobes, lesion on liver, tan spot on liver lobe, and kidney surface pitted. Moderate to severe erythema, slight edema, followed by skin desiccation were noted. LD₅₀ greater than 5.0 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

3. Skin Irritation Study: Rohm and Haas; May 11, 1982, Report # 80R 0200.

Procedure: Six New Zealand rabbits received 0.5 ml of the test material at abraded and intact skin sites under occlusive wrap for 24-hour exposure. Observations were made at 24 and 72 hours, and at seven days after treatment.

Results: At 24 hours, 6/6 animals had severe erythema (1/6 = 3, 5/6 = 4) and edema (6/6 = 4). At 72 hours, slight to severe erythema (scores of 1 to 4) and edema (scores of 1 to 4). Primary Irritation Score was 0.3. At day seven, 6/6 slight to severe erythema (scores of 1 to 3) and 2/6 slight edema (scores of 1). Blanching, eschar, desiccation and desquamation noted.

Study Classification: Core Guideline Data.

Toxicity Category: II - WARNING

4. Eye Irritation Study: Rohm and Haas; May 11, 1982; Report # 80R 0200.

Procedure: Nine New Zealand rabbits received 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed 20-30 seconds after treatment. Observations were made at 4, 24, 48 and 72 hours, 7, 14 and 21 days after treatment.

Results: At 24 hours, 6/6 animals of the unwashed group and 3/3 animals of the washed group had corneal opacity (4/6 = 20, 2/6 = 40) (1/3 = 10, 1/3 = 15, 1/3 = 20); iris irritation (4/6 = 2.5, 2/6 = 5) (1/3 = 2.5, 2/3 = 5); cumulative conjunctive irritation (3/6 = 14, 2/6 = 16, 1/6 = 14) (2/6 = 14, 1/6 = 16).

At seven days, 6/6 and 2/3 corneal opacity (2/6 = 20, 2/6 = 30, 1/6 = 40, 1/6 = 45) (1/3 = 5, 1/3 = 10); no iris irritation; cumulative conjunctive irritation (3/6 = 2, 1/6 = 4, 1/6 = 10) (2/3 = 2, 1/3 = 4).

At 14 days, 6/6 and 2/3 corneal opacity (2/6 = 5, 1/6 = 10, 1/6 = 15), 2/6 = 80) (1/3 = 5, 1/3 = 20); 4/6 and 1/3 ; cumulative conjunctive irritation (2/6 = 2, 1/6 = 6, 1/6 = 8) (1/3 = 2).

At 21 days, 4/6 corneal opacity (1/6 = 10, 3/6 = 40); 2/6 cumulative conjunctive irritation (1/6 = 2, 1/6 = 8).

Bumpy irregular surface of cornea, hair loss on lower lid; blood vessels growing on cornea and hair loss on upper lid observed.

Study Classification: Core Guideline Data

Toxicity Category: I - DANGER

5. Skin Irritation Study: Rohm and Haas; Report # 80R 0200; May 11, 1982.

Procedure: Six New Zealand rabbits received 0.5 ml of the test material at abraded and intact skin sites under occlusive wrap for 4-hour exposure. Observations made at 5, 24 and 72 hours and at seven days.

Results: No irritation. Primary Irritation score was zero.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION.

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6. Skin Irritation Study: Rohm and Haas; Report # 81R 0186; October 19, 1981.

Procedure: Six New Zealand rabbits received test material under occlusive wrap for 24-hour exposure. Observations made for 24 and 72 hours and at seven days.

Results: At 24 hours, moderate to severe erythema (scores of 1 to 4) and edema/scores of 1 to 4). At 72 hours, moderate to severe erythema (scores of 1 to 4) and slight to well defined edema (scores of 1 and 2). Primary Irritation Study = 4.9. Severe erythema and slight edema present at seven days. Eschar, small white spots on application site, blanching and desiccation also observed.

Study Classification: Core Supplementary Data. Dosage must be given.

Acifluorfen

Page _____ is not included in this copy.

Pages 5 through 16 are not included in this copy.

The material not included contains the following type of information:

- _____ Identity of product inert ingredients.
- _____ Identity of product inert 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.
- _____ A draft product label.
- _____ The product confidential statement of formula.
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