Date: December 20, 1983

Subject: EPA Registration Number: 524-332
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From: Delores J. Graham
EHB/HS E 12/20/83

To: Robert Taylor
Product Manager (25)

Applicant: Monsanto Company
1101 17th Street
Washington, D.C. 20036

Active Ingredient:
Sodium sesqui salt of [N-(phosphono-
methyl) glycine] 75%
Inert Ingredients 25%

Background: Submitted Acute Oral, Acute Dermal Eye Irritation and Primary Skin Irritation studies to support change in signal word from WARNING to CAUTION. Studies conducted by Monsanto Data under accession number 251485. Method of Dosage not indicated

Recommendations:
(1) EHB/HS finds these data acceptable to support conditional registration of this product. 229

(2) Based on data submitted thus far the appropriate signal word is CAUTION. However an acute Inhalation Study was not submitted and one must be submitted or a justification as to why this study is not necessary for this product. Providing the Acute Inhalation data

falls in the toxicity category of CAUTION, the labeling as submitted would be acceptable.

Label:

Label:

(1) Please note revised labeling may be necessary upon submission of acute inhalation data.

Review:

(1) Acute Oral Toxicity Study; Monsanto Company; Study Number 800298; March 16, 1981.

Procedure: Five male and five female Sprague-Dawley rats weighing between ~~84 and 240~~ 178 and 259 grams received 5,000 mg/kg of the test material orally. Observations made three times within the first eight hours after dosing, then twice daily thereafter for 15 days. Necropsy performed on all animals.

Results: No mortalities. Toxic signs reported included animals sedate, diarrhea, and ptosis. No abnormalities at necropsy reported. LD50 for males and females is greater than 5,000 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

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(2) Acute Dermal Toxicity Study: Monsanto Company; Study Number: 800299; March 16, 1981.

Procedure: Five male and five female New Zealand rabbits received 5,000 mg/kg of the test material at intact skin sites under occlusive wrap for 24 hour exposure. Observations made three times during first eight hours after dosing, then twice daily thereafter for 15 days. Necropsy performed on all animals.

Results: No ~~mortalities~~ mortalities. Necrosis of the skin in the exposure area reported in one female and two males on days 6 and 7, however skin regained normal appearance without scabs or sloughing of skin. No abnormalities reported at necropsy. LD50 for males and females greater than 5000.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

(3) Primary Skin Irritation Study: Monsanto Company; Study Number: 800300; March 16, 1981

Procedure: Six New Zealand rabbits received 0.5 grams of the test material at two abraded and two intact skin sites per animal under occlusive wraps for 24 hour exposure period. Observations made at 24 and 72 hours after treatment.

Results: At 24 hours, the animals had slight erythema (1/6-1) and no edema. Erythema had cleared at 72 hours. Primary Irritation Index was zero.

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Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

(4) Eye Irritation Study: Monsanto Company; Study Number: 800301; March 16, 1981.

Procedure: Nine New Zealand rabbits received 0.1ml (59mg) of the test material in one eye each. Twenty seconds after treatment the treated eyes of three of the rabbits were washed with physiological saline. Observations were made at 24, 48 and 72 hours after treatment.

Results: At 24 hours 1/6 animals of the unwashed group and 1/3 of the washed group had conjunctivae irritation (1/6=2)(1/3=2). At 72 hours, conjunctive irritation present in 1/6 animals (1/6=2), but had cleared at 96 hours post treatment.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION