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

001814

APR 29 1982

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Robert Taylor (25)
Registration Division (TS-767)

SUBJECT: Glyphosate; Roundup; EPA Reg.#524-308; Miscellaneous Data; 21-Day Rabbit Dermal and Acute Rat Inhalation Studies CASWELL #661A; Acc. Nos.: 247188, 247228

Recommendation:

The submitted toxicology studies are acceptable as Core-Minimum Data.

Review:

1. Acute Inhalation Toxicity of Roundup Formulation to Male and Female Sprague-Dawley Rats (Monsanto Study#810093; DMEH Project Number: ML-81-201; 3/17/82)

Eight groups of 5M and 5F Sprague-Dawley rats were exposed for 4 hours to analytical concentrations of 1.10, 1.99, 2.39, 2.46, 2.56, 2.96 and 3.42 ml/L of Roundup. Observation was for 14 days.

Results: LC_{50} = 3.28 mg/L (3.00 - 4.10 mg/L) both sexes

Toxic Signs: chromorhinorrea, gasping, congestion of eyes, hypoactivity, piloerection

Body Weight: Survivors gained weight

Necropsy: Reddish or blood-congested lungs

Toxicity Category III: Caution

Classification: Core-Minimum Data

2. A 21-Day Dermal Toxicity Study with Glyphosate in Rabbits (IRDC Project#401-168; 3/10/82)

Technical Glyphosate was dermally applied under occlusion to four groups of 10 male and 10 female NZW rabbits, one-half with intact skin and one-half with abraded skin, five days per week for three consecutive weeks at dose levels of 0 (control), 100, 1000, and 5000 mg/kg/day as a paste with physiological saline. Criteria evaluated included mortality, toxic signs, body weight, food consumption, dermal irritation, hematology, clinical chemistry, organ weights, gross and microscopic examination of tissues.

Results: No effects considered to be treatment-related were noted with respect to mortality, toxic signs, body weight, food consumption, hematology, clinical chemistry, organ weights and gross and microscopic examination of tissues. No dermal irritation was observed in the controls or 100 and 1000 mg/kg/day groups. Slight erythema and edema was noted in some of rabbits in the 5000 mg/kg/day group.

Conclusion: The NOEL for toxicity is 1000 mg/kg/day. The LEL for toxicity is 5000 mg/kg/day and the effect was dermal irritation evidenced as slight erythema and edema.

Classification: Core-Minimum Data

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4/28/8

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