



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

008470

JUL 25 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Carbaryl
Acute Oral Toxicity Study-Rat (81-1)

Project No.: 1-1615
TOX Chem No.: 160

FROM: Ray Landolt *7/16/91*
Review Section I
Toxicology Branch II
Health Effects Division (H7509C)

TO: Dennis Edwards, PM 19
Insecticide-Rodenticide Branch
Registration Division (H7505C)

THRU: Mike Ioannou, Section Head *M. Ioannou 7/17/91*
Review Section I
Toxicology Branch II
Health Effects Division (H7509C)
and
Marcia van Gemert, Branch Chief *M van Gemert 7/22/91*
Toxicology Branch II
Health Effects Division (H7509C)

Registrant: Rhone-Poulenc Ag Company, letter of June 18, 1991
EPA Reg. No. 264-333

Action Requested: The registrant has submitted an acute oral toxicity study, conducted with Sevin® Brand XLR Plus Carbaryl Insecticide (43.1%), to replace the study found invalid due to the questionable identity of the test material (DER 008435).

Conclusion: This study conducted in rats with Sevin® Brand XLR Plus Insecticide (43.1%):

1. is acceptable and satisfies the guideline data requirement (81-1) for an acute oral toxicity study and
2. supports Toxicity Category III precautionary labeling for oral toxicity and the signal word Caution.

Reviewed By: Ray Landolt *7/16/91*
Section I, Toxicology Branch II - H7509C
Secondary Reviewer: Mike Ioannou *7/17/91*
Section I, Toxicology Branch II - H7509C

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DATA EVALUATION REPORT

Study Type: Acute Oral Toxicity- Rats (81-1)

TOX Chem No. 160
MRID No. 419191-01
Project No. 1-1615

Test Material: Sevin® Brand XLR Plus Carbaryl Insecticide- 44.3%

Classification: Carbamate

Common Name: Carbaryl (1-naphthyl N-methylcarbamate)

Study No.: 8150-91

Date of Study: June 5, 1991

Sponsor: Rhone-Poulenc Ag Company

Testing Facility: Stillmeadow, Inc

Title of Report: Acute Oral Toxicity Study in Rats with Sevin XLR Plus

Author: Janice O. Kuhn, Ph.D.

Quality Assurance: Tracy C. Wooten

Conclusion: Classification of Data - Guideline

This study satisfies the guideline data requirement (81-1) for an acute oral toxicity study.

Toxicity Category: This study supports Toxicity Category III precautionary labeling for oral toxicity and the signal word Caution.

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Experimental Design:

Animals: Young adult Harlan Sprague Dawley rats weighing between 229 to 282 g for males and 182 to 219 g for females were fasted for at least 16 hours prior to dosing.

Method: The undiluted test material (44.3%), a cream colored liquid of Lot No. 60613002, was administered by oral intubation to five animals per sex per dose level of 250, 550, and 1000 mg/kg.

The animals were observed for mortality and signs of toxicity at 0.5, 3, and 6 hours during the day of treatment (Day 0), then once daily for 14 days. Body weights were recorded initially, then on days 7 and 14 of the study. All animals were subjected to gross necropsy.

Results: LD₅₀ Males - 867 mg/kg (562 - 1336 mg/kg) Slope = 2.0.

Females- 575 mg/kg (459 - 721 mg/kg) Slope = 5.5.

Combined- 698.5 mg/kg (543.4 - 897.8 mg/kg) Slope = 2.5.

Signs of toxicity: At the 550 mg/kg level piloerection, tremors salivation, lacrimation and decreased activity were observed in males and females within 30 minutes of dosing lasting 24 hours for males and four days for females. In addition, exophthalmos and polyuria were observed within 3 hours lasting 6 hours for males and four days for females. Diarrhea, chromodacryorrhea and ataxia were observed for females at the 24 hour interval lasting for 96 hours.

Body weight gain: Survivors maintained a normal body weight gain over the 14 day period.

Necropsy: Gross necropsy findings of those animals found dead within 0.5 to 6 hours were diarrhea, a white slurry and gas in the stomach. No abnormal findings were reported at the terminal sacrifice.