

US EPA ARCHIVE DOCUMENT



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

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MEMORANDUM:

Subject: EPA File Symbol/EPA Reg. No.: 7001-337 / Weed and Grass
Killer

From: Ian Blackwell, Biologist *CRB 7/1/92*
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

To: Robert J. Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head *E 8/18/92*
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

Applicant: J.R. Simplot Company
16777 Howland Road
P.O. Box 198
Lathrop, CA 95330

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Sodium Chlorate (NaClO ₃)	30.00
Sodium Metaborate Tetrahydrate	66.00
Diuron [3-(3,4-Dichlorophenyl)-1,1-dimethylurea]	1.25
<u>Inert Ingredient(s):</u>	<u>2.25</u>
Total:	100.0%

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BACKGROUND: The J.R. Simplot Company has submitted acute oral toxicity, acute dermal toxicity, primary eye irritation and primary dermal irritation studies in support of Weed and Grass Killer. The studies were conducted by Toxikon Corporation. The MRID numbers are 420985-01 through 420985-04. A primary eye irritation study of this product was previously by D. Graham, 5/19/86. Based on that study the signal word was "WARNING". Also according to that review, the product was originally registered under the cite-all method and there was no previous acute toxicity data submitted.

RECOMMENDATIONS:

1. The acute oral toxicity study is not acceptable and is classified as supplementary. The study classification will be reconsidered upon submission of the following data:
 - a. Provide individual daily observations for test animals.
 - b. Provide complete necropsy findings for each animal.
 - c. Specify if material tested was identical to product for which registration is sought.
2. The acute dermal toxicity study is graded guideline data and is acceptable to support the product.
3. The primary eye irritation study is acceptable and classified as core-guideline data.
4. The primary dermal irritation study is graded supplementary and must be reconducted. This study is graded core-supplementary because the test material was not moistened upon application to the test animals as per Subdivision F guidelines.
5. PRS requests that acute inhalation toxicity and dermal sensitization studies be submitted for this product .

LABELING:

1. The signal word is "WARNING" based on the primary eye irritation study.
2. The precautionary statements should be revised to:

"Causes substantial but temporary eye injury. Harmful if absorbed through skin. Do not get in eyes, on skin or on clothing. Wear goggles or face shield when handling. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse."
3. The statement of practical treatment for ocular exposure should be the first statement of practical treatment listed. The statements of practical treatment should be changed to the following:

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"If in eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention."

"If on skin: Wash with plenty of soap and water. Get medical attention."

4. Labeling revisions may be required upon submission of the outstanding data.

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DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1)

Product Manager: 25
MRID No.: 420985-01

Reviewer: I. Blackwell
Report Date: 10/2/91
Report No.: 91G-0375

Testing Facility: Toxikon Corporation
Authors: George B. FitzGerald, Ph.D.

Quality Assurance (40 CFR §160.12): Included

Test Material: Weed and Grass Batch #87032501

Species: Sprague-Dawley Rats
Age: young adult, 49 to 74 days
Weight: 204.3 to 252.8 grams Sex: 20 males + 20 females
Source: Charles River Laboratories

Conclusion:

1. LD₅₀ (mg/kg): Males =
Females =
Combined =
2. The estimated LD₅₀ is
3. Tox. Category: Classification: supplementary

Procedure (Deviations from §81-1):

Time of onset and duration of toxic effects are not provided.
Gross necropsy findings not reported for individual animals.
Vague descriptions of toxic effects found at gross necropsy.
Test substance specified as only "Weed and Grass".

Results:

Dosage (mg/kg)	(Number Killed/Number Tested)		
	Males	Females	Combined
5000	4/5	4/5	8/10
4500	2/5	5/5	7/10
4000	0/5	1/5	1/10
3500	0/5	0/5	0/10

Observations: Signs of toxicity were tachypnea, lethargy, somnolence, ataxia, anesthesia, catalepsy, loss of body fluids, cyanosis, weight loss and prostration.

Gross Necropsy: hemorrhaging of stomach and small intestine, "signs of minor toxic effects to their kidneys", and other "minor signs of toxicity".

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DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2)

Product Manager: 25
MRID No.: 420985-02

Reviewer: Ian Blackwell
Report Date: 7/16/91
Report No.: 91G-0376

Testing Laboratory: Toxikon Corporation
Author(s): George B. FitzGerald

Quality Assurance (40 CFR §160.12): Included

Test Material: Weed & Grass "off-white" "granular"

Species: New Zealand White rabbits
Weight: 2.39 to 2.97 kg **Age:** 10 to 12 weeks
Source: Eastern Rabbit Breeding Laboratory

Summary:

1. **LC₅₀ (mg/kg):** **Males = > 2000 mg/kg**
 Females = > 2000 mg/kg
 Combined = > 2000 mg/kg
2. **The estimated LD₅₀ is > 2000 mg/kg**
3. **Tox. Category:** III **Classification:** guideline

Procedure (Deviation From §81-2):

Results:

Reported Mortality

DOSAGE	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
2000 mg/kg	0/5	0/5	0/10

Observations: Necrosis of the skin (4/10 animals) was the only apparent sign of toxicity noted. Very slight to moderate-to-severe erythema was noted on day 1. Very slight erythema was noted in 9/10 on day 2, in 7/10 on days 3 and 4, and 4/10 on day 7. One animal displayed necrotic skin on days 8 through 14. One animal (female) displayed very slight erythema on days w through 14. No edema was noted.

There were no abnormal findings noted upon gross necropsy.

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DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: 25
MRID No.: 420985-03

Reviewer: Ian Blackwell
Report Date: 7/17/91
Report No.: 91G-0374

Testing Laboratory: Toxikon Corporation
Author(s): George B. FitzGerald, Ph.D.

Quality Assurance (40 CFR §160.12): Included

Test Material: Weed and Grass
Dosage: 0.1 g

Species: New Zealand White rabbit
Sex: 3 males + 3 females
Weight: 2.18 to 2.43 kg Age: 10 to 12 weeks (young adult)
Source: Eastern Rabbit Breeding Laboratory

Summary:

1. Toxicity Category: II
2. Classification: guideline

Procedure (Deviations From §81-4):

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Cornea Opacity	0/6	4/6	4/6	4/6	0/6	0/6	0/6	0/6
Iris	0/6	0/6	0/6	0/6	0/6	0/6	0/6	0/6
Conjunctivae								
Redness	6/6	6/6	6/6	6/6	6/6	4/6	0/6	0/6
Chemosis	6/6	0/6	0/6	1/6	2/6	1/6	0/6	0/6
Discharge	6/6	0/6	1/6	1/6	1/6	1/6	---	---

Additional Observations: No obvious signs of toxicity were observed during the course of this study.

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DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5)

Product Manager: 25
MRID No.: 420985-04

Reviewer: Ian Blackwell
Report Date: 6/27/91
Report No.: 91G-0377

Testing Laboratory: Toxikon Corporation
Author(s): George B. FitzGerald

Quality Assurance (40 CFR §60.12): Included

Test Material: Weed & Grass
Dosage: 0.5 g

Species: New Zealand White rabbit

Age: 10 to 12 weeks

Sex: 3 males + 3 females

Weight: 2.46 to 2.61 kg

Source: Eastern Rabbit Breeding Laboratory

Summary:

1. **Toxicity Category:**
2. **Classification:** supplementary

Procedure (Deviations From §81-5):

The granular test material was not moistened upon application to the test animals as per guidelines.

Results: No erythema nor edema were exhibited at the test sites (nor at the control sites). No signs of toxicity were exhibited.