

2-28-92

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

MEMORANDUM:

Subject: EPA File Symbol/EPA Reg. No.: 7001-339
Ureabor Nonselective Weed and Grass Killer

From: Olga Odiott, Biologist *Olga Odiott*
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
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

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Applicant: J.R. Simplot Company

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Sodium metaborate tetrahydrate	66.5 %
Sodium chlorate	30.0 %
Bromacil	1.5 %
<u>Inert Ingredient(s):</u>	2.0 %
Total:	100.0 %

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BACKGROUND

J.R. Simplot Company submitted acute oral, acute dermal and skin irritation studies to support Reg.No. 7001-339. The studies were requested by PRS (review dated 9/20/90) along with acute inhalation and skin sensitization studies.

The product is classified in category I for eye irritation exposure (previously submitted data).

RECOMMENDATION

RSB/PRS finds the studies acceptable data.

Acute inhalation and skin sensitization studies are necessary to complete the acute toxicity profile for this product.

LABELING (Further label revisions may be necessary upon submittance of outstanding data.)

The signal word is DANGER, based on eye toxicity.

The first three sentences of the Precautionary statements should be revised to read: "Corrosive. Causes irreversible eye damage. Due to corrosive nature may be harmful or fatal if swallowed."

Revise the Statements of Practical Treatment as follows:

If in eyes: Flush with plenty of water. Get medical attention.

If swallowed: Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician or Poison Control Center.

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

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

Revise the Environmental Hazards Statements as follows:

The statement: "Keep out of lakes, streams or ponds." should be revised to read as follows: " Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark."

Revise the Storage and Disposal statements as follows:

The sentence "Pesticides wastes are toxic." should read: "Pesticides wastes are acutely hazardous."

Note to PM:

This product fits the criteria for restricted use classification

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due to eye toxicity. PM should decide if alternative label language is sufficient to offset this hazard and offset the requirement for restricted use classification."

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

Product Manager:25
MRID No.:420986-01
Testing Facility:Toxicon Corp.
Author(s):George FitzGerald
Species:Sprague-Dawley rats
Age:young adult
Weight:200-253 gm
Source:Charles River Lab. WIlmington, MA
Test Material:Ureabor, batch # 90190201
Quality Assurance (40 CFR §160.12): attached

Reviewer: O. Odiott
Report Date:10/01/91
Report No. 91G0371

Conclusion:

1. LD₅₀ (mg/kg): Males =
 Females =
 Combined = 3.76 +/- 0.37 g/kg
2. The estimated LD₅₀ is
3. Tox. Category: III Classification: Guideline

Procedure (Deviations from §81-1):**Results:**

Dosage	(Number Killed/Number Tested)		
	Males	Females	Combined
3.6 g/kg	1/5	2/5	3/10
4.2 g/kg	5/5	5/5	10/10
4.8 g/kg	5/5	5/5	10/10
5.0 g/kg	4/5	5/5	9/10

Symptoms & Gross Necropsy Findings:

Cyanosis, catalepsy, tachypnea, lethargy, loss of fluids, somnolence, prostration and tremors were observed. At necropsy, hemorrhaging in the stomach and the small intestine were observed.

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

Product Manager:25
MRID No.:420986-02
Testing Laboratory:Toxicon Corporation
Author(s):George FitzGerald
Species:New Zealand white rabbit
Weight:2.0 -3.0 kg
Source:Eastern Rabbit Breeding Lab. Taunton, MA
Test Material: Ureabor, batch # 90190201
Quality Assurance (40 CFR §160.12): attached

Reviewer: O. Odiott
Report Date:07/16/91
Report No.:91G-0372

Summary:

1. **LC₅₀ (mg/kg):** Males =
Females =
Combined =
2. The estimated LD₅₀ is >2.0 g/kg
3. **Tox. Category:** III **Classification:** Guideline

Procedure (Deviation From §81-2):**Results:****Reported Mortality**

DOSAGE	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
2.0 g/kg	0/5	0/5	0/10

Symptoms & Gross Necropsy Findings:

Very slight to well defined erythema was observed in 8/10 animals. No other signs of toxicity noted. No abnormalities observed at necropsy.

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

Product Manager:25
MRID No.:420986-03
Testing Laboratory:Toxicon Corporation
Author(s):George FitzGerald
Species:New Zealand white rabbit
Age:young adult
Sex:male & female
Weight:2.0 - 3.0 kg
Dosage:0.5 gm
Test Material: Ureabor, batch # 90190201
Quality Assurance (40 CFR §160.12):attached

Reviewer: O. Odiott
Report Date:06/27/91
Report No.:91G-0373

Summary:

1. The Primary Irritation Index =
2. Toxicity Category: IV
3. Classification: Core Minimum

Procedure (Deviations From §81-5):

It was not specified if the test substance (a granular) was moistened for application .

Results:

Erythema or edema were not observed at any time.

Special Comments:

Although it is not specified if the test substance (a solid) was moistened for application purposes, based on the acute dermal study it is clear that the skin irritation toxicity category will be IV. Based on erythema/edema observations included on the acute dermal report, 5/10 animals showed very slight erythema and 3/10 animals showed well-defined erythema after a 24 hours application treatment. It was also indicated that the symptoms were cleared by day 2 after treatment.

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