MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 612-8
Propel Plant Growth Regulator

FROM: William S. Woodrow WSW 1-7-92
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C) E 1/30/92

TO: C. Giles-Parker / J. Stone (PM 22)
Fungicide - Herbicide Branch
Registration Division (H75-05C)

APPLICANT: Unocal Chemicals
3960 Industrial Blvd.
West Sacramento, CA 95691

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
2-hydroxypropionic acid	80.0%
Inert Ingredient(s):	20.0%
Total	100.0%

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BACKGROUND

Unocal Chemicals requested approval of Precautionary Labeling changes submitted in a revised product label (PROPEL Plant Growth Regulator - EPA Reg No. 6(2-8). Henry Jacoby cited an acute inhalation study data gap (Oct. 23, 1979). The Registrant made reference to an inhalation study under MRID NO. 404907-1; (Woodrow reviewed this study :—

RECOMMENDATION

1) The acute inhalation toxicity study currently reviewed by Woodrow is not acceptable, and was graded Supplementary Data :

a. No separate gravimetric chamber samples (for chamber concentration determination) WERE TAKEN. It would have been possible to determine chamber concentration values from the Cascade Impactor results (sampled at 5L/min.), except that the number of minutes or length of time the two samples were collected was not given.

b. The particle size distribution was not given.

MMAD values (no GSD ranges) were calculated. The per cent of particles (by size range), and the cumulative percent of particles (by size range) should have been presented.

c. An animal mortality table should have been presented - indicating the sex of the one animal that died in the test group (no mortality table of any kind was presented).

2) Current acute toxicity profile for Propel Plant Growth Regulator (612-8):

Study	Toxicity Category
acute oral	III
acute dermal	III
Eye irritation (not required - pH < 2.0)	I (assume I)
Skin irritation	I
Dermal sensitization - Not a sensitizer -	

3) The Registrant must submit a new acute inhalation toxicity study. Acute inhalation study referenced (MRID NO. 404907-01, Lab. NO. I-7083-112) was not acceptable.

4) This product should be considered for ~~restricted~~ RESTRICTED USE CLASSIFICATION, based on the fact that

it is a severe skin irritant and exhibits a pH value of ≤ 2.0; unless PM TEAM DECIDES alternative labeling language can compensate for these hazards. AND THE NEED FOR RESTRICTED USE CLASSIFICATION. E

LABELING

1) The DANGER signal word is appropriate.
2) Revise the Precautionary Statements to read as follows:

"Corrosive. Causes irreversible eye damage. Causes skin burns. Harmful ~~[illegible]~~ if swallowed. Do not get in eyes, ON SKIN or on clothing. Wear goggles, face shield or safety glasses. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

3) Make the following changes to the Statements of Practical Treatment:

"If in eyes: Flush with plenty of water. Call a physician.

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

PM Note: Upon receipt of the requested acute inhalation study, Precautionary Labeling may require revision.

IF SWALLOWED: DRINK PROMPTLY A LARGE QUANTITY OF MILK, EGG WHITE, GELATIN SOLUTION, OR IF THESE ARE NOT AVAILABLE, LARGE QUANTITIES OF WATER. AVOID ALCOHOL. NOTE TO PHYSICIAN: PROBABLE MUCOSAL DAMAGE MAY CONTRAINDICATE THE USE OF GASTRIC LAVAGE. E

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3)

Product Manager: (22) 1-8-88
Reviewer: W. Woodrow
MRID No.: 404907-01
Report Date: 1-7-92
Testing Laboratory: Microbiological Assoc.
Report No. T-7083-112
Author(s): R. M. David
Species: Rat, Fischer 344
Sex: 5M+5F (9-10 wks. old)
Weight: not given
Source: Charles River Breeding Labs., Raleigh, N.C.
Test Material: SY-83 (Profel)
Quality Assurance (40 CFR §160.12): yes (Q.A. + G.L.P.)

Summary: (see page 4 for supplementary reasons)

1. LC_{50} (mg/kg): Males = ____; Females = ____; Combined = ____
2. The estimated LC_{50} is ____
3. Mean Concentration: ____
4. Tox. Category : ____. Classification: Supplementary

Procedure ~~(Deviations From §81-2)~~: Animals quarantined approx. 21 days. 5M+5F rats exposed for 4 hours to test material. 5M+5F rats exposed for 4 hours to air alone (control). Exposure chamber (vol. not given) was

Results:

Reported Mortality

Exposure Concentration (mg/L)	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
7.94 mg/L ???	1/5	0/5	1/10
air alone	0/5	0/5	0/10

~~Symptomology & Gross~~ Necropsy Findings:

cylindrical, arranged for nose only rat exposure. Animals held in place c̄ soft sponge. Animals were observed for mortality and/or pharmacotoxic signs at 1,3 hrs post treatment, and once daily to 14 days. Complete necropsies performed on all animals day 15.

Body weights recorded days 0, 7 & 14.
Aerosol generation made using a Collision nebulizer (BGI Industries). Compressed air attached to nebulizer, outlet to a 4 liter glass jar. Room air allowed to dilute aerosol before drawing into chamber. Chamber air flow 5 L/min. Samples collected from exposure chamber for chamber concentration and particle size distribution. Gravimetric chamber concentration measured by passing chamber samples through pre-weighed glass fiber filters; increased filter wt. ÷ L air sampled = mg/L. Particle size measurements made using Mercer 7 stage Cascade Impactor. Pre-weighed glass cover slips placed onto each stage. Impactor air flow rate of 5 L/min. MMAD calculated.

Results:

1) Chamber Concentration. The Cascade Impactor samples were used in an attempt to determine the chamber concentration (separate gravimetric samples were not taken).

Filter Size (μ)	0.5	0.2 (mg)
	0.8	6.4
	1.4	15.1
	2.2	15.1
	3.7	14.3
	6.1	8.7
	10.0	

Cascade Impactor Results

1st Sample

Wt. (mg)	0.2	0.5 (μ filter size)
	6.9	0.8
	15.1	1.4
	15.1	2.2 MMAD = 2.14 μ
	14.3	3.7
	8.7	6.1
	2.0	10.0
	0.3	

Wt. (mg)	0.5	0.5 (μ filter size)
	10.4	0.8
	14.0	1.4
	13.7	2.2 MMAD = 2.03 μ
	13.6	3.7
	8.0	6.1
	2.8	10.0
	0.3	

The testes stated (no calculations presented) that the Chamber concentration (based on a time-weighted average) was 7.94 mg/L

MMAD's of 2.14 μ and 2.03 μ (as shown above).

Clinical observations: Largely displayed by female rats - "Transient respiratory response to test material"
Necropsy: No gross abnormalities revealed.

Study Classification: Supplementary:

1) No separate gravimetric chamber samples (for chamber concentration). It would have been possible to determine chamber concentration from the Cascade Impactor results (sampled at 5 L/min), except that the no. of minutes, or the length of time the two samples were collected was not given.
2) The particle size distribution was not given. MMAD values (no GSD ranges) were calculated. the per cent of particles (log size range) and the cumulative per cent of particles (log size range) should have been presented.
3) An animal mortality chart (table) should have been presented — indicating the sex of the one animal that died in the test group.

Tox Chem. No. 517R Lactic Acid

File Last Updated

Current date 1-7-92

Study/Species/Lab/Study# Date	Material	MRID No.	Results	Tox. Cat.	Core Grade
Woodrow 9-24-87 Rat LD50	Propel			III	
Woodrow 9-24-87 Dermal irritation	"		severe irritant	I	
Woodrow 9-24-87 Eye irritation	"		study waived; ph < 2.0	assume I	
Jocelyn Stewart 9-10-86 Dermal Sensitization	"		not a sensitizer	-	
Allen Vaughn EEB Branch [Ref. from Tox. Branch Acute dermal study	"		LD50 >2.0 g/kg	III	
acute inhalation LC50, Rat. microbiological ASSOC. # I-7083-112 1-8-88	Propel "	404907 -01	LC50 not determined (No chamber conc. - part. size distribution provided)	-	supplementary

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