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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Received on
PM-22 Team
JAN 10 1994

MEMORANDUM

Subject: EPA Reg. No.: 612-8

From: Mark J. Perry, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (H7505W)

MJP
8-18-93

To: Cynthia Giles-Parker, PM 22
Fungicide-Herbicide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (H7505W)

Applicant: Unocal Corp.
1201 W. 5th Street
Los Angeles, CA

FORMULATION FROM LABEL:

	% by wt.
Active Ingredient(s): 2-Hydroxypropionic acid	80.0%
Inert Ingredient(s):	20.0%
Total:	100%

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BACKGROUND

Unocal Corporation has provided additional data as requested by W. Woodrow (1/30/92) in the review of an inhalation study submitted in support of the product Propel (EPA Reg. No. 612-8). Propel is a plant growth regulator with 2-Hydroxy-propionic acid (80.0%) as the active ingredient. The additional acute inhalation data was submitted under MRID number 426594-01 and the initial study (MRID # 404907-01) was performed by Microbiological Associates, Inc.

RECOMMENDATION

The data submitted in response to the 1/30/93 PRS review is acceptable. However, after re-review of this study, PRS has additional questions:

a. Under the "Conditions for Animal Exposures" section, the study report states that "Five rats were restrained per unit, 10 per group (5 male and 5 female)." As a result, PRS requests a complete description of the animal exposure chamber including the "unit" component mentioned above. Further, a statement which explains exactly how the animals were exposed and whether or not all ten animals were exposed to the same test atmosphere at the same time is requested.

b. There seems to be some confusion regarding the actual (gravimetric) and the nominal concentrations. On pages 8 and 12 of the study report the nominal concentration is stated to be 7.94 mg/L. However, the study report also states that the "time-weighted average" was 7.94 mg/L. Further, the "time-weighted average" or gravimetric concentration claim is supported by the sampling data. PRS requests that the registrant provide clarification on this point. More specifically, are the nominal and gravimetric concentrations exactly the same? If not, what is the actual nominal concentration for this study?

This study may be upgraded following the submission of the above requested study information.

LABELING

The appropriate labeling will be determined following the submission of the requested data.

NOTE TO PM: Due to eye and skin irritation, this product meets the criteria for restricted use classification. The PM should decide if the label contains sufficient alternative labeling language to offset the hazard and the need for this classification.

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ACUTE TOXICITY PROFILE

Acute Oral	Category III
Acute Dermal	Category III
Acute Inhalation	Supp
Eye Irritation	Category I
Dermal Irritation	Category I
Dermal Sensitization	Negative

* See 1/30/92 W. Woodrow review