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

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OPP OFFICIAL RECORD  
HEALTH EFFECTS DIVISION  
SCIENTIFIC DATA REVIEWS  
EPA SERIES 361

MAR - 3 1994

PC 063502

MEMORANDUM

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Subject: EPA ID # 063502: Mineral Oil - Review of Acute Toxicity Studies

MRID No.: 416853-11; 416853-12

DP barcode: D195602; D195963

PC Code: 063502 46

Submission No.: S451180; S451183

Casewell No.: 580AA

From: Paul Chin, Ph.D. *Paul Chin 2/23/94*  
Section 2  
Toxicology Branch I  
Health Effects Division (H7509C)

To: Kathryn Davis/Bonnie Adler, PM 52  
Reregistration Division (H7508W)

Thru: Joycelyn Stewart, Ph.D. *J/S 2/25/94*  
Section Head  
Section 2, Toxicology Branch I  
Health Effects Division (H7509C) *K/R 2/11/94*

Registrant: PureGro Co.

CONCLUSIONS:

Two acute toxicity studies with mineral oil were reviewed by the Toxicology Branch I. All studies are classified as acceptable and they satisfy the guideline requirements (81-2) and (81-3) for acute dermal and inhalation toxicity studies, respectively.

The summaries of the reviews are shown on the attached table. [Detailed reviews are appended to this memorandum.]

REQUESTED ACTION:

The Reregistration Division requested that the Toxicology Branch review the above two acute toxicity studies with mineral oil.

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ACUTE TOXICITY DATA FOR MINERAL OIL

Citation	MRID No.	Results	Tox. Categ.	Coregrade
81-2 Acute Dermal Species:rabbit	416853 -11	LD50 > 2 g/kg for males and females	III	acceptable
81-3 acute inhalation Species: rat	416853 -12	LC50 > 3.5 mg/L	III	acceptable

Primary Reviewer: Paul Chin, Ph.D. *Paul Chin 2/4/94*  
 Section 2, Tox. Branch 1 (H7509C)  
 Secondary Reviewer: Joycelyn Stewart, Ph.D., Section Head *J. Stewart 2/2/94*  
 Section 2, Tox. Branch 1 (H7509C)

DATA EVALUATION REPORT

STUDY TYPE: Acute Dermal (81-2)/Rabbit  
P. C. No: 063502  
MRID No: 416853-11  
TEST MATERIAL: 90 Neutral Oil  
SYNONYMS: Pure Gro/Unocal ; mineral oil  
SPONSOR: PureGro Co.  
 1276 Halyard Dr., West Sacramento, CA 95691  
TESTING FACILITY: Product Safety Lab,  
 725 Cranbury Rd, East Brunswick, NJ 08826  
Report No: T-8840  
REPORT TITLE: Acute Dermal Toxicity Study in  
 Rabbits: Limit Test  
AUTHOR(S): R. Shapiro  
REPORT ISSUED: April 5, 1989

CONCLUSIONS: 90 Neutral Oil (Pure Gro/Unocal) was administered dermally to 5 rabbits per sex for 24 hours at 2000 mg/kg. Slight to moderate erythema and edema were noted at the dosed site of all animals at patch removal. The irritation lasted for 9 days after dosing. By day 10, all signs of irritation disappeared. No adverse clinical signs, mortality, or effects at necropsy were detected.

Toxicity category: III.  
 Core classification: Acceptable.  
 LD50 > 2000 mg/kg for males and females.

A: MATERIALS:

1. Test compound: 90 Neutral Oil (Pure Gro/Unocal); Lot No. 074-UR20A; clear light yellow liquid with purity of 100 %.
2. Test animals: Species: Rabbit, Strain: New Zealand, Age: young adult (unspecified age), Weight: 2100-2700 g at

study initiation, Source: Davidson's Mill Farm, S. Brunswick, NJ., Acclimation period: 6 days.

B. METHODS:

- Twenty-four hours before application of test material, rabbits were prepared by clipping the skin free of hair over approximately 10% of the body surface (dorsal and ventral surfaces from scapular to pelvic area).
- No test site was abraded.
- Test material, 2000 mg/kg, was administered dermally to 5 rabbits per sex.
- The test material, undiluted, was applied to the patch and then placed over the test site. The entire trunk of each animal was then wrapped with a rubberized elastic cloth to avoid removal of the patches and to prevent evaporation. The test material remained in contact with the skin for 24 hours. At the end of 24 hours, the bandaging was removed and the skin was wiped with gauze sponges to remove excess test material.
- Rabbits were placed in neck collars and they were observed at 1, 2, 4, and 24 hours post-dosing, then at least once a day for 14 consecutive days.
- Rabbits were weighed at 0, 7, and 14 days following dosing.
- Gross necropsy was performed on all animals that died on study and on all survivors which were sacrificed on day 14.
- A signed and dated Quality Assurance statement was present.
- A signed and dated GLP statement was present.

C. RESULTS AND DISCUSSION:

No clinical signs were noted in any animal. One rabbit had reduced feces at days 11 and 14 and no feces at days 12 and 13.

All animals gained or maintained weight between day 0 and 14.

Slight to moderate erythema and edema were noted at the dosed site of all animals at patch removal and these irritation lasted for 9 days after dosing. By day 10, all signs of irritation disappeared.

At gross necropsy, all tissues and organs appeared normal except for lung discoloration commonly found in animals euthanized by sodium pentobarbital cardiac injection. Findings in lung which are not considered treatment-related were as follows: slightly red (1 male, 2 female), moderately red (1 male), moderately bright red (1 male, 2 female), extremely red (1 male), and extremely bright red (1 male, 1 female).

Since no animals died at 2000 mg/kg, a repeat test is not required. The guidelines allow a limit dose of 2000 mg/kg.

The LD50 was stated in the report to be > 2000 mg/kg.

Primary Reviewer: Paul Chin. Ph.D. *Paul Chin. 2/4/94*  
Section 2, Tox. Branch 1 (H7509C)  
Secondary Reviewer: Joycelyn Stewart, Ph.D., Section Head *J. Stewart*  
Section 2, Tox. Branch 1 (H7509C)

DATA EVALUATION REPORT

STUDY TYPE: Acute Inhalation (81-3)/Rat  
P. C. No: 063502  
MRID No: 416853-12  
TEST MATERIAL: 90 Neutral Oil  
SYNONYMS: Pure Gro/Unocal ; mineral oil  
SPONSOR: PureGro Co.  
1276 Halyard Dr., West Sacramento, CA 95691  
TESTING FACILITY: Product Safety Lab,  
725 Cranbury Rd, East Brunswick, NJ 08826  
Report No: T-8841  
REPORT TITLE: Acute Inhalation Toxicity  
Study in Rats: Limit Test  
AUTHOR(S): R. Shapiro  
REPORT ISSUED: April 25, 1989

EXECUTIVE SUMMARY: 90 Neutral Oil (Pure Gro/Unocal) was administered in an acute inhalation study for 4 hours to 5 Sprague Dawley rats per sex at 3.5 mg/L. The LC50 was found to be greater than 3.5 mg/L. The particle size of the test material was reported as a mass median aerodynamic diameter (MMAD) of 2.6 micrometers (um) with a geometric standard deviation (GSD) of 1.7. Greater than 97.9% of the particles were in the respirable range. Three animals died within 1 day of exposure.

Toxicity category: III.  
Core classification: Acceptable.  
LC50 = greater than 3.5 mg/L

A. MATERIALS:

1. Test compound: 90 Neutral Oil (Pure Gro/Unocal); Lot No. 074-UR20A; clear light yellow liquid with purity of 100%.

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2. Test animals: Species: Rat, Strain: Sprague Dawley, Age: Unspecified young adult, Weight: 203-224 g, Source: Hilltop Lab Animals, Scottdale, PA., Acclimation period: 7 days.

3. Environment: Temperature: 68-74 degrees F, Humidity: 30-70%.

4. Inhalation conditions: Exposure was by whole body for 4 hours. The exposure chamber was a rectangular perspex chamber with a volume of 100 liters. The test material was metered to the atomization nozzle through 1.5 mm ID teflon tubing, using a Sage Peristaltic Pump. Compressed air was supplied at 10 liters per minute (L/min).

B. METHODS:

- Concentrations of test material in the breathing zone were determined 7 times during 4 hour exposure through removal of gravimetric samples from the chamber. Samples were collected using membrane filters in filter holders attached by 1/4 inch tygon tubing to a sampling pump. Filter papers were weighed before and after collection to determine the mass collected. The collections were carried out for 5 minutes at air flows of 4 L/min.

- The particle size range in the test atmosphere was determined in an Andersen cascade impactor periodically during 4 hour exposure. The filter paper collection stages were weighed before and after collection to determine the mass collected at each stage. The mass collected at each stage was determined gravimetrically and used to determine the MMAD. The MMAD and GSD were determined graphically using 2 cycle logarithmic probit axes.

- Chamber air flow varied between 27.4 and 30.0 with a mean of 28.9 L/min. The exposure period was 4 hours and the times for 90 and 99% equilibration of the chamber atmosphere were 8 and 15.9 minutes, respectively.

- Nominal atmospheric concentrations was determined by the total amount of test material delivered to the chamber divided by the total volume of air passing through the chamber.

- Animals were observed preexposure, every 15 minutes during the first exposure hour and every 30 minutes thereafter through exposure termination (if possible), immediately after dosing.

- Rats were weighed on day 1, 2, 4, 7, 10, and 14.

- Gross necropsy was performed on all animals that died on study and on all survivors which were sacrificed on day 14.

- Doses given and lethality are presented in the table under results.

- A signed and dated Quality Assurance statement was present.

- A signed and dated GLP statement was present.

C. RESULTS and DISCUSSION:

The particle size of the test material was reported as a mass median aerodynamic diameter (MMAD) of 2.6 micrometers (um) with a geometric standard deviation (GSD) of 1.7 based on two samplings. Greater than 97.9% of the particles were in the respirable range. The weight percent of the particle size range at each stage of the Anderson impactor was not reported.

The mean gravimetric chamber concentration was 3.5 mg/L and the nominal chamber concentration was 67.9 mg/L based on seven samplings. Although not reported, the high ratio of nominal/analytical concentration (approx. 19) indicates a loss of the test material from the exposure atmosphere due to the observed occurrence of impaction on animals, on cages, and the walls of the chamber.

90 Neutral Oil (Pure Gro/Unocal) administered via inhalation for 4 hours to 5 rats per sex per group at 3.5 mg/L resulted in mortality in 3 animals (2 male, 1 female) by day 1 and remaining 7 animals survived (see Table below). Labored breathing, hunched posture, moist rales, and lethargy was the most common observation prior to death. One animal showed signs of cyanosis.

	Analytical conc. of test material mg/L	Number animals that died (Day of death)			
		Male	Total	Female	Total
Test Group	3.5	2 (1)	2/5	1 (1)	1/5

Surviving animals was sacrificed on day 14.

The remaining 7 survivors showed hunched posture. In addition, two females had moist rales and one female showed irregular, labored breathing, yellow anogenital staining and dry red nasal discharge. All survivors recovered by day 7 and gained weight by day 14.

Necropsy findings of the dead animals were extreme dark red discoloration of the lungs, gaseous distention of the stomach and discoloration of the liver (mottled brown/purple) and/or intestines (yellow). Necropsy finding in three of the survivors was slight red lung discoloration. All other tissues and organs were unremarkable.

The Toxicity Category is III.

a:\acin-mo.12 (mo = mineral oil)