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Du Pont HLR 391-89

Study Title

Approximate Lethal Dose (ALD) of [redacted] in Rats

Author

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Study Completed On

July 21, 1989

Performing Laboratory

E. I. du Pont de Nemours and Company, Inc.
Haskell Laboratory for Toxicology and Industrial Medicine
Elkton Road, P. O. Box 50
Newark, Delaware 19714

[redacted]

Laboratory Project ID

Haskell Laboratory Report No. 391-89

GENERAL INFORMATION

Material Tested:	[redacted]
Medical Research No.:	[redacted]
Haskell No.:	17,869
Physical Form:	White dispersion
Purity:	[redacted]
Composition:	[redacted]
Synonyms:	[redacted]
Other Code:	[redacted]
Stability:	The test material was assumed to be stable under the conditions of administration.
Sponsor:	Chemicals and Pigments Department E. I. du Pont de Nemours and Company, Inc. Wilmington, Delaware
Material Submitted By:	[redacted] Chemicals and Pigments Department E. I. du Pont de Nemours and Company, Inc. Jackson Laboratory Deepwater, New Jersey
In-Life Phase Initiated - Completed:	6/12/89 - 7/3/89
Notebook:	[redacted]

There are 6 pages in this report.

Distribution: [redacted]

Approximate Lethal Dose (ALD) of

[redacted] in Rats

SUMMARY

[redacted] approximately 100% pure) was administered as a single oral dose by intragastric intubation to male rats. No deaths occurred and no adverse clinical signs of toxicity were observed. Under the conditions of this test, the ALD was greater than 11,000 mg/kg of body weight. This material is considered to be very low in toxicity (ALD greater than 5000 mg/kg) when administered as a single oral dose.

Work by: Anne M. Grandizio
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Study Director

JWS:alr:HLR29.16

QUALITY ASSURANCE DOCUMENTATION

STUDY: [redacted] Approximate Lethal Dose (ALD) of [redacted] in Rats
H# 17,869

AUDITS:

Items Audited	Audit Dates
Records, Report	7/20/89

SHORT-TERM AUDIT REPORT NUMBER: [redacted]
DATE FINDINGS REPORTED TO MANAGEMENT AND STUDY DIRECTOR: 7/20/89

Reported by: William J. Lynam — 7/21/89

William J. Lynam
Quality Assurance Auditor

Date

INTRODUCTION

The purpose of this test was to determine an approximate lethal dose of [redacted] when administered as a single oral dose to male rats. The ALD was defined as the lowest dose administered which caused death either on the day of dosing or within 14 days post exposure. This study was conducted according to the applicable EPA Good Laboratory Practice Regulations. Areas of noncompliance are documented in the study records. No deviations existed that significantly affected the validity of the study.

MATERIALS AND METHODS

A. Animal Husbandry

Male Crl:CD®BR rats, approximately 7 weeks old, were received from Charles River Breeding Laboratories, Raleigh, North Carolina. Rats were housed singly in suspended, stainless steel, wire-mesh cages. Each rat was assigned a unique identification number which was recorded on a card affixed to the cage. Purina Certified Rodent Chow® #5002 and water were available ad libitum. Rats were quarantined, weighed, and observed for general health for approximately one week prior to testing. Animal rooms were maintained on a timer-controlled, 12-hour light/12-hour dark cycle. Environmental conditions of the rooms were targeted for a temperature of 23 ± 2°C and relative humidity of 50 ± 10%. Excursions outside these ranges were of small magnitude and/or brief duration and did not adversely affect the validity of the study.

B. Protocol

The test material was dispersed in distilled water and administered to one rat per dose rate by intragastric intubation. Dose rates administered ranged from 2300 to 11,000 mg/kg of body weight in increments of approximately 50%. Additionally, one rat was dosed at 670 mg/kg. The dosing day was test day one; postexposure day 14 was test day 15. Following administration of the test material, rats were observed for clinical signs of toxicity. Surviving rats were weighed and observed daily until signs of toxicity subsided, and then at least 3 times per week throughout the 14-day postexposure period. Observations for mortality were made daily throughout the study.

C. Records Retention

All raw data and the final report will be stored in the archives of Haskell Laboratory for Toxicology and Industrial Medicine, E. I. du Pont de Nemours and Company, Inc., Newark, Delaware or in the Du Pont Records Management Center, Wilmington, Delaware.

RESULTS

A. Dosage and Mortality Data

The dosage regimen and the mortality resulting over the 15-day test period are detailed below. No deaths occurred.

Dosage (mg/kg)	Dose Volume (mL)	Emulsion Concentration (mg/mL)	Initial Body Weight (g)	Mortality
670	1.1	150	241	No
2300	3.7	150	242	No
3400	1.7	500	247	No
5000	2.4	500	244	No
7500	3.6	500	239	No
11,000	5.6*	500	253	No

* Administered in two portions, approximately 15 minutes apart.

B. Clinical Signs

The rat dosed at 11,000 mg/kg exhibited lethargic behavior approximately one hour after dosing. The rats dosed at 5000 or 7500 mg/kg had slight weight losses (4 or 5% of initial body weight) one day after dosing. No other clinical signs of toxicity were observed.

CONCLUSION

Under the conditions of this study, the ALD for [redacted] was greater than 11,000 mg/kg of body weight. This material is considered to be very low in toxicity (ALD greater than 5000 mg/kg) when administered as a single oral dose to male rats.