Study Title

Approximate Lethal Dose (ALD) of H-21460 in Rats

Laboratory Project ID

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Author

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Performing Laboratory

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GENERAL INFORMATION

Substance Tested:	[redacted]
Synonyms/Codes:	• H-21460 [redacted]
Physical Form:	Yellow liquid
Composition:	[redacted]
Contaminants:	[redacted]
Purity:	[redacted]
Submitter's Notebook No.:	[redacted]
CAS Registry No.:	[redacted]
Sponsor:	DuPont Specialty Chemicals E. I. du Pont de Nemours and Company Wilmington, Delaware
Study Initiated - Completed:	1/17/96 - 2/29/96
In Life Phase Initiated - Completed:	1/18/96 - 2/5/96

Approximate Lethal Dose (ALD) of H-21460 in Rats

SUMMARY

H-21460 was administered as a single oral dose by intragastric intubation to male rats. No deaths occurred, and no clinical signs of toxicity were observed in any animals. Under the conditions of this test, the ALD was greater than 11,000 mg/kg of body weight. This substance is considered to be very low in toxicity (ALD greater than 5000 mg/kg) when administered as a single oral dose.

SIGNATURE PAGE

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INTRODUCTION

The purpose of this test was to determine an approximate lethal dose of H-21460 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.

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. The rats were tail-marked, using a water-insoluble marker, with the last 3 digits of the animal number. Purina® Certified Rodent Chow® #5002 and water were available ad libitum.

Haskell Laboratory has an animal health monitoring program. This program is monitored and administered by the Laboratory Veterinarian. Water samples are periodically analyzed for total bacterial counts and for the presence of coliforms, lead, and other contaminants. Additionally, samples from freshly washed cages and cage racks are periodically analyzed to assure adequate sanitation by the cagewashers. Data from this program are maintained separately from study records. Animal feed is certified by the manufacturer to meet specified nutritional requirements and to be free of a list of specified contaminants. On the basis of these analyses, there is no evidence suggesting that contaminants were present in the feed or water in amounts which may have interfered with the results of this study.

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°C ± 1°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 substance was dosed neat and administered to 1 rat per dose rate by intragastric intubation. The density of the test substance was 1.1 g/mL or 1100 mg/mL. In the absence of visible evidence to the contrary, the test substance was assumed to be stable under the conditions of administration. Dose rates administered

ranged from 2300 to 11,000 mg/kg of body weight in increments of approximately 50%. Additionally, 1 rat was dosed at 670 mg/kg. The dosing day was test day 1; postexposure day 14 was test day 15. Following administration of the test substance, rats were observed for clinical signs of toxicity. Rats were weighed and observed at least 3 times a week throughout the 14-day observation period. Observations for mortality and signs of illness, injury, or abnormal behavior were made daily throughout the study. Pathological examinations of test animals were not performed.

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, Newark, Delaware or in the DuPont 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 during the study.

Dosage (mg/kg)	Dose Volume (mL)	Density Concentration (mg/mL)	Initial Body Weight (g)	Mortality
670	0.16	1100	260	No
2300	0.54	1100	259	No
3400	0.79	1100	256	No
5000	1.2	1100	260	No
7500	1.6	1100	237	No
11,000	2.5	1100	247	No

B. Clinical Signs

No clinical signs of toxicity were observed during the tudy.

CONCLUSION

Under the conditions of this study, the ALD for H-21460 was greater than 11,000 mg/kg of body weight. This substance is considered to be very low in toxicity (ALD greater than 5000 mg/kg) when administered as a single oral dose to male rats.