Study Title

Approximate Lethal Dose (ALD) of H-20431 in Rats

Laboratory Project ID

Haskell Laboratory Report No. 90-94

Author

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Performing Laboratory

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Haskell Laboratory for Toxicology and Industrial Medicine
Elkton Road, P. O. Box 50
Newark, Delaware 19714

Medical Research No. [redacted]

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GENERAL INFORMATION

Substance Tested: [redacted]

Synonyms/Codes:

- H-20431
- [redacted]

Physical Form: Tan milky liquid

Purity: Approximately 99.5%

Composition: H-20431 [redacted]

Contaminants: [redacted]

CAS Registry No.: None available

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GENERAL INFORMATION (CONT.)

Sponsor:	Specialty Chemicals E. I. du Pont de Nemours and Company Wilmington, Delaware
Study Initiated - Completed:	1/6/94 - 3/15/94
In Life Phase Initiated - Completed:	1/17/94 - 2/9/94

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Approximate Lethal Dose (ALD) of

H-20431 in Rats

SUMMARY

H-20431 was administered as a single oral dose by intragastric intubation to male rats. No deaths occurred and no clinical signs of toxicity were observed during the study. 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 to male rats.

Work by: Carol Finlay
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Approved by: John W. Sarver
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Reviewed and Approved for Issue: Carol Finlay 3/15/94
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CF/alw

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INTRODUCTION

The purpose of this test was to determine an approximate lethal dose of H-20431 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, Kingston, New York. 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 2 digits of the animal number.

Purina Certified Rodent Chow® #5002 and water were available ad libitum. Haskell Laboratory has a monitoring program which consists of periodic food and water analysis for contaminants. This program is monitored and administered by the Laboratory Veterinarian; data from this program are maintained separately from study records. 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 ± 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 substance was mixed with deionized water and administered to 1 rat per dose rate by intragastric intubation. 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, the rats were observed for clinical signs of toxicity. The rats were weighed and observed at

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least 3 times per week throughout the 14-day recovery period. Observations for mortality 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)	Mixture Concentration (mg/mL)	Initial Body Weight (g)	Mortality
670	1.1	150	255	No
2300	3.6	150	235	No
3400	2.7	300	242	No
5000	4.1	300	248	No
7500	5.9[a]	300	237	No
11,000	9.4[a]	300	256	No

[a] Administered in 2 portions, 15 minutes apart.

B. Clinical Signs

No clinical signs of toxicity were observed during the study.

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CONCLUSION

Under the conditions of this study, the ALD for H-20431 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.

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