



BIOSEARCH INCORPORATED  
P.O. BOX 8598, PHILADELPHIA, PENNSYLVANIA 19101  
TELEPHONE: (215) 739-4499

HLO-501-82 [REDACTED]  
[REDACTED]

Project Number: [REDACTED]

SUMMARY OF RESULTS OF AN ACUTE ORAL TOXICITY LD<sub>50</sub> STUDY

Conducted for:

E. I. du Pont de Nemours & Company  
Haskell Laboratory

Date of Report:

July 26, 1982

H-14,533 [REDACTED]

Acute Oral Toxicity LD<sub>50</sub> - Male Rats.

The LD<sub>50</sub> and 19/20 Confidence Limits = 2,150 (1,961 - 2,358) mg/kg.



# BIOSEARCH INCORPORATED

P.O. BOX 8598, PHILADELPHIA, PENNSYLVANIA 19101

TELEPHONE: (215) 739-4499

Page 1 of 3

Project Number:

[REDACTED]

Submitted to:

E. I. du Pont de Nemours & Company  
Haskell Laboratory  
Elkton Road  
Newark, Delaware 19711

Material:

E. I. du Pont de Nemours & Company - H-14,533 [REDACTED]

Sample Received:

4/30/82

Study Initiated:

5/18/82

Study Completed: 6/29/82

Date of Report:

7/26/82

Test:

Acute Oral Toxicity LD<sub>50</sub> - Rats

Object of Test:

To study the acute oral toxicity in rats of the subject material.

Procedure:

Five groups of ten male albino rats of the outbred Sprague-Dawley Strain weighing between 200 and 300 gm each were employed in this study. The rats were deprived of food but not water overnight prior to dosing. Each animal was weighed and dosed by direct administration of the experimental material into the stomach by means of a syringe and dosing needle.

The animals were housed and maintained in compliance with the Animal Welfare Act (Pub. L-94-279) 9 CFR Part 3.

Husbandry Conditions:

Temperature - 72°F ± 2°F

Relative Humidity - 45% ± 5%

Light - 12 hour light/dark cycle

Diet - Wayne Lab-Blox and tap water were provided ad libitum.

Based on our current knowledge no contaminants were known to be in this diet or water that might be expected to interfere with the objectives of the study.

Caging - Stainless steel with elevated wire mesh flooring  
male rats/cage

Bedding - Techboard  
Shepherd Products Company  
Kalamazoo, Michigan 49005

The sample was dosed as a 10% w/v suspension in water.

Company Sanitized. Does not contain TSCA CBM

Project Number:

[REDACTED]

Page 2 of 3

E. I. du Pont de Nemours & Company - H-14,533

Acute Oral Toxicity LD<sub>50</sub> Study.

Procedure:  
(continued)

The following dosage levels were administered;

1,580 mg/kg  
2,000 mg/kg  
2,510 mg/kg  
3,160 mg/kg  
3,980 mg/kg

Following administration the animals were allowed food and water ad libitum for the 14 day observation period during which time the rats were observed for signs of toxicity and mortalities.

Animals were observed frequently on the day of dosage, and twice per day thereafter (morning and afternoon). Individual weights were recorded on the day of dosage, weekly thereafter, and prior to sacrifice. The animals were euthanized at the conclusion of the observation period with carbon dioxide. Gross autopsies were performed on all animals which died during the 14 day observation period and also on all survivors of the 14 day observation period.

The LD<sub>50</sub> was calculated employing the Thompson Moving Average Method as modified by Weil, (Biometrics, September, 1952, Vol. 8, No. 3, pp 249-263).

All the raw data is on file in the archives of Biosearch, Incorporated, Philadelphia, Pennsylvania

Results:

See Table 1.

Conclusion:

The subject material when studied in male albino rats has an acute oral LD<sub>50</sub> of 2,150 mg/kg with 19/20 Confidence Limits of from 1,961 to 2,358 mg/kg.

Barbara A. Costello  
Barbara A. Costello, M.Ag.  
Laboratory Supervisor

7/26/82  
Date

Karl L. Gabriel  
Karl L. Gabriel, V.M.D., Ph.D.  
Study Director

7-26-82  
Date

This report is in compliance with  
current GLP's

James Affrime  
James Affrime  
Quality Assurance Officer

7/26/82  
Date

Company Sanitized. Does not contain TSCA CB1

Project Number: [REDACTED]

TABLE 1

Acute Oral Toxicity LD<sub>50</sub> - Males

Material: E. I. du Pont de Nemours & Company - H-14,533 [REDACTED] as 10% w/v suspension in water.  
Concentration: 100 mg/ml

| Dosage Level mg/kg | Number of Animals Dosed | Mortalities Days |   |   |   |   |   |   |   |   |    |    |    |    |    | Total Survived 14 Days | Avg. Initial Weight gm | 7th Day Wt. gm | Avg. Final Weight gm |
|--------------------|-------------------------|------------------|---|---|---|---|---|---|---|---|----|----|----|----|----|------------------------|------------------------|----------------|----------------------|
|                    |                         | 1                | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |                        |                        |                |                      |
| 1,580              | 10                      | 0                | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0  | 0  | 0  | 0  | 0  | 1                      | 259                    | 284            | 249                  |
| 2,000              | 10                      | 0                | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0  | 0  | 0  | 0  | 0  | 2                      | 270                    | 207            | 229                  |
| 2,510              | 10                      | 0                | 0 | 1 | 0 | 2 | 1 | 0 | 0 | 0 | 0  | 0  | 3  | 2  | 0  | 9                      | 239                    | 189            | 193                  |
| 3,160              | 10                      | 1                | 3 | 0 | 0 | 0 | 1 | 2 | 0 | 0 | 1  | 0  | 2  | -  | -  | 10                     | 242                    | 190            | -                    |
| 3,890              | 10                      | 3                | 2 | 2 | 1 | 0 | 2 | - | - | - | -  | -  | -  | -  | -  | 10                     | 247                    | -              | -                    |

Observations:

The LD<sub>50</sub> and 19/20 Confidence Limits = 2,150 (1,961 - 2,358) mg/kg.

- 1,580 mg/kg - All of the animals appeared ruffled after 3 hours. They appeared normal after 24 hours. The death of 1 animal on day 6 was not preceded by any abnormal clinical signs. The remaining animals continued to appear normal throughout the observation period.
- 2,000 mg/kg - All of the animals appeared ruffled after 3 hours. They appeared normal after 24 hours. The deaths of animals on days 4 and 7 were not preceded by any abnormal clinical signs. The remaining animals continued to appear normal throughout the observation period.
- 2,510 mg/kg - All of the animals appeared ruffled after 3 hours. They appeared normal after 24 hours. Deaths subsequently occurred over several days as indicated. The animals appeared to slowly waste away until death occurred.
- 3,160 mg/kg - All of the animals appeared ruffled after 3 hours. One death occurred within the first 24 hours. The remaining animals appeared normal after 24 hours. Deaths subsequently occurred over several days as indicated. The animals appeared to slowly waste away until death occurred.
- 3,980 mg/kg - All of the animals appeared ruffled after 3 hours. Three deaths occurred within the first 24 hours and the surviving animals appeared to be in generally poor health after 24 hours. They subsequently died on the days noted.

Note: All the animals surviving the observation period lost weight.

Gross Pathology: Gross pathologic examination revealed nothing remarkable.

The LD<sub>50</sub> was calculated employing the Thompson Moving Average Method as modified by Weil, (Biometrics, September, 1952, Vol. 8, No. 3, pp 249-263).

Company Sanitized. Does not contain TSCA CBI