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Andrea V. Malinowski
Corporate Counsel

DuPont Legal
Wilmington Office Buildings
1007 Market Street
Wilmington, DE 19898
302-774-6443 Tel 302-774-4812 Fax
andrea.v.malinowski@usa.dupont.com E-mail

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Re: 8EHQ-1106-16892A (November 8, 2006)
DuPont HLR 38-93 (1-096)
Supplemental Submission - Revised Public Copy

Dear Section 8(e) Coordinator:

Please find enclosed a revised public copy of the above-identified report, which was previously submitted to EPA and assigned the 8EHQ number referenced above. There is no confidential business information claimed in this revised public copy.

Very truly yours,

Andrea V. Malinowski

Enclosure
- DuPont HLR 38-93 – 11 pages

8EHQ-07-16892

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096

Study Title

Inhalation Approximate Lethal Concentration
of H-19250 in Rats

Author

Anthony S. Panepinto

Study Completed

February 1,1993

Performing Laboratory

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

Medical Research Project No.

9248-001

Laboratory Project ID

Haskell Laboratory Report No. 38-93

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This study was conducted according to EPA Good Laboratory Practice Standards (40 CFR 792). Any areas of noncompliance are documented in the study records. No deviations existed that affected the validity of the study.

Submitter: E. I. du Pont de Nemours and Company

Sponsor: Du Pont Chemicals
E. I. du Pont de Nemours and Company
Wilmington, Delavare

Study Director: A.S. Panepinto 02/01/93
Anthony S. Panepinto, M.S. Hygiene, C.I.H.
Toxicologist
Chronic, Biochemical, & Inhalation Toxicology

GENERAL INFORMATION

Material Tested: Alkanol XC

Synonyms:
- o Alkanol XC surfactant
- o Sodium alkylnaphthalene sulfonate
- o H-19250

Physical Form: Solid (powder)

Purity: 88-90% as sodium alkylnaphthalene sulfonate

Composition: 88-90% Sodium alkylnaphthalene sulfonate
7-9% Sodium sulfate;
2-3% Water

Stability: The test material was assumed to be stable throughout the exposure phase of the study

Submitter's Notebook No. N/A

CAS Registry No.: N/A

Sponsor: Du Pont Chemicals
E. I. du Pont de Nemours and Company
Wilmington, Delaware

Study Initiated/Completed: 04-21-92/02-01-93

In-Life Phase Initiated/Completed: 05-14-92/06-10-92

Inhalation Approximate Lethal Concentration (ALC) of H-19250 in Rats

SUMMARY

Five groups of 6 male Crl:CD®BR rats each were exposed to an atmosphere of H-19250 for a single, 4-hour exposure period. The test atmospheres were generated by suspension of the solid test material in a stream of filtered air. During exposures, the concentration of the test material present was determined by gravimetric analysis. In the 14-day recovery period pursuant to the exposures, each rat was weighed and observed for clinical signs of toxicity.

Rats were exposed to 0.12, 0.46, 0.80, 1.2, or 4.8 mg/L of H-19250. A single particle size determination was taken during each exposure to characterize the respirability of the test atmosphere. The mass median aerodynamic diameter (MMAD) present during the individual exposures was 3.0 um at 0.12 mg/L, 3.5 um at 0.46 mg/L, 3.8 um at 0.80 mg/L, 5.6 um at 1.2 mg/L, and 2.3 um at 4.8 mg/L H-19250. The percentage of particles less than 1 um in diameter ranged between 4.5% and 20%.

No mortality was observed following exposures at 0.12 mg/L and 0.46 mg/L H-19250. The lowest concentration in which mortality was observed was 0.80 mg/L. All rats exposed at the 1.2 mg/L and 4.8 mg/L exposure levels died during or immediately following exposure. Immediately following exposure rats were observed to have oral, nasal, and ocular discharges, irregular respiration, wet perineum, gasping and lethargy. Other clinical signs of toxicity observed in rats exposed to H-19250 included hunched posture, diarrhea, and stained perineum. Weight losses were observed in all rats the day following the 0.12 mg/L and 0.46 mg/L exposures. All rats exposed at 0.80 mg/L experienced weight loss lasting up to 3 days following exposure. In general, all surviving rats gained weight over the remainder of the recovery period.

Under the conditions of this test, the approximate lethal concentration (ALC) for H-19250 is 0.80 mg/L. On an acute inhalation basis, H-19250 is considered to be moderately toxic (ALC 0.20 - 0.80 mg/L).

Technical Work and
Report Preparation by: Clarence Hutt III
Clarence Hutt III
Toxicology Technician

Reviewed and
Approved for issue:
Anthony S. Panepinto, M.S. Hygiene, C.I.H.
Study Director

QUALITY ASSURANCE DOCUMENTATION

(H-19250)

Dates of Inspection:

Conduct - 5/14/92

Records, Report(s) - 9/23-25,28-29/92; 10/5-6/92

Date(s) Findings Reported to:

Study Director - 10/6/92

Management - 1/11/93

Reported by: Paul Jeffrey Chapman 1/11/93

P. Jeff Chapman
Quality Assurance Auditor

Date

INTRODUCTION

The purpose of this study was to determine an inhalation approximate lethal concentration (ALC) for H-19250. The ALC was defined as the lowest atmospheric concentration tested which caused the death of 1 or more exposed rats either on the day of exposure or within at least 14 days post exposure.

TEST MATERIAL

The test material was supplied by the sponsor as a light tan powder. The purity of the material was 88 - 90% as reported by the sponsor.

MATERIALS AND METHODS

A. Animals

Young adult male Crl:CD®BR rats were received from Charles River Breeding Laboratories, Kingston, New York. The rats were approximately 7 weeks of age on arrival.

Rats have historically been used in safety evaluation studies for acute inhalation toxicity testing and their use is specified in the EPA, OECD, and MAFF Japan guidelines for acute inhalation toxicity testing. The Crl:CD®BR rat has been chosen based on consistently acceptable health status and the extensive experience with the strain at this laboratory.

B. Animal Husbandry

Quarantine and Animal Selection. Rats were quarantined after arrival for 6 days prior to testing. They were housed individually in 5" x 11" x 7" suspended, stainless steel, wire-mesh cages. Rats were weighed and observed 3 times during the quarantine period. Rats used on this study were obtained from the general population of stock rats released from quarantine.

Housing. Rats were housed either singly or in pairs during the test period in 8" x 14" x 8" suspended, stainless steel, wire-mesh cages.

Animal Room Environment. The animal rooms were maintained on a timer-controlled, 12-hour light/12-hour dark cycle. Environmental conditions of the rooms were within temperatures of 23 ± 2°C and a relative humidity of 50 ± 10%. Any excursions outside these ranges were of small magnitude and/or brief duration and did not adversely affect the validity of the study.

Identification. Each rat was assigned a unique 6-digit identification number which corresponded to a numbered card affixed to the cage. The rat assigned the lower number in each cage was identified by a slash in the right ear. Prior to exposure, tails of the rats and cage cards were color-coded with water-insoluble markers so that individual rats could be identified.

Feed and Water. Except during exposure, Purina Certified Rodent Chow® #5002 and tap water from the Wilmington Suburban Water Corporation were available ad libitum.

C. Study Design

Five groups of 6 male rats each were exposed nose-only for 4-hour periods to an atmosphere of H-19250. Rats ranged in weight from 248 to 291 grams at the time of exposure.

Rats could not be observed for mortality and clinical signs of toxicity during the exposure due to the dense chamber atmosphere and/or the test material covering the inside of the chamber. Mortality and clinical signs of toxicity were observed immediately following exposure. During a 14-day, post-exposure, recovery period, rats were observed each day for mortality. Rats were weighed and observed for clinical signs of toxicity daily, excluding test days 5, 6, 7, 12, and 13 for the 0.12 mg/L group, test days 4, 5, 10 and 11 for the 0.46 mg/L group, and test days 11 and 12 for the 0.80 mg/L group. All rats exposed at 1.2 mg/L or 4.8 mg/L died during or immediately following exposure.

D. Inhalation Exposure Conditions

During the exposures, rats were individually restrained in perforated, stainless steel cylinders with conical nose pieces. The restrainers were inserted into the face plate of a 29-L cylindrical, glass exposure chamber so that only the nose of each rat protruded into the chamber.

Chamber airflow was set at the start of the exposures and adjusted as needed throughout the 4-hour period. Chamber temperature was targeted at 23 ± 2°C. Temperature was measured continually with a Omega HH-51 digital thermometer and recorded initially then three times during each exposure. Relative humidity was targeted at 50 ± 10%. Humidity in the exposure chamber was measured 3 times during each exposure with a Reuter Stokes RSS-230 Micro-Psychrometer. Chamber oxygen concentration was targeted to at least 19% and measured with a Biosystems Model 3100R oxygen analyzer three times during each exposure.

E. Atmosphere Generation

Test atmospheres of H-19250 were generated by suspension of the test material in a stream of filtered air. The solid test material was metered into a glass transfer tube using a K-Tron twin screw volumetric feeder which was controlled by a K-Tron Series 6300 digital speed controller. A baffle positioned immediately inside the exposure chamber was used to promote uniform chamber distribution of test material. Chamber concentrations were controlled by varying the feed rates at which the test material flowed to the transfer tube.

Test atmospheres were exhausted through a high-capacity dust filter and a Balston® particulate filter prior to discharge into the fume hood.

F. Characterization of Chamber Atmosphere

The atmospheric concentration of H-19250 was determined at approximately 30-minute intervals by gravimetric analysis. Approximately 2- to 10-liter samples of chamber atmospheres were drawn from the breathing zone of the rats through a 25 mm filter cassette that contained a preweighed Gelman glass fiber (Type A/E) filter. The filters were weighed on a Cahn C-30 Microbalance. The atmospheric concentration of H-19250 was calculated from the difference in the pre- and post-sampling filter weights.

A sample to determine the particle size distribution (mass median aerodynamic diameter and percent particles less than 1, 3, and 10 µm diameter) was taken with a Sierra® Series 210 cyclone preseparator/cascade impactor and Sierra® Series 110 Constant Flow Air Sampler.[1]

G. Records Retention

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

RESULTS

A. Exposure Conditions

Five, 4-hour exposures were conducted with groups of 6 male rats each exposed to chamber atmospheres consisting of H-19250 at 0 12, 0.46, 0.80, 1.2, or 4.8 mg/L of H-192).

Chamber concentration data are presented in Table 1. A single particle size sample was taken during each exposure. Data characterizing the particle size of the chamber atmosphere are summarized in Table 2.

TABLE 1

Characterization of H-19250 Atmospheres and Associated Rat Mortality

Dust Particulate Concentration (mg/L)[a]				Mortality
Mean	S.D.	Range	n	(# deaths/# exposed)
0.12	0.021	0.09 - 0.16	8	0/6
0.46	0.14	0.24 - 0.68	8	0/6
0.80	0.21	0.54 - 1.3	9	1/6
1.2	0.14	1.0 - 1.4	8	6/6
4.8	1.1	4.0 - 6.8	9	6/6

[a] Represents the mean, standard deviation (S.D.), range, and number of samples (n) for each exposure. Values are expressed as 2 significant figures.

TABLE 2

Characterization of H-19250 Particle Size Distribution

Particulate Concentration (mg/L)	n	Mass Median Aerodynamic Diameter (µm)	Geometric Standard Deviation	% Particles by mass <1 um	<3 um	<10 um
0.12	1	3.0	2.2	10	50	93
0.46	1	3.5	2.3	7	44	88
0.80	1	3.8	2.4	6	40	87
1.2	1	5.6	2.5	5	28	74
4.8	1	2.3	2.6	20	60	94

During each exposure, the chamber airflow was held constant. Chamber airflow, temperature, relative humidity, and oxygen content are presented in Table 3. Although chamber relative humidity was out of the targeted range for the 0.12, 0.46, 0.80, and 1.2 mg/L exposures, the environmental conditions were considered acceptable for conduct of this study.

TABLE 3

Chamber Environment

Mean Aerosol Concentration (mg/L)	Total Chamber Airflow[b] (L/min)	Temperature Range °C	Relative Humidity Range (%)	Oxygen (%)
0.12	33	23 - 24(4)[a]	33 - 36(3)	21(3)
0.46	33	23 - 24(4)	26 - 32(3)	21(3)
0.80	33	23 - 24(4)	34 - 45(3)	21(3)
1.2	33	23 - 24(4)	34 - 38(3)	21(3)
4.8	33 - 47	23 - 24(4)	46 - 47(3)	21(3)

[a] The number in parentheses represents the number of observations taken for each exposure.
[b] Airflow is approximate.

B. Mortality, Clinical Signs, and Body Weights

A summary of the mortalities that occurred following exposures is in table 1. There was no mortality associated with the 0.12 and 0.46 mg/L exposure level. One of 6 rats exposed at 0.80 mg/L died following exposure. Four of 6 rats exposed at 1.2 mg/L died during exposure the remaining 2 rats died following exposure. Six of 6 rats exposed at 4.8 mg/L died during exposure.

Clinical signs could not be assessed during exposures due to the heavy chamber atmosphere and/or the test material coating the inside of the chamber. Upon removal of the rats from restrainers oral, ocular, and nasal discharges were observed and rats were lethargic. Other clinical observations included irregular respiration, hunched posture, gasping, and wet perineum.

Weight losses were observed in rats on the day following exposures to 0.12 mg/L and 0.46 mg/L H-19250. Some rats exposed to 0.80 mg/L exhibited weight losses for 3-4 days post exposure. In general, surviving rats gained weight over the 14-day recovery period.

CONCLUSION

The purpose of this study was to determine the approximate lethal concentration (ALC) of H-19250. Under the conditions of this test, the ALC is 0.80 mg/L. On an acute inhalation basis, H-19250 is moderately toxic.

REFERENCES

[1]. Calculation described in Sierra Instruments, Inc., Bulletin 7-79-219IM, Instruction Manual: Series 210 Ambient Cascade Impactors and Cyclone Preseparators.

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Doris Duffy
E. I. du Pont de Nemours & Co.
1007 Market Street
D-7096-1
Wilmington, DE 19898

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