ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ- 06-16600	89110000097	2/7/11

COMMENTS: Commun S (DECLASS)

DOES NOT CONTAIN CBI

33,2960

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

RECEIVED
OPPT CBIC

11 FEB -7 PM 1:16

February 3, 2011

VIA CERTIFIED MAIL
Certified Mail Receipt No. 7001-2510-0006-9113-2343

Attn: TSCA Declassification Coordinator
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
Document Control Office (7407M)
Washington, D.C. 20460

Public Copy
No CBI

Re: Declassification Activity-TSCA §8(e) Submission
8EHQ Bar Code Number: 8EHQ-06-16600
Other EPA Identifier(s): 88070000018/S; 8EHQ-1006-16600A
DuPont HLR 47-95 (1-001)
Supplemental Submission - Revised Public Copy of Report

Dear TSCA Declassification Coordinator:

This submission is made in connection with the EPA 2010 CBI Declassification Challenge initiative.

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. Any information still claimed as confidential business information (CBI) in the attached report has been redacted and replaced by brackets. The originally assigned 8EHQ number (as bar coded on the submission) has been added by the submitter to the first page of the enclosed revised public copy of the report. Other EPA identifying numbers stamped on the submission or provided on the EPA website are referenced above.

Very truly yours,

Andrea V. Malinowski

8EHQ-06-16600

Enclosure
- DuPont HLR 47-95 – 8 pages

8911000097

CONTAINS NO CBI

Revised Public Copy
Originally Assigned 8EHQ Number:
8EHQ-06-16600
Company Sanitized - No CBI

1-001

TRADE SECRET

Study Title

Inhalation Approximate Lethal Concentration (ALC) of H-20611 in Rats

Laboratory Project ID

Haskell Laboratory Report No. 47-95

Author

Thomas A. Kegelman

Study Completed

March 24, 1995

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. 9892-001

INHALATION APPROXIMATE LETHAL CONCENTRATION (ALC) OF H-20611 IN RATS

GENERAL INFORMATION

Test Substance: TLF-8291

Synonyms/Codes: TLF-8291

Haskell No.: 20611

C.A.S. Registry No.: None available

Purity: Not supplied by sponsor

Physical Form: Liquid

Composition: TLF-8291 contains (wt. %)

[ ]
Alkyltrialkoxysilane
Alkyltrimethylammonium chloride
Acetic acid
Water

Contaminants: Unknown

Stability: The test substance was expected to be stable throughout the exposure phase of the study

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

Study Initiated/Completed: 4/25/94 - 3/24/95

In-Life Study Initiated/Completed: 4/26/94 - 5/17/94

INHALATION APPROXIMATE LETHAL CONCENTRATION (ALC) OF H-20611 IN RATS

SUMMARY

Three groups of six male Crl:CD®BR rats each were exposed nose-only for a single, four-hour period to H-20611 aerosols in air. Test atmospheres were generated by nebulization of H-20611 in air, and concentrations of H-20611 were determined by gravimetric analysis. Rats were weighed and observed for clinical signs of toxicity during a 14-day recovery period.

Rats were exposed to aerosols of H-20611 at average concentrations of 360, 470 or 840 mg/m³. The mass median aerodynamic diameters for the aerosols tested ranged from 2.8 to 3.6 µm. Rats died following exposure to H-20611 at concentrations of 470 mg/m³ or greater; deaths occurred on test days 2, 4, 5 and 9. The fractional mortalities for the 470 and 840 mg/m³ exposure groups were 1/6 and 5/6, respectively.

Some notable clinical signs of toxicity observed during this study included compound-stained fur, lung noise, labored breathing, wet perineum, lethargy, gasping, ocular discharges, partially closed eyes, cloudy eyes, and hunched posture. These signs were typically observed from test day two to test day five. Rats from the 360 and 470 mg/m³ groups either gained weight or exhibited slight to severe weight losses from test day two to test day four. One rat in the 470 mg/m³ was found dead on test day five; the remaining five rats from this group displayed normal weight gain and no clinical signs of toxicity from test day 4 to 15. Rats from the 840 mg/m³ exposure group were found dead on test days 2, 4 and 9. One rat from this exposure group was sacrificed in extremis on test day four. All rats from the 840 mg/m³ displayed severe weight loss (one rat in this group lost 42% of its original body weight by test day eight).

Under the conditions of this study, the ALC for H-20611 is 470 mg/m³. On an acute inhalation basis, H-20611 is considered to be moderately toxic (ALC between 200 and 800 mg/m³).

Work by: M. A. Pulliam
M. A. Pulliam, B.S.
Toxicology Technician
Inhalation Toxicology

Report Prepared by: Brian P. Shertz
Brian P. Shertz
Toxicology Technician
Inhalation Toxicology

Reviewed and Approved for Issue by Study Director: Thomas A. Kegelman — Date 3/24/95
Thomas A. Kegelman, A.A.S.
Toxicology Associate
Inhalation Toxicology

INHALATION APPROXIMATE LETHAL CONCENTRATION (ALC) OF H-20611 IN RATS

INTRODUCTION

The objective of this study was to determine a four-hour inhalation approximate lethal concentration (ALC) of H-20611 in male rats. The ALC is defined as the lowest atmospheric concentration tested which caused the death of one or more exposed rats either on the day of exposure or within at least 14 days following exposure. The inhalation route of exposure was chosen based on the expected route of potential human exposure and was requested by the sponsor.

MATERIALS AND METHODS

A. Test Substance

The test substance, H-20611 was supplied by the sponsor as a white liquid.

B. Animals

Young adult, male Crl:CD®BR rats were obtained from Charles River Breeding Laboratories, Kingston, New York.

Rats have historically been used in safety evaluation studies 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.

C. Animal Husbandry

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

Housing. During the test period, rats were housed either singly or in pairs in 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 targeted to be within a temperature range of 23 ± 2°C and a relative humidity range 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.

Identification. Each rat was assigned a unique six-digit identification number which corresponded to a numbered card affixed to the cage. Prior to exposure, tails of the rats and cage cards were coded with water-insoluble markers so that individual rats could be identified.

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

Haskell Laboratory has an animal health monitoring program. The following procedures are performed periodically:

- o Water samples are analyzed for total bacterial counts, and the presence of coliforms, lead, and other contaminants.
- o Feed samples are analyzed for the presence of bacteria and fungi.

Haskell Laboratory uses certified animal feed. The feed is guaranteed by the manufacturer to meet specified nutritional requirements and to be free of a list of specified contaminants.

This monitoring program is administered by the laboratory animal veterinarian. Data are maintained separately from study records and are not included in the final report.

D. Study Design

Three groups of six male rats each were exposed nose-only for a four-hour period to aerosols of H-20611 in air. Rats were approximately eight weeks of age at the time of exposure and ranged in weight from 213 to 275 grams.

Rats from all exposure groups were observed for mortality and clinical signs of toxicity during exposure and immediately following exposure. During a 14-day post-exposure period, surviving rats from all groups were observed each day for mortality, and were weighed and observed for clinical signs of toxicity daily (weekends excluded unless warranted by the health status of the rats.)

E. Inhalation Exposure Conditions

During the exposure, rats were individually restrained in perforated stainless steel cylinders with conical nose pieces. The restrainers were inserted into the face plate of a 17-L cylindrical, glass exposure chamber so that only the nose of each rat extended into the chamber.

Chamber airflow was set at the beginning of the exposure and adjusted, if necessary, to maintain the desired chamber atmospheric concentration. Total chamber airflow was monitored continually with a Brooks Model 5851 Mass Flow Controller. Airflow was recorded initially and whenever changes were made. Chamber temperature was targeted at 23 ± 2°C and was measured continually with a glass mercury thermometer and recorded three times during each exposure. The chamber relative humidity was targeted at 50 ± 10% and was measured twice during each exposure with a Reuter Stokes RSS-230 Micro-Psychrometer. Chamber oxygen concentration was targeted to at least 19% and was measured with a Biosystems Model 3100R oxygen analyzer twice during each exposure.

F. Atmosphere Generation

Chamber atmospheres were generated by nebulization of H-20611 in air with a Spraying Systems nebulizer. The test substance was metered into the nebulizer with a Harvard Model 22 syringe drive. Filtered houseline air, introduced at the nebulizer, atomized the test substance and carried the aerosol into the exposure chamber. A dispersion plate located near the chamber inlet was used to promote uniform aerosol distribution throughout the chamber. Chamber concentrations of H-20611 were controlled by varying the test substance feed rate to the aerosol generator.

Test atmospheres were exhausted through a scrubber containing water, a dry-ice cold trap, and an MSA filter prior to discharge into the fume hood.

G. Characterization of Chamber Atmosphere

The atmospheric concentration of H-20611 was determined at approximately 30-minute intervals by gravimetric analysis. Known volumes of chamber atmosphere 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 Model C-30 Microbalance®. The atmospheric concentration of H-20611 was calculated from the difference in the pre- and post-sampling filter weights, and the total airflow through the filter.

Air samples were taken from the exposure chamber to determine the particle size distribution (mass median aerodynamic diameter and geometric standard deviation) with a Sierra® Series 210 cyclone preseparator/cascade impactor and Sierra® Series 110 Constant Flow Air Sampler([1]).

H. 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 DuPont Records Management Center, E. I. du Pont de Nemours and Company, Wilmington, Delaware.

RESULTS

A. Exposure Conditions

Animals were exposed to H-20611 at concentrations of 360, 470 or 840 mg/m³. The aerosols generated in this study were considered to be respirable in rats. The mass median aerodynamic diameters (MMAD) ranged from 2.8 to 3.6 µm. Pertinent test atmosphere characteristics and associated animal mortality are shown in the following table.

CHARACTERIZATION OF TEST ATMOSPHERES AND ASSOCIATED ANIMAL MORTALITY

Aerosol Concentration (mg/m³)[a]			Aerosol Size			
Mean	S.D.	Range	MMAD[b] (µm)	GSD[c]	Percent < 10 µm[d]	Mortality (# deaths/# exposed)
360	110	210 - 520	3.6	2.5	88	0/6
470	270	240 - 1100	3.0*	2.5*	90*	1/6
840	330	400 - 1300	2.8	2.3	93	5/6

[a] Represents the mean, standard deviation (S.D.) and range for each exposure. Based on eight samples per exposure. Values are reported to two significant figures.

[b] The MMAD (Mass Median Aerodynamic Diameter) is based on one particle size sample taken during each exposure.

[c] Geometric Standard Deviation.

[d] Percent aerosol mass having aerodynamic equivalent diameters of less than 10 µm.

* Problem with particle size sample taken during exposure; this sample was obtained after the exposure was over using the same generation parameters that were used during the exposure.

Chamber temperature ranged from 19 to 22°C, chamber relative humidity ranged from 60 to 80%, chamber airflow was 18 L/min, and the oxygen concentration was 21%. Although chamber temperature and relative humidity were outside the targeted parameters, these deviations were considered not to have adversely affected the results of this study.

B. Mortality, Clinical Signs, and Body Weights

Deaths occurred at H-20611 concentrations of 470 mg/m³ or greater. One of six rats died in the 470 mg/m³ group, and five of six rats died in the 840 mg/m³ group. Deaths occurred within eight days of exposure.

Following exposures, wh he rats were removed from their restrainers clinical signs of toxicity included ocular discharge and partially closed eyes; compound stained fur and wet faces; wet inguinal ar. perineal areas; diarrhea; lethargy or weakness; labored breathing, lung nois: and gasping.

During the recovery period, notable clinical signs of toxicity included compound-stained fur, lung noise, labored breathing, wet perineum, lethargy, gasping, colored eye discharges. partially closed eyes, cloudy eyes, and hunched posture. Less frequently observed clinical signs included diarrhea, facial hair loss, stained perineum, ruffled fur, discolored fur, and piloerection. In general, clinical signs of toxicity were observed from one to seven days after exposure.

Weight losses were observed in all groups following exposure. On test day two, weight losses ranged from 3.6 to 16% of initial body weight (except for one rat in the 360 mg/l exposure group which gained weight). One rat from the 840 mg/m³ group continued to lose weight until test day eight, at which time it had lost 42% of its original body weight. This rat was found dead on test day nine. After test day three, rats from the 360 and 470 mg/l groups that survived through the recovery period. generally displayed normal weight gains for the remainder of the recovery period. One rat in the 840 mg/m³ group lost 1 initial body weight on test day two, and then displayed no clinical signs of toxicity and only one incidence of transient weight loss throughout the remainder of the recovery period.

CONCLUSION

Under the conditions of this study, the ALC for H-20611 is 470 mg/m³. On an acute inhalation basis, aerosols of H-20611 are considered to be moderately toxic (ALC between 200 to 800 mg/m³).

REFERENCES

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