

Study Title

Subchronic Inhalation Toxicity Study with [REDACTED] in Rats

Laboratory Project ID

Haskell Laboratory Report No. 696-92

Author

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Study Completed On

December 21, 1994

Performing Laboratory

E. I. du Pont de Nemours and Company
Haskell Laboratory for Toxicology and Industrial Medicine
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Medical Research No.

[REDACTED]

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GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This study was conducted in compliance with EPA TSCA (40 CFR 792) Good Laboratory Practice Standards except for the deviation documented and explained below.

1. A characterization of the test substance was not performed prior to the initiation of the study.

The deviation did not affect the integrity of the study.

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

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

Study Director:

A. Ghantous

12, 21, 94

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GENERAL INFORMATION

Material Tested:

[REDACTED]

Medical Research No.:

[REDACTED]

Haskell No.:

17375

Physical Form:

[REDACTED]

Purity:

[REDACTED]

Composition:

[REDACTED]

GENERAL INFORMATION (continued)

Synonyms:

[REDACTED]

Other Codes:

[REDACTED]

Stability:

The test material was assumed to be stable throughout the exposure phase of the test.

Sponsor:

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

In-Life Phase

Initiated - Completed:

10/17/88 - 11/11/88

Study

Initiated - Completed:

10/7/88 - 12/21/94

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Subchronic Inhalation Toxicity Study with [REDACTED] in Rats

SUMMARY

This study was carried out to determine the toxic effects of repeated inhalation of sublethal concentrations of [REDACTED] aerosol. Three groups of ten male CrI:CD®BR rats were exposed six hours/day, five days a week for two weeks, (excluding Saturdays and Sundays) to design concentrations of 1, 5, or 10 mg/m³ of [REDACTED] aerosol in air. A control group of ten male rats was exposed simultaneously to air only. At the end of the exposure period, blood and urine samples were collected for clinical analyses, and five rats per group were sacrificed for pathological examinations. The remaining rats were retained for a 14-day post-exposure observation period and then subjected to the same clinical and pathologic examinations.

During as well as immediately following each exposure most rats including control animals exhibited nasal and/or ocular discharges. One control animal and one rat in the low-dose group exhibited ocular discharge and/or ocular opacity during the post-exposure observation period. No other clinical signs were observed in any animals during this time.

At the end of the exposure period a statistically significant decrease in mean urine volume and increase in mean urine osmolality were noted in all [REDACTED] aerosol exposed rats compared to the control rats. During this period there was also a significant decrease in the absolute lung weight of rats in the low-dose level. The clinical chemistry and organ weight differences were not dependent on [REDACTED] aerosol exposure concentration.

Under the conditions of this test the no-observed effect level (NOEL), based on clinical signs, body weight, clinical pathology, and histopathology, was 10 mg/m³ [REDACTED] aerosol.

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Subchronic Inhalation Toxicity Study with [REDACTED] in Rats

SIGNATURE PAGE

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H. Ghantous 12, 21, 94
Hanan N. Ghantous, Ph.D.
Study Director

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QUALITY ASSURANCE DOCUMENTATION

(H-17375)

Dates of Inspection:

Conduct - 10/24,27/88, 11/3,11/88

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11/17,18/92, 12/20/94

Date Findings Reported to:

Study Director - 5/5,9/89, 11/18/92, 12/21/94

Management - 5/5,9/92, 12/11/92, 12/21/94

Reported by:

James Mackay II
James Mackay II
Quality Assurance Auditor

12/21/94
Date

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INTRODUCTION

[REDACTED] Human exposure to this compound is possible through inhalation. In an acute four-hour inhalation study clinical signs observed in [REDACTED] exposed rats included nasal, ocular, and respiratory irritation.⁽¹⁾ The approximate lethal concentration (ALC) of [REDACTED] is 21 mg/m³.⁽¹⁾ To date no exposure limits for this test material have been established. The purpose of the present study was to evaluate the toxicity associated with repeated exposure to [REDACTED] aerosol in male rats.

MATERIALS AND METHODS

A. General Experimental Design

Four groups of ten male rats were used to assess the toxic effects of repeated [REDACTED] aerosol inhalation exposures on body weights, clinical signs, clinical pathologic and histopathologic parameters. Three test groups were exposed to design concentrations of 1, 5, or 10 mg/m³ of [REDACTED] aerosol in air. A control group of rats matched for age, sex, and body weight was exposed simultaneously to air only. The highest exposure concentration of [REDACTED] aerosol was selected based on the results of two rangefinding studies, where groups of male rats were exposed for several days to mean concentrations of approximately 7 or 13 mg/m³ without signs of toxicity, and consideration of an established approximate lethal concentration of 21 mg/m³. In the present study rats were exposed six hours/day, five days a week for two weeks, (excluding Saturdays and Sundays) and five animals from each exposure group were retained for a 14-day post-exposure recovery period. All rats were monitored for body weight changes and clinical signs of toxicity throughout the study.

At the end of the exposure period, blood and urine samples were collected from all rats for clinical analyses, and five rats per group were sacrificed for pathologic examination. After 14 days of recovery, the remaining rats were given similar clinical and pathologic examinations. The complete protocol and amendments to the protocol for this study are attached as Appendix A.

B. Animal Husbandry

Seven-week-old Crl:CD®BR rats (born 8-22-88) were received from Charles River Breeding Laboratories, Inc., Raleigh, North Carolina on 10/10/88. Rats were housed one per cage in 5" x 11" x 7" stainless steel, wire mesh cages suspended above cageboards. Each rat was assigned a six-digit identification number which was recorded on a card that was affixed to the cage. Rats were quarantined for six days prior to testing, and were weighed and observed three times during the quarantine period. During this time, rats were assigned to four treatment groups of ten male rats each. The rats were grouped using a computer randomization program such that there were no statistically significant differences in the groups' mean body weights prior to the start of

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the first exposure. After grouping, each rat was assigned a one- to two-digit identification number that was tattooed on the rat's tail and recorded on a card affixed to their respective cages. Upon grouping, rats were housed in pairs in 8" x 14" x 8" cages. Rats were approximately eight weeks old and weighed between 217 and 247 grams at the start of the exposures. Except during the exposures, Purina Certified Rodent Chow® #5002 and water were available ad libitum.

C. Exposure Protocol, Atmosphere Generation, and Analysis

1. Exposure Protocol

Four groups of ten male rats were individually restrained in perforated, stainless steel cylinders with nonperforated conical nose pieces. Each restrainer was inserted into a face plate on the exposure chambers such that only the nose of each rat protruded into the chamber. The exposures were conducted six hours/day, five days/week for two weeks, (excluding Saturdays and Sundays) and were followed by a 14-day recovery period. Three test groups were exposed nose-only to design concentrations of 1, 5, or 10 mg/m³ of [REDACTED] aerosol in air (groups III, V and VII, respectively). A control group was exposed to air only (group I).

2. Atmosphere Generation

Mixed aerosol/vapor atmospheres of [REDACTED] were generated with a Spraying Systems air atomizing nozzle using a high pressure air stream. The test material was metered into the spray nozzle with a Harvard model 975 compact infusion pump and atomized with high pressure air. The aerosol was passed through a one-liter glass cyclone to assist in the removal of larger non-respirable particles before being introduced to a cylindrical, glass 38-liter exposure chamber. Each chamber was fitted with a baffle to enhance aerosol dispersion. Atmospheric concentrations of [REDACTED] were controlled by regulating, (1) the delivery rate of the test material at the syringe drive (approximate range 20-200 µl/min), (2) the generation air (approximate range 5-21 L/min), and (3) the dilution air (approximate range 21-43 L/min). Exposure chamber atmospheres were exhausted through a dry ice cold trap and a MSA cartridge filter prior to discharge into a fume hood. The control group was exposed to air only (approximately 30 L/min) in an exposure system of similar design.

3. Analysis of the Test Atmospheres

Generation of [REDACTED] atmospheres by the method described above produces both an aerosol of [REDACTED] and vapors of acetone and ethylene glycol. Based on a previous inhalation study with [REDACTED] the design aerosol concentrations of 1, 5, or 10 mg/m³ would not produce toxicologically significant concentrations of vapor.⁽¹⁾ In the present study, no analysis of vapor was made. Atmospheric aerosol concentrations of [REDACTED] were determined by gravimetric analysis at approximately 30-minute intervals. At the high and intermediate design exposure levels (10 or 5 mg/m³) known volumes of chamber atmospheres were drawn through preweighed Gelman glass fiber filters. Filters were weighed on a Cahn Model 26 automatic Electrobalance®. Atmospheric concentrations of [REDACTED] were calculated from the filter

weight gain, determined from the pre- and post-sampling filter weights. A TSI Model 8510 Piezobalance® was used to monitor the low-design exposure concentration (1 mg/m³).

During each exposure, chamber temperatures were measured with mercury thermometers, relative humidities were measured with a Belfort Instrument Psychron, and chamber oxygen contents were measured with a Biosystems, Inc., Model 3100R oxygen monitor.

D. Body Weights and Clinical Observations

During the exposure period, rats were weighed and individually observed for clinical signs of toxicity before each exposure. Groups of animals were observed for clinical signs of toxicity during and immediately following each exposure. An evaluation of group acoustical response was also made during the exposures. During the recovery period, all rats were weighed and observed daily, Saturdays and Sundays excluded except when warranted by the rats' condition.

E. Clinical Pathology

Urine samples were collected overnight from all surviving rats after the ninth exposure, and from the remaining rats on the 13th day of recovery. Samples were analyzed for volume, osmolality, urobilinogen, pH, hemoglobin or occult blood, glucose, protein, bilirubin and ketone by personnel from the Clinical Pathology Section of Haskell Laboratory. The color and transparency of each sample was noted, and the sediment from each sample was examined microscopically.

A blood sample was taken from the orbital sinus of each rat after the tenth exposure, and from each remaining rat on the 14th day of recovery. Blood samples were analyzed for hemoglobin concentration, hematocrit, erythrocyte count, platelet count, leukocyte count, and relative numbers of neutrophils, band neutrophils, lymphocytes, atypical lymphocytes, eosinophils, monocytes and basophils by personnel from the Clinical Pathology Section of Haskell Laboratory. Mean corpuscular volume, mean corpuscular hemoglobin and mean corpuscular hemoglobin concentration were calculated (Wintrobe erythrocyte indices) from the erythrocyte data. Serum activities of alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase, and serum concentrations of urea nitrogen, creatinine, total protein and cholesterol were also measured.

F. Pathology

The ten rats per exposure group were each subdivided into groups of five based on computer generated random number tables. The five rats per group were sacrificed after the tenth exposure by sodium pentobarbital anesthesia and exsanguination for gross and histopathologic evaluations. On the 14th day of the post-exposure recovery period the remaining rats of each group were similarly sacrificed and evaluated. The lungs, liver, kidneys, spleen and testes were weighed at necropsy, and representative samples of the following

tissues were obtained for microscopic examination: heart, lungs, mesenteric lymph nodes, nasal cavities (nose), trachea, liver, pancreas, esophagus, stomach, duodenum, jejunum, ileum, cecum, colon, rectum, kidneys, urinary bladder, sternum (bone and marrow), spleen, thymus, thyroid gland, adrenal glands, brain, eyes, testes, epididymides, and any other organ or tissue with gross lesions.

G. Statistical Analysis

Mean body weights and body weight gains for test rats were compared to controls during the exposure and recovery periods. Data were statistically analyzed by a one-way analysis of variance. Exposure group values were compared to controls by the least significant difference test when the ratio of variance (F) indicated a significant among-to-within group variation. Significant differences were declared at the 0.05 probability level. The statistical analyses used to evaluate the clinical pathology data, mean organ weights ("absolute" weights) and mean organ-to-body weight ratios ("relative" weights) are described in Appendices E and F, respectively.

H. Records Retention

All raw data (including slides and paraffin-blocked tissues) and final reports 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 Nemours and Company, Inc., Wilmington, Delaware.

RESULTS AND DISCUSSION

A. Exposure Conditions

In the test chambers, chamber temperature ranged from approximately 20 to 24°C, relative humidity ranged from approximately 53 to 71%, and chamber oxygen content was approximately 21%. In the control chamber, chamber temperature ranged from approximately 19 to 24°C, relative humidity ranged from approximately 60 to 73%, and chamber oxygen content was approximately 21%. The mean atmospheric concentrations measured in the chambers as well as particle size characterization for each exposure concentration are presented in Tables 1 and 2, respectively. Daily atmospheric characterization data are presented in Appendix B.

B. Body Weights

The mean body weights of rats exposed to 1, 5, or 10 mg/m³ [REDACTED] aerosol were indistinguishable from control group values during the exposure and post-exposure recovery periods. One or two mean body weight gain values in the low- and high-exposure groups during the study were significantly different from control values. These differences were isolated and did not represent a toxicological response dependent on [REDACTED] aerosol concentration. Daily mean body weights and mean body weight gains are presented in Tables 3 and 4, respectively. Individual body weights are presented in Appendix C.

C. Mortality and Clinical Signs

During the first exposure to 10 mg/m³ aerosol rats were observed with clear nasal discharge. Most other study animals (including controls) exhibited red nasal discharge during exposures. No animals had a decreased acoustical response at any time evaluated.

Immediately following each exposure, most animals studied (including controls) exhibited red nasal and/or red ocular discharges. These responses were not related to the concentration of the test compound. In the post-exposure period (on median test day 16) a control animal and one rat exposed to 1 mg/m³ of [REDACTED] aerosol had left ocular discharge, and left ocular discharge and corneal opacity, respectively. The post-exposure responses were likely to be related to the orbital sinus technique used for blood sampling. A summary of observed clinical signs is presented in Table 5. Clinical signs of individual animals are in Appendix D.

D. Clinical Pathology

Clinical pathologic examination revealed several statistically significant findings, however, these physiologic changes were not dependent on exposure concentration of test material. Following the exposure period a statistically significant decrease in mean urine volume and increase in mean urine osmolality were observed in all [REDACTED] aerosol-exposed groups compared to the control mean. Such changes in clinical chemistry are normally associated with

dehydration, however, other indices of dehydration such as coincident significant increases in blood total protein, urea nitrogen, and hematocrit concentrations were not present. Significant findings were observed in mean serum cholesterol at the end of the exposure period in the high-dose group, as well as in mean blood lymphocyte and serum creatinine at the end of recovery in the intermediate- and low-dose groups, respectively. Clinical Pathology Report No. 10-89 is attached as Appendix E.

E. Pathology

No compound related effects were observed at any [REDACTED] exposure concentration tested. Absolute mean lung weight was significantly decreased at the end of the exposure period in the low-dose group compared to mean value in the control group. This finding was isolated and was probably a reflection of the lower mean body weight within the group. The decrease in lung weights did not exhibit a relevant dose-response relationship. In addition, no histopathological changes were found in the lungs. Thus, these effects were unrelated to exposure and there was no evidence of a toxic effect of [REDACTED] on lung tissue. Pathology Report No. 6-89 is attached as Appendix F.

CONCLUSIONS

The results indicated that repeated inhalation exposure to 1, 5, or 10 mg/m³ [REDACTED] aerosol had no toxicological effects in male rats. Under the conditions of this test the no-observed effect level was 10 mg/m³ [REDACTED] aerosol.

REFERENCES

1. Haskell Laboratory Report No. [REDACTED] Inhalation Approximate Lethal Concentration of [REDACTED]

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Subchronic Inhalation Toxicity Study with [REDACTED]

TABLES

Note:
Data are reported to two significant figures.

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Subchronic Inhalation Toxicity Study with [REDACTED]

TABLE 1
ATMOSPHERIC CONCENTRATIONS OF [REDACTED] AEROSOL (mg/m³)

<u>Group No.</u>	<u>Design Concentration</u>	<u>n</u>	<u>Mean</u>	<u>S.D.</u>	<u>Range</u>
I	0	-	-	-	-
III	1	720	1.3 ^a	0.87	0.0 - 5.0
V	5	120	4.8 ^b	1.5	0.10 - 8.3
VII	10	120	11 ^b	4.0	2.2 - 33

- Refers to values that were not determined.
Values shown represent the mean, standard deviation (S.D.), range, and number of measurements (n) for ten exposures at each exposure concentration.

^a Values based on Piezobalance® analyses.

^b Values based on filter weights obtained immediately after sampling and assumed to represent the amount of polymer present as an aerosol. This assumption is consistent with the method of reporting [REDACTED] aerosol exposure concentration in HLR No. [REDACTED] [REDACTED] aerosol concentration is expressed on a weight/volume basis (mg/m³).

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Subchronic Inhalation Toxicity Study with [REDACTED]

TABLE 2

PARTICLE SIZE CHARACTERIZATION OF [REDACTED] ATMOSPHERES

Design Concentration (mg/m ³)	n ^a	% Particles ^b		MMD(μ m) ^c
		< 3 μ m	< 10 μ m	
0	-	-	-	-
1	2	73	97	1.6
5	2	80	96	1.1
10	2	86	99	1.0

- Refers to values that were not determined.

^a Number of measurements that were made during the entire course of ten exposures for each concentration of aerosol.

^b Percent by weight of particles with aerodynamic diameters (AD) less than 3 μ m and less than 10 μ m. Represents the mean value from two exposures.

^c Mass median aerodynamic diameter. Represents the mean value from two exposures.

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Subchronic Inhalation Toxicity Study with [REDACTED]

TABLE 3

MEAN BODY WEIGHTS OF MALE RATS

Group:	I	III	V	VII
Design Concentration (mg/m ³):	<u>0</u>	<u>1</u>	<u>5</u>	<u>10</u>
Days On Test	<u>Body Weight (g)</u>			
<u>Exposure Period</u>				
1	233.4(8.0) ^a	232.4(9.5)	232.2(7.7)	233.0(9.0)
2	238.3(11.9)	235.2(9.9)	235.1(12.1)	235.5(14.0)
3	243.5(12.9)	242.9(9.5)	240.3(12.3)	243.4(13.8)
4	250.7(13.1)	247.9(11.7)	246.1(12.2)	250.0(13.3)
5	256.6(12.7)	256.1(11.8)	253.2(13.4)	253.7(13.3)
8	286.2(11.9)	283.2(13.4)	277.0(18.1)	282.5(16.3)
9	291.0(12.3)	286.7(12.7)	284.7(18.1)	286.8(17.6)
10	297.4(12.6)	292.5(15.4)	289.4(18.7)	291.5(17.1)
11	305.4(14.6)	295.8(14.8)	294.8(18.4)	295.8(17.1)
12	306.1(10.5)	290.5(22.3)	295.4(20.6)	299.1(17.2)
<u>Recovery Period</u>				
15	319.3(6.9)	319.2(29.8)	303.3(18.8)	317.8(23.0)
16	323.6(5.8)	325.5(25.8)	304.1(20.2)	320.8(21.6)
17	334.1(8.7)	335.1(29.1)	314.6(19.1)	331.0(23.4)
18	340.3(7.4)	339.3(32.3)	316.9(18.8)	337.3(25.6)
19	347.7(6.3)	350.9(30.5)	322.1(21.5)	345.1(23.4)
22	369.8(7.4)	370.7(31.9)	345.5(22.0)	363.9(26.8)
23	378.4(10.0)	381.4(32.6)	355.0(22.6)	374.9(28.9)
24	385.3(12.0)	388.5(35.4)	360.1(20.9)	381.9(30.1)
25	392.0(12.4)	399.0(37.3)	365.6(19.4)	385.1(28.6)
26	388.5(9.4)	388.7(28.6)	364.3(21.8)	375.1(26.0)

^a Values in parentheses are standard deviations.

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Subchronic Inhalation Toxicity Study with [REDACTED]

TABLE 4

MEAN BODY WEIGHT GAINS OF MALE RATS

Group:	I	III	V	VII
Design Concentration (mg/m ³):	<u>0</u>	<u>1</u>	<u>5</u>	<u>10</u>
Days On Test	<u>Body Weight Gain (g)</u>			
<u>Exposure Period</u>				
1 - 2	4.9(7.3) ^a	2.8(3.1)	2.9(7.2)	2.4(6.9)
2 - 3	5.2(7.0)	7.7(3.7)	5.2(3.6)	7.9(2.8)
3 - 4	7.2(3.8)	5.0(4.4)	5.7(2.6)	6.7(3.6)
4 - 5	5.9(5.3)	8.2(5.7)	7.2(3.5)	3.6(2.4)
5 - 8	29.6(2.4)	27.1(6.0)	23.8(7.1)	28.9(4.9)
8 - 9	4.8(3.3)	3.5(2.8)	7.7(4.8)	4.2(2.9)
9 - 10	6.3(4.0)	5.8(4.3)	4.7(2.5)	4.8(1.9)
10 - 11	8.1(3.9)	3.3(3.4) ^b	5.4(2.3)	4.2(2.6) ^b
11 - 12	0.7(6.8)	-5.3(12.9)	0.6(4.8)	3.3(6.6)
<u>Recovery Period</u>				
12 - 15	17.0(5.5)	26.4(4.8) ^b	17.1(3.8)	20.6(6.3)
15 - 16	4.3(3.0)	6.3(4.9)	0.8(7.7)	3.0(1.8)
16 - 17	10.4(3.8)	9.6(4.5)	10.5(3.4)	10.2(2.0)
17 - 18	6.2(3.1)	4.2(4.4)	2.3(2.3)	6.3(4.2)
18 - 19	7.5(2.2)	11.6(2.8)	5.3(4.8)	7.8(3.0)
19 - 22	22.0(4.6)	19.8(3.7)	23.3(7.6)	18.8(3.8)
22 - 23	8.7(4.5)	10.7(1.9)	9.5(5.6)	11.0(2.9)
23 - 24	6.9(3.6)	7.1(3.6)	5.1(2.9)	7.1(2.5)
24 - 25	6.7(3.7)	10.5(2.4)	5.4(2.6)	3.2(2.6)
25 - 26	-3.5(4.9)	-10.3(11.4)	-1.3(4.0)	-10.0(10.8)

^a Values in parentheses are standard deviations.

^b Significant statistical differences from control, alpha = 0.05.

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Subchronic Inhalation Toxicity Study with [REDACTED]

TABLE 5

SUMMARY OF CLINICAL OBSERVATIONS IN MALE RATS^a

Group ^b :	I	III	V	VII
Design Concentration (mg/m ³):	<u>0</u>	<u>1</u>	<u>5</u>	<u>10</u>
<u>Observation</u>	<u>Number of Rats Exhibiting Sign</u>			
Colored Discharge, Left Eye	1 (16) ^c	1 (16)	0	0
Corneal Opacity, Left Eye	0	1 (16)	0	0

^a Excluding clinical signs observed during or immediately following exposure.

^b Ten rats per group at study start

^c The number in parentheses is the median day on test the sign was first observed.

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Subchronic Inhalation Toxicity Study with [REDACTED]

APPENDIX A

Protocol and Protocol Amendments

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PROTOCOL

SUBCHRONIC INHALATION TOXICITY STUDY
WITH [REDACTED] IN RATS

STUDY

Subchronic Inhalation Toxicity Study [REDACTED]

Medical Research No. [REDACTED]
Proposed In-Life Starting Date: 10/17/88
Proposed In-Life Completion Date: 11/11/88

Haskell No. 17,375

PURPOSE

[REDACTED] is considered to be extremely toxic by inhalation with a 4-hr approximate lethal concentration of 21 mg/m³ [REDACTED]. The purpose of this study is to determine the effects of repeated exposure to sublethal concentrations of [REDACTED] by inhalation in male rats.

STUDY CONDUCT

This standard protocol and the Acute and Developmental Toxicology Division's SOP's constitute the protocol for this study. Except as documented in the Acute and Developmental Toxicology Division's SOP's and study records, this study will be conducted according to the U.S. Environmental Protection Agency Good Laboratory Practice Standards (40 CFR Part 792).

TEST FACILITY

This study will be conducted at Haskell Laboratory for Toxicology and Industrial Medicine, E. I. du Pont de Nemours and Company, Inc., P. O. Box 50, Elkton Road, Newark, Delaware 19714.

SPONSOR

The sponsor of this test is the Chemicals and Pigments Department of the Du Pont Company. The address of the sponsor is the corporate headquarters of E. I. du Pont de Nemours and Company, Inc., Wilmington, Delaware. The sponsor's approval of the test protocol is indicated by the sponsor's signature on the Medical Research Project proposal which authorizes the conduct of the test. The date of the sponsor's approval is the date the sponsor authorized the test.

ROUTE OF ADMINISTRATION

Animals will be exposed to the test material by inhalation. The inhalation route is specified by the sponsor of the test. Generally, the inhalation route is chosen based on the potential for human exposure to the test material by inhalation, or because inhalation testing is specified by the appropriate regulatory agency(s).

DURATION OF THE STUDY

The starting date of the study will be defined as the day that study animals are first exposed to the test material. The completion date of the in-life portion of the study will be defined as the last day of the recovery period. The completion date of the entire study will be defined as the date the final report is issued.

TEST MATERIAL

Identification

The test material is [REDACTED]

[REDACTED] Information on the purity, composition, contaminants, synonyms, departmental codes, CAS registry number, basic physical properties, unusual hazards, and hazardous material classification(s) are provided by the sponsor on the Haskell Laboratory Sample Evaluation form. The original form will be retained in the official Medical Research file for the study in Haskell's Information Section. A copy of the form will be included in the study records.

Stability

Unless otherwise indicated on the Sample Evaluation form and in the absence of visible or analytical evidence to the contrary, the test material will be assumed to be stable under the conditions of this test.

Degree of Absorption

For the purpose of this test, it will be assumed that all of the test material that is inhaled will be absorbed. No attempt will be made to establish the actual dose each rat received. All toxic effects will be reported as a function of the exposure concentrations rather than as a function of dose.

TEST SYSTEM AND HUSBANDRY

Species/Strain	Cr1:CD®BR rats
Sex	Male
Source	Charles River Breeding Laboratories, Raleigh, North Carolina
Age	Approximately 8 weeks old at the start of exposures
Weight Range	Approximately 210 to 250 grams
Number per Group	10

Justification of Test System

Rats have historically been used in safety evaluation studies, and their use is specified by the appropriate regulatory agency(s). This strain of rats has been well characterized in this laboratory.

Quarantine and Stock

Rats will be quarantined for a minimum of 6 days prior to testing. Rats will be weighed and observed at least twice during the quarantine period. In the absence of clinical signs to the contrary, rats are assumed to be free of any disease or condition that may interfere with the purpose of this study.

Selection of Animals

To group the rats, the total number of rats to be used on the test plus a few extra rats will be arbitrarily assigned to a pretest group. Any rat that

has been gaining weight at a normal rate and has no overt signs of disease is acceptable for testing. The rat(s) with the lowest and highest body weights will be culled from the sample. The remaining rats will be divided into groups by computer randomization such that the pretest mean body weights of all groups are similar ($p > 0.05$). Rats will be grouped based on their body weights days prior to the first exposure. Rats will be selected for sacrifice based on random number tables.

Control of Bias

To control bias, rats will be randomly assigned to control and treatment groups. No significant differences between test groups that may affect the outcome of this study are expected. In the absence of evidence to the contrary, toxic effects following inhalation of the test material will be interpreted as being the result of exposure to the test material.

Identification

Each rat will be assigned a unique 6-digit identification number which is recorded on a card affixed to the cage. Upon grouping, each rat will be assigned a 1-3 digit identification number that will be tattooed on the rat's tail and recorded on the cage card. Tattoo numbers and corresponding 6-digit numbers will be recorded in the study records. Prior to exposure, rats' tails and cage cards may be color-coded with water-insoluble markers to identify the exposure group to which each rat belongs.

Housing Environment

Except as restricted by facility design, animal rooms will be maintained at approximately $50 \pm 10\%$ relative humidity and $23 \pm 2^\circ\text{C}$ on a 12 hour/12 hour light/dark cycle. Unless judged by the study director or the site veterinarian to have significantly affected the results of a study, the actual relative humidity and temperature ranges incurred will be recorded but will not be included in the final report. Except during exposures, rats will be housed in suspended, stainless steel, wire-mesh cages. Rats will be housed either singly in 5" x 11" x 7" cages, or singly or in pairs in 8" x 14" x 8" cages. Except during exposures, Purina Certified Rodent Chow® #5002 and tap water from the Wilmington Suburban Water Corporation (WSWC) will be available ad libitum.

Food Contaminants

The potential effects of dietary contaminants have been considered and, on the basis of the manufacturer's data, contaminant levels are believed to be within acceptable ranges. To supplement these data, feed is periodically analyzed for selected heavy metals, pesticides, and nitrosamines. Records of the results of these analyses are maintained by the site veterinarian. No other contaminants reasonably anticipated to be present in the feed are expected to interfere with the results of this study.

Water Contaminants

The potential effects of water contaminants reported by WSWC have been considered and appear to be within acceptable ranges. To supplement these data, laboratory water is periodically monitored for selected microorganisms, pesticides, heavy metals and halogens reasonably anticipated to be present in the water supply. Records of the results of these analyses are maintained by the site veterinarian and the Quality Assurance Section.

STUDY DESIGN

General Study Design

Four groups of 10 male rats will be exposed to the test material by inhalation 6 hours/day, 5 days/week for 2 weeks. The exposure period will be followed by a 14-day recovery period. Three test groups will be exposed to design concentrations of 0.5, 1.5 or 5 mg/m³ [REDACTED] in air. A procedural control group will be exposed to air only. Rats will be weighed and observed throughout the exposure and recovery periods. At the end of the exposure period, blood and urine samples will be collected from 10 rats per group for clinical analysis, and 5 rats per group will be killed for pathologic examination. After the 14-day recovery period, the remaining rats will be subjected to the same clinical and pathological examinations. Any variations in this study design will be documented in the study records and in a protocol amendment.

Exposure Concentrations

Three exposure concentrations (targeted at 0.5, 1.5 or 5 mg/m³ [REDACTED]) and an air control will be tested during this study. Ideally, 1 exposure concentration will cause no adverse effects, 1 concentration will cause marginal effects, and 1 concentration will severely stress the rats without causing death. However, the preliminary design concentrations may be refined after observing the effects of repeated-dose rangefinding.

Control Group(s)

An air-exposed control group will be subjected to the same experimental conditions and evaluation(s) as the test groups.

Rangefinding

Preliminary rangefinding exposures will be conducted before the initiation of the study. Rangefinding trials at the planned exposure concentrations will be conducted without rats to establish the generation parameters needed to

achieve the desired atmospheric concentrations. In addition, rangefinding exposures may be conducted with rats at the high-level exposure concentration to help predict whether 10 exposures to the design concentration will cause adverse effects without killing the rats. The estimates of potential effects will be based mainly on body weights changes. Based on the results of the rangefinding exposures, the selected exposure concentrations may be adjusted accordingly. The results of the rangefinding exposures will be included in the study records, but will ordinarily not be included in the final report.

Exposure Mode

Rats will be individually restrained in a perforated, stainless steel cylinders with conical, nonperforated nose pieces and exposed nose-only. Each restrainer will be inserted into a face plate attached to a 38 liter glass cylindrical exposure chamber such that only the nose of each rat protrudes into the chamber.

Duration of Exposure

Each group of rats will be exposed 6 hours/day, 5 days/week for 2 weeks to an atmosphere of the test material in air. The starting time of each exposure will be defined as the time when the generation system is turned on. The ending time of each exposure will be defined as the time when the generator is turned off. Rats will be exposed to the test material during both the time it takes for the chamber to reach concentration, and the time it takes for the chamber to blow down. After each exposure, the rats will be returned to their cages. The exposure period will be defined as the period between initiation of the first exposure and completion of the 10th exposure. The recovery period will be defined as the period between completion of the 10th exposure and euthanasia of the last rat.

Viability Checks

Each rat will be weighed and observed daily prior to exposures. Unless restricted by the physical characteristics of the test atmospheres or exposure systems, observations of group clinical signs will be taken during each exposure. After each exposure, rats will be observed for clinical signs before they are returned to their cages. During the recovery period, remaining rats will be weighed and observed daily, weekends and holidays excluded unless warranted by the rats' condition.

Endpoints

The primary end points in this study include body weights, clinical observations, organ weights, gross and microscopic pathological changes, and

changes in clinical chemical, hematologic, and urinalysis parameters in the test rats as compared to controls. Additional endpoints may be added at the request of the sponsor or at the discretion of the study director, and will be documented in the study records.

Collection of Specimens

Urine samples will be collected overnight from 10 rats per group after the 9th exposure, and from 5 rats per group on the 13th day of recovery. Each urine sample will be labeled with the rat number from which the specimen was collected. Each sample will be analyzed by personnel of the Clinical Pathology Section of Haskell Laboratory for volume, osmolality, urobilinogen, pH, blood, sugar, protein, bilirubin and ketone. The color and transparency of each specimen will be noted, and the sediment from each sample will be examined microscopically. Additional analyses may be performed at the discretion of the study director or the Clinical Pathology staff, and will be documented in the Clinical Pathology report or in the study records.

Carbon dioxide will be used to lightly anesthetize each rat prior to blood sampling. Blood samples will be collected from the orbital sinus of 10 rats per group after the 10th exposure and from 5 rats per group on the 14th day of recovery. Samples will be analyzed by the Clinical Pathology staff for erythrocyte count, hemoglobin concentration, hematocrit, platelet count, leukocyte count, and relative numbers of neutrophils, band neutrophils, lymphocytes, atypical lymphocytes, eosinophils, monocytes and basophils. Mean corpuscular volume, mean corpuscular hemoglobin and mean corpuscular hemoglobin concentration will be calculated from the erythrocyte data. Serum activities of alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase, and serum concentrations of urea nitrogen, creatinine, total protein and cholesterol will be measured. Additional analyses may be performed at the discretion of the study director or the Clinical Pathology staff, and will be documented in the Clinical Pathology report or in the study records. The procedures and methods for analyzing samples are documented in the Clinical Pathology Section's SOP's.

Post Mortem Observations

Five rats per group will be killed after the 10th exposure, and 5 rats per group will be killed on the 14th day of recovery for gross and histopathologic examination. Rats will be killed by pentobarbital anesthesia and exsanguination by the Pathology staff of Haskell Laboratory. The lungs, liver, kidneys, spleen and testes will be weighed at necropsy. Each rat will be given a complete gross examination, and the following organs and tissues will be examined microscopically: liver, kidneys, urinary bladder, heart, lungs, nasal cavities, pancreas, thymus, spleen, adrenal glands, thyroid gland, mesenteric lymph nodes, trachea, esophagus, stomach, duodenum, jejunum,

ileum, cecum, colon, rectum, sternum, bone marrow, testes, epididymides, brain and eyes. Additional organs and tissues may be examined at the discretion of the study director or the Pathology staff, and will be documented in the Pathology report or in the study records. All remaining organs and tissues will be incinerated. The procedures and methods for analyzing organs and tissues are documented in the Pathology Section's SOP's.

Statistical Analyses

Mean body weights for test rats will be compared to controls during the exposure and recovery periods. Data will be statistically analyzed by one-way analysis of variance. Test rats will be compared with controls by least significant difference test when the ratio of variance (F) indicates a significant among-to-within group variation. Significance will be judged at the 0.05 probability level. Any additional statistical comparisons will be documented in the study records.

Statistical analyses of clinical pathology and organ weight data will be conducted by the appropriate personnel; the methods used will be documented in the Clinical Pathology and Pathology supplementary reports, respectively.

ADMINISTRATION OF THE TEST MATERIAL

Atmosphere Generation

Attempts will be made to generate respirable atmospheres of the test material which approximate the physical form of the test material expected to be encountered in human exposure situations. Test atmospheres will be generated dynamically using airflows needed to achieve at least 10 air changes per hour. Attempts will also be made to evenly distribute the test material throughout the exposure chamber.

For [REDACTED] attempts will be made to generate particles of respirable size. Ideally, at least 90% of the test atmosphere will be composed of particles smaller than 10 μ m aerodynamic diameter, with a mass median aerodynamic diameter of less than 3 μ m. If the ideal particle size cannot be attained, the most respirable atmosphere practically attainable will be tested. The general principles of generation and safety procedures are documented in the Acute and Developmental Toxicology Division's SOP's. Actual generation equipment and conditions will be documented in the study records.

Chamber Conditions

Ideally, the chamber conditions will be similar to housing conditions (i.e., temperature of $23 \pm 2^\circ\text{C}$, relative humidity of 40-60%). However, temperature and humidity variations outside of these ranges are commonly encountered due to the generation procedures used and the characteristics of

the test material itself. These variations are not expected to significantly affect the results of this type of study. The minimum acceptable chamber oxygen concentration will be 19%.

Analyses of the Test Atmosphere

A suitable analytical method will be approved by the study director to monitor the atmospheric concentrations of the test material in the breathing zone of the animals within the exposure chamber. The primary method for determining the atmospheric concentration of [REDACTED] will be gravimetric analysis. Unless prohibited by the nature of the test material, the chamber temperatures, relative humidities and chamber oxygen contents will be monitored. The general principles of monitoring chamber atmospheres are documented in the Acute and Developmental Toxicology Division's SOP's. Details of the analytical method(s) used will be documented in the study records.

Frequency of Measurements

The atmospheric concentration of the test material in the breathing zone of the animals will be determined daily by gravimetric analysis at approximately 30-minute intervals for each exposure chamber, when possible. More or less frequent samples may be taken at the discretion of the study director. The chamber airflow will be recorded at the start of exposure and any time an adjustment in airflow is made. When possible, chamber temperatures, relative humidities and oxygen concentrations will be monitored at least once per exposure per chamber. Samples for particle size analysis will be collected at least once during the study for each exposure chamber. The actual frequency of measurements will be recorded in the study records.

DISPOSAL OF WASTE MATERIALS

Unless otherwise indicated in the study records, waste materials will be packaged with absorbent material in polyethylene-lined fiberpacs and incinerated.

RECORDS RETENTION

All raw data (including slides and paraffin-blocked tissues) and final reports 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, Inc., Wilmington, Delaware.

FINAL REPORT

A final report will be written which includes, but is not limited to, the items cited in CFR 40, Part 792, Subpart J, Section 792.185.

CHANGES IN PROTOCOL

Changes in protocol will be documented in protocol amendments signed by the Study Director.

Prepared by:

Dolores E. Malek 10/7/88

Dolores E. Malek, Ph.D.
Study Director

Approved by:

Nancy C. Chromey 10/7/88

Nancy C. Chromey, Ph.D.
Manager

Acute and Developmental Toxicology Division

CENTRAL RESEARCH AND DEVELOPMENT DEPARTMENT
HASKELL LABORATORY FOR TOXICOLOGY
AND INDUSTRIAL MEDICINE

cc: Quality Assurance

May 19, 1989

TO: MEDICAL RESEARCH PROJECT NO. [REDACTED]
FROM: DOLORES E. MALEK

PROTOCOL AMENDMENT #1

TWO WEEK SUBCHRONIC INHALATION TOXICITY STUDY OF [REDACTED]

Haskell Laboratory No. 17375

Medical Research No. [REDACTED]

1. Design Concentration of [REDACTED] has been changed:

Protocol - 0.5, 1.5 and 5 mg/m³
Study - 1, 5, 10 mg/m³

2. Time when the test animals were grouped has been changed:

Protocol - states that rats will be "grouped" based on their body weights days prior to the first exposure.
Study - rats were "grouped" based on their body weights the morning of (within a few hours) the first exposure.

Prepared by:

Dolores E. Malek

5/19/89

Dolores E. Malek, Ph.D.

Study Director

Research Toxicologist

Acute and Developmental Toxicology Division

Company Sanitization and Environmental TSCA CS

CENTRAL RESEARCH AND DEVELOPMENT DEPARTMENT
HASKELL LABORATORY FOR TOXICOLOGY
AND INDUSTRIAL MEDICINE

cc: Quality Assurance

June 12, 1989

TO: MEDICAL RESEARCH PROJECT NO. [REDACTED]
FROM: DOLORES E. MALEK

PROTOCOL AMENDMENT #2

TWO-WEEK INHALATION TOXICITY STUDY WITH [REDACTED] IN RATS

Haskell Laboratory No. 17375

Medical Research No. [REDACTED]

The title of the study has been changed from "Subchronic Inhalation Toxicity Study with [REDACTED] in Rats" to "Two-Week Inhalation Toxicity Study with [REDACTED] in Rats".

Prepared by:

Dolores E. Malek

06 /12/ 89

Dolores E. Malek, Ph.D.

Study Director

Research Toxicologist

Acute and Developmental Toxicology Division

PROTOCOL AMENDMENT #3

MR Number: [REDACTED] Study Code: [REDACTED] Haskell Number: 17,375

Descriptive Title of Study: Two-Week Inhalation Toxicity Study with [REDACTED]
in Rats

Compound Name: [REDACTED]

As of 02/05/91, Judith C. Stadler will replace Dolores E. Malek as study director for the purpose of completion and issuance of the final report.

Judith C. Stadler 2/5/91
Judith C. Stadler, Ph.D.
Senior Research Toxicologist
Acute Toxicology

Dolores E. Malek 2/5/91
Dolores E. Malek, Ph.D.
Research Toxicologist
Acute Toxicology

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CENTRAL RESEARCH AND DEVELOPMENT DEPARTMENT
HASKELL LABORATORY FOR TOXICOLOGY
AND INDUSTRIAL MEDICINE

cc: Quality Assurance

November 11, 1992

TO: MEDICAL RESEARCH PROJECT NO. [REDACTED]

PROTOCOL AMENDMENT #3

Descriptive Title of Study: Two-Week Inhalation Toxicity Study with [REDACTED]
in Rats

Test Substance Name: [REDACTED]

The Study Protocol, issued 10-07-88, is amended as follows:

Prepared By:

Presently Reads:

"Dolores E. Malek, Ph.D.
Study Director"

Amend to Read:

"Hanan N. Ghanous, Ph.D
Study Director"

Prepared by:

Maryanne M. Wilford

Maryanne M. Wilford
Toxicology Associate

Approved by:

Hanan N. Ghanous

Hanan Ghanous
Study Director

11/11/92

CENTRAL RESEARCH AND DEVELOPMENT DEPARTMENT
HASKELL LABORATORY FOR TOXICOLOGY
AND INDUSTRIAL MEDICINE

cc: Quality Assurance

December 11, 1992

TO: MEDICAL RESEARCH PROJECT NO. [REDACTED]

PROTOCOL AMENDMENT #5

Descriptive Title of Study: Two-Week Inhalation Toxicity Study with [REDACTED]

Test Substance Name: [REDACTED]

The Study Protocol Ammendment, issued 11-11-92, is amended as follows:

Title:

Presently Reads:
"PROTOCOL AMENDMENT #3"

Amend to Read:
"PROTOCOL AMENDMENT #4"

Amendment:

Presently Reads:
"Prepared By:

Presently Reads:
Dolores E. Malek, Ph.D.
Study Director

Amend to Read:
Hanan N. Gbantous, Ph.D
Study Director"

Amend to Read:

"As of June 1, 1992, Hanan N. Gbantous will replace Judith C. Stadler as study director for this study."

Prepared by: Maryanne M. Wilford
Maryanne M. Wilford
Toxicology Associate

Approved by: H. Gbantous
Hanan Gbantous
Study Director

12/11/92

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CENTRAL RESEARCH AND DEVELOPMENT DEPARTMENT
HASKELL LABORATORY FOR TOXICOLOGY
AND INDUSTRIAL MEDICINE

TO: MEDICAL RESEARCH PROJECT NO. ([REDACTED])

PROTOCOL AMENDMENT #6

1. Protocol Amendment #2 is amended as follows:

The title of the study is changed from "Two-Week Inhalation Toxicology Study with [REDACTED] in Rats" to "Subchronic Inhalation Toxicology Study with [REDACTED] in Rats".

The titles on all study protocol amendments are amended to reflect this change.

2. The study protocol is amended as follows:

Page 5, Water Contaminants, sentence 3 is amended to read "Records of the results of these analyses are maintained by the site veterinarian."

Approved by:

H. Ghantous

Hanan Ghantous
Study Director

Date

12/21/94

Subchronic Inhalation Toxicity Study with [REDACTED]

APPENDIX B

Daily Atmospheric Analyses

Note:

Data are reported to two significant figures.

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Subchronic Inhalation Toxicity Study with [REDACTED]

Appendix B

Daily Atmospheric Analyses

Control: 0 mg/m³

Exposure No.	Concentration (mg/m ³) [REDACTED]			Chamber ^a Temp. (°C)	Relative ^b Humidity (%)	Oxygen ^c Content (%)
	Mean	S.D.	Range			
1	-	-	-	20 - 24	63	21
2	-	-	-	20 - 23	60	21
3	-	-	-	20 - 24	68	21
4	-	-	-	19 - 23	73	21
5	-	-	-	20 - 23	63	21
6	-	-	-	20 - 24	64	21
7	-	-	-	19 - 23	69	21
8	-	-	-	19 - 23	65	21
9	-	-	-	19 - 22	67	21
10	-	-	-	20 - 22	68	21

Design Concentration: 1 mg/m³

Exposure No.	Concentration (mg/m ³) [REDACTED]			Chamber ^a Temp. (°C)	Relative ^b Humidity (%)	Oxygen ^c Content (%)
	Mean	S.D.	Range			
1	0.92	0.46	0.25 - 3.6	22 - 23	61	21
2	1.3	0.93	0.05 - 4.2	22 - 24	62	21
3	1.3	1.3	0.0 - 4.6	22 - 23	61	21
4	0.69	0.27	0.25 - 1.6	20 - 23	64	21
5	0.96	0.19	0.50 - 1.5	21 - 24	55	21
6	1.7	1.0	0.15 - 3.8	22 - 24	58	21
7	1.4	1.1	0.0 - 5.0	21 - 22	61	21
8	1.3	0.84	0.0 - 3.7	21 - 22	58	21
9	1.5	0.39	0.65 - 2.2	20 - 22	62	21
10	1.5	0.95	0.10 - 3.8	20 - 22	58	21

- Refers to values that were not determined.

^a Range of two measurements per exposure.^b One measurement per exposure.^c One measurement per exposure.^d Mean of 72 measurements per exposure.

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Subchronic Inhalation Toxicity Study with [REDACTED]

Appendix B (continued)Daily Atmospheric AnalysesDesign Concentration: 5 mg/m³

Exposure No.	[REDACTED] Concentration (mg/m ³)			Chamber ^b Temp. (°C)	Relative ^c Humidity (%)	Oxygen ^d Content (%)
	Mean	S.D.	Range			
1	4.6	0.67	3.3 - 5.4	22 - 23	63	21
2	5.6	1.6	2.6 - 7.8	21 - 23	61	21
3	3.7	2.5	0.10 - 8.1	21 - 23	56	21
4	4.1	1.3	1.5 - 5.7	20 - 22	69	21
5	5.2	1.7	2.6 - 8.3	20 - 22	53	21
6	4.6	1.0	3.1 - 7.3	20 - 24	56	21
7	4.7	0.97	2.3 - 5.9	20 - 22	65	21
8	6.2	1.2	4.0 - 8.0	20 - 22	58	21
9	4.8	1.5	3.1 - 7.6	20 - 22	62	21
10	4.5	1.0	3.0 - 6.6	20 - 22	60	21

Design Concentration: 10 mg/m³

Exposure No.	[REDACTED] Concentration (mg/m ³)			Chamber ^b Temp. (°C)	Relative ^c Humidity (%)	Oxygen ^d Content (%)
	Mean	S.D.	Range			
1	9.5	1.5	6.0 - 11	22 - 24	69	21
2	8.7	2.9	2.2 - 14	22 - 24	71	21
3	11	3.2	5.2 - 16	22 - 24	54	21
4	11	2.1	7.8 - 15	21 - 23	62	21
5	13	5.7	8.7 - 27	22 - 23	53	21
6	9.3	0.84	8.4 - 11	22 - 24	58	21
7	12	1.0	10 - 13	21 - 24	61	21
8	13	1.4	11 - 16	21 - 23	58	21
9	17	6.9	6.2 - 33	20 - 23	62	21
10	9.1	1.7	4.4 - 11	20 - 23	58	21

^a Mean of 12 measurements per exposure.^b Range of two measurements per exposure.^c One measurement per exposure.^d One measurement per exposure.

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Subchronic Inhalation Toxicity Study with [REDACTED]

APPENDIX C

Individual Body Weights of Male Rats

Note:

All weights are reported in grams.

SD = Rats sacrificed after the tenth exposure for pathological examination.

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Subchronic Inhalation Toxicity Study with [REDACTED]

Appendix CIndividual Body Weights of Control Male RatsGroup I

<u>Rat No.</u>	<u>Days on Test</u>							
	1	2	3	4	5	8	9	10
447112	231.9	235.1	222.2	228.2	245.1	276.9	278.0	281.7
447113	237.2	234.3	242.2	241.0	247.1	275.8	276.9	284.9
447114	245.3	259.8	268.0	277.0	284.4	311.3	314.1	324.9
447115	226.9	220.9	232.2	244.2	248.4	277.5	287.8	293.9
447116	228.2	233.6	239.4	248.7	254.1	283.3	284.7	292.5
447117	235.9	244.0	248.1	257.0	259.9	292.2	297.6	303.2
447118	244.1	256.6	259.0	262.8	273.5	301.4	308.2	309.9
447119	218.9	231.9	239.9	246.1	251.0	284.7	292.4	291.4
447120	229.8	234.3	239.6	249.7	253.6	280.1	288.0	297.1
447121	236.2	232.5	244.4	252.5	249.2	279.0	282.6	294.1

<u>Rat No.</u>	<u>Days on Test</u>							
	11	12	15	16	17	18	19	22
447112	289.4	299.4	307.6	314.0	319.1	329.5	337.4	357.8
447113	294.0	304.9	322.7	325.3	338.1	342.8	348.9	371.1
447114	337.2	329.3	SD (day 12)					
447115	296.4	303.3	324.8	324.8	339.8	345.8	351.8	376.9
447116	293.0	296.6	SD (day 12)					
447117	313.0	312.5	SD (day 12)					
447118	319.4	315.1	SD (day 12)					
447119	303.3	297.1	318.7	324.2	333.7	336.0	347.1	374.2
447120	308.2	306.6	322.7	329.9	339.6	347.3	353.5	368.8
447121	300.2	296.2	SD (day 12)					

Company Sanitized. Does not contain TSCA CBI

Subchronic Inhalation Toxicity Study with [REDACTED]

Appendix C (continued)Individual Body Weights of Control Male RatsGroup I (continued)

Rat No.	<u>Days on Test</u>			
	23	24	25	26
447112	364.1	369.0	373.7	378.1
447113	376.3	377.9	386.1	382.2
447114				
447115	392.1	399.8	403.7	400.0
447116				
447117				
447118				
447119	379.3	389.3	401.9	396.7
447120	380.4	390.5	394.7	385.6
447121				

Company Sanitized. Does not contain TSCA CB

Subchronic Inhalation Toxicity Study with [REDACTED]

Appendix C (continued)Individual Body Weights of Male Rats
Exposed to 1 mg/m³ [REDACTED]Group III

<u>Rat No.</u>	<u>Days on Test</u>							
	1	2	3	4	5	8	9	10
447122	240.6	243.4	249.8	250.6	260.3	285.3	290.9	289.9
447123	221.1	228.3	239.0	245.0	248.6	279.4	281.5	284.4
447124	229.4	234.9	243.7	250.6	250.4	284.2	288.3	294.2
447125	236.6	237.8	241.2	248.2	254.2	282.5	284.4	286.2
447126	241.2	242.0	248.5	251.5	269.1	286.4	283.5	288.6
447127	217.0	221.0	230.6	235.0	245.0	265.6	272.5	278.7
447128	232.7	231.8	232.0	234.5	247.7	278.0	284.0	291.5
447129	233.8	236.1	247.2	245.5	259.4	280.3	283.9	294.1
447130	247.1	253.9	261.8	276.2	281.3	316.8	319.9	334.0
447131	224.7	223.1	235.1	241.9	244.6	273.2	277.7	283.0

<u>Rat No.</u>	<u>Days on Test</u>							
	11	12	15	16	17	18	19	22
447122	296.8	270.3	SD (day 12)					
447123	288.8	280.7	SD (day 12)					
447124	302.5	305.8	325.4	328.4	340.4	340.4	354.2	373.0
447125	291.2	295.9	SD (day 12)					
447126	292.2	292.3	315.6	321.5	330.3	336.5	349.3	363.3
447127	282.1	265.7	294.5	308.0	310.5	314.5	328.5	349.1
447128	289.3	297.9	SD (day 12)					
447129	292.6	296.6	SD (day 12)					
447130	335.0	337.4	366.6	367.6	382.0	392.5	400.0	423.9
447131	287.3	262.5	293.7	301.8	312.3	312.5	322.6	344.1

^a Design concentration.

Subchronic Inhalation Toxicity Study with [REDACTED]

Appendix C (continued)Individual Body Weights of Male Rats
Exposed to 1 mg/m³ [REDACTED]Group III (continued)

Rat No.	<u>Days on Test</u>			
	23	24	25	26
447122				
447123				
447124	383.3	388.6	401.3	398.7
447125				
447126	376.7	382.9	391.6	384.3
447127	357.3	366.0	373.9	360.8
447128				
447129				
447130	435.3	447.8	461.2	432.5
447131	354.4	357.4	367.2	367.3

^a Design concentration.

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Subchronic Inhalation Toxicity Study with [REDACTED]

Appendix C (continued)Individual Body Weights of Male Rats
Exposed to 5 mg/m³ [REDACTED]Group V

<u>Rat No.</u>	<u>Days on Test</u>							
	1	2	3	4	5	8	9	10
447132	229.1	242.1	248.2	253.8	263.2	289.8	302.3	303.0
447133	235.9	247.2	251.0	253.1	264.5	280.7	291.0	296.3
447134	240.5	249.7	259.4	264.5	274.1	312.4	314.7	319.4
447135	218.1	215.6	219.0	227.1	230.7	251.7	259.9	263.8
447136	232.9	237.8	235.2	237.3	243.9	262.8	268.9	270.1
447137	235.3	230.8	238.3	245.7	256.3	283.0	290.2	296.0
447138	242.1	244.9	248.4	254.3	255.1	287.0	288.1	294.1
447139	221.3	220.9	226.9	231.3	237.2	259.1	261.0	265.8
447140	231.2	221.6	231.6	237.4	246.9	262.8	274.5	279.4
447141	235.5	240.5	245.2	256.0	260.3	281.1	296.3	306.0

<u>Rat No.</u>	<u>Days on Test</u>							
	11	12	15	16	17	18	19	22
447132	307.7	310.5	SD (day 12)					
447133	302.0	305.0	316.6	320.9	328.0	331.4	341.4	353.1
447134	327.6	326.3	SD (day 12)					
447135	270.0	267.9	288.1	277.3	292.3	297.7	303.9	326.4
447136	277.1	282.8	300.5	302.0	309.6	311.5	309.1	338.8
447137	300.3	306.9	327.9	326.8	339.7	341.3	349.5	380.1
447138	299.4	299.8	SD (day 12)					
447139	274.6	268.3	283.5	293.5	303.2	302.4	306.8	328.9
447140	281.4	274.1	SD (day 12)					
447141	308.1	312.8	SD (day 12)					

^a Design concentration.

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Subchronic Inhalation Toxicity Study with [REDACTED]

Appendix C (continued)Individual Body Weights of Male Rats
Exposed to 5 mg/m³ [REDACTED]^aGroup V (continued)

<u>Rat No.</u>	<u>Days on Test</u>			
	23	24	25	26
447132				
447133	366.7	367.1	370.6	370.0
447134				
447135	330.7	337.3	344.1	343.7
447136	343.5	351.3	360.6	353.1
447137	388.1	392.5	395.8	399.4
447138				
447139	346.0	352.5	356.7	355.2
447140				
447141				

^a Design concentration.

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Subchronic Inhalation Toxicity Study with [REDACTED]

Appendix C (continued)Individual Body Weights of Male Rats
Exposed to 10 mg/m³ [REDACTED]Group VII

<u>Rat No.</u>	<u>Days on Test</u>							
	1	2	3	4	5	8	9	10
447142	243.5	256.1	262.9	265.7	270.1	303.6	313.0	314.5
447143	224.5	214.0	226.3	231.1	237.3	255.5	260.5	265.6
447144	230.1	233.7	238.4	251.2	252.7	287.8	295.1	297.6
447145	238.9	248.4	253.0	265.3	265.7	296.2	301.6	306.3
447146	240.9	241.2	250.3	255.7	263.7	296.4	298.5	305.1
447147	224.7	227.3	234.5	242.3	247.3	272.7	274.7	282.5
447148	231.7	230.3	240.5	247.4	250.5	277.7	277.9	283.1
447149	236.2	232.8	242.7	249.4	253.3	283.7	285.1	291.0
447150	243.0	252.4	262.4	263.8	266.7	293.2	299.0	304.4
447151	216.9	218.5	222.6	228.5	229.2	258.5	262.1	265.3

<u>Rat No.</u>	<u>Days on Test</u>							
	11	12	15	16	17	18	19	22
447142	321.3	319.4	345.0	347.2	359.1	366.0	370.8	391.6
447143	273.8	273.6	287.8	293.5	302.5	308.6	316.3	330.9
447144	302.2	295.7	SD (DAY 12)					
447145	307.6	318.6	SD (DAY 12)					
447146	311.6	307.7	336.3	338.0	350.7	362.7	367.5	391.0
447147	289.3	294.8	SD (DAY 12)					
447148	285.3	291.5	310.5	312.1	320.0	326.4	337.5	357.3
447149	292.6	293.8	309.2	313.1	322.6	322.8	333.3	348.7
447150	306.4	320.5	SD (DAY 12)					
447151	267.5	274.9	SD (DAY 12)					

^a Design concentration.

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Subchronic Inhalation Toxicity Study with [REDACTED]

Appendix C (continued)Individual Body Weights of Male Rats
Exposed to 10 mg/m³ [REDACTED]Group VII (continued).

<u>Rat No.</u>	<u>Days on Test</u>			
	23	24	25	26
447142	407.1	412.9	412.2	397.8
447143	341.0	345.5	348.6	333.2
447144				
447145				
447146	402.9	412.8	415.3	392.6
447147				
447148	365.1	374.6	380.7	383.9
447149	358.3	363.9	368.8	368.1
447150				
447151				

^a Design concentration.

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Subchronic Inhalation Toxicity Study with [REDACTED]

APPENDIX D

Individual Clinical Observations of Male Rats

Note:

NR = Not Recovered. Rat exhibited given sign at last weighing.
Clinical observations do not include signs observed during or immediately following exposure.

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Subchronic Inhalation Toxicity Study with [REDACTED]

Appendix DIndividual Clinical Observations of Male Rats

<u>Rat No.</u>	<u>Observation</u>	<u>Day First Observed</u>	<u>Day Last Observed</u>
<u>Control</u>			
447112	Slight red discharge, left eye	16	23

Design concentration: 1 mg/m³

447131	Slight black discharge, left eye	16	22
	Corneal opacity, left Eye	16	16

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Subchronic Inhalation Toxicity Study with [REDACTED]

APPENDIX E

Clinical Pathology Report No. 10-89

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CLINICAL PATHOLOGY REPORT NO. 10-89

SUBCHRONIC INHALATION TOXICITY STUDY
WITH [REDACTED] IN RATS

MEDICAL RESEARCH PROJECT NO. [REDACTED] HASKELL LABORATORY NO. 17375

Sponsor: DuPont Specialty Chemicals

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SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED] IN RATS

Summary

Male Crl:CD\BR rats were exposed by inhalation to [REDACTED] at design concentrations of 0 (control) 1, 5, or 10 mg/m³ six hours per day for ten days.

There were no biologically significant clinical laboratory findings which were attributable to exposure to the test material.

Under the conditions of this study the no-observable-effect level in male rats was considered to be 10 mg/m³ for the hematologic, clinical-chemical, and urinalysis parameters measured.

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Procedure

Four groups of ten male Crl:CD®BR rats were exposed, by inhalation, for six hours per day for ten days to [REDACTED] at design concentrations of 0 (control), 1 (low), 5 (intermediate), or 10 (high) mg/m³.

After the tenth exposure (12 DAYS ON TEST) blood was taken from the orbital sinus of each rat for enumeration of erythrocytes (RBC), leukocytes (WBC), and platelets (PLAT); analysis of hemoglobin concentration (Hb) and hematocrit (Ht); and determination of relative numbers of neutrophils (Neut), band neutrophils (Band), lymphocytes (Lymph), atypical lymphocytes (Alym), monocytes (Mono), eosinophils (Eosin), and basophils (Baso). Absolute values for the various types of leukocytes were calculated from the leukocytic data. Mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC) were calculated from the erythrocytic data. Blood cell counts, hemoglobin concentration, and Wintrobe indices were determined on an Ortho® model ELT-8ds hematology analyzer. Differential cell counts were determined on a Hematrak® Automated Differential System cell counter.

Serum activities of alkaline phosphatase (ALP), alanine aminotransferase (ALT), and aspartate aminotransferase (AST) and serum concentrations of urea nitrogen (BUN), creatinine (CREAT), total protein (TPROT), and cholesterol (CHOL) were measured on an Coulter DACOS® clinical chemistry analyzer using Coulter DART® reagents.

One day prior to the 12-day bleeding time, an overnight (approximately 16-hour) urine specimen was collected from each rat to measure volume, (VOL), osmolality (OSMOL), urobilinogen (UROBL), and pH; and to determine the presence of hemoglobin or occult blood (BLOOD), glucose, protein, bilirubin, and ketone (acetoacetic acid). Osmolality was determined on a Micro Diagnostics model AO-10 osmometer. Urine biochemical constituents were measured manually using Ames Multistix® urine chemistry dipsticks. Urine appearance (color and transparency) was recorded and the sediment from each specimen was microscopically examined.

After the 12-day sampling time, five rats from each group were killed for pathologic evaluation.

Following a 14-day recovery period (26 DAYS ON TEST), the hematologic and clinical chemical (serum and urine) measurements were repeated on the remaining five rats from each group.

Statistical Analyses

A one-way analysis of variance (ANOVA) and Bartlett's test were calculated for each sampling time. When the F-test from ANOVA was

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significant, the Dunnett test was used to compare means from the control group and each of the groups exposed to [REDACTED]. When the results of the Bartlett test were significant ($p \leq 0.005$), the Kruskal-Wallis test was employed and the Mann-Whitney U test was used to compare means from the control group and each of the groups exposed to [REDACTED]. Significance was judged at the 5% probability level.

Results

Statistically significant results are summarized in Table 1. Group means and standard deviations for hematologic (Table 2), clinical chemical (Table 3), and urinalysis (Table 4) data are presented after the Discussion and Conclusions. Data for individual animals are listed in Appendix A.

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Discussion and Conclusions

A statistically significant decrease in mean urine volume and increase in mean urine osmolality were observed in all treatment groups. Biologically, the differences from the control group were small to moderate and of questionable biological significance. Additionally, they did not occur in a dose-related manner. These urinalysis findings suggest dehydration, but other indicators of hemoconcentration/dehydration (such as an increase in protein, urea nitrogen, and Ht) were not significantly different from the control group. Therefore, the statistically significant urinalysis findings were considered unrelated to exposure to the test material and of equivocal significance biologically.

After the 14-day recovery period there were no biologically significant clinical laboratory findings observed.

Statistically significant clinical laboratory results listed in Clinical Pathology Text Table 1 and not specifically addressed above were considered within the range of expected biologic variation and unrelated to exposure to the test material.

Under the conditions of this study the no-observable-effect level in male rats was considered to be 10 mg/m³ for the hematologic, clinical chemical and urinalysis parameters measured.

DRH:b1
CP 13.26

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H-17375

SUBCHRONIC INHALATION TOXICITY WITH [REDACTED]

CLINICAL PATHOLOGY TEXT TABLE 1

SUMMARY OF STATISTICALLY SIGNIFICANT HEMATOLOGIC
AND CLINICAL CHEMICAL FINDINGS FOR MALE RATS

<u>Sampling Time</u>	<u>12 DAYS ON TEST</u>	<u>26 DAYS ON TEST</u>
<u>Measurement</u>		
<u>Hematology</u>		
Lymph	-	↓ V
<u>Clinical Chemistry (Serum)</u>		
CREAT	-	↓ III
TPROT	↓ VII	-
CHOL	↓ VII+	-
<u>Clinical Chemistry (Urine)</u>		
VOL	↓ III,V,VII	-
OSMOL	↑ III,V,VII	-

↑ = Significantly higher than controls by Dunnett or
Mann-Whitney U (+) criteria

↓ = Significantly lower than controls by Dunnett or
Mann-Whitney U (+) criteria

- = Not statistically significant

Group Designation and Concentration (mg/m³)

III - Low (1)
V - Intermediate (5)
VII - High (10)

Due to analytical and inter-animal variability, the number of animals per group, and other experimental design factors, statistical significance should not be interpreted as inferring biological or toxicological significance. See the discussion section for an interpretation of biologically significant results.

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SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

TABLE 2

SUMMARY OF HEMATOLOGIC FINDINGS FOR MALE RATS

TESTS	CONCENTRATION (mg/m ³)	SAMPLING TIME	
		12 DAYS ON TEST	26 DAYS ON TEST
RBC x10 ⁶ /ul	0	7.03(0.35) ^a	7.41(0.34)
	1	7.09(0.38)	7.16(0.30)
	5	6.84(0.32)	7.25(0.32)
	10	6.75(0.19)	7.38(0.34)
Hb g/dl	0	14.6(0.8)	15.0(0.9)
	1	15.1(0.8)	14.4(0.4)
	5	14.7(0.7)	15.0(0.7)
	10	14.4(0.7)	15.2(0.8)
Ht %	0	49.(2.)	50.(2.)
	1	49.(2.)	49.(1.)
	5	48.(2.)	50.(2.)
	10	47.(1.)	51.(2.)
MCV fl	0	69.(1.)	68.(1.)
	1	70.(1.)	68.(1.)
	5	70.(1.)	69.(1.)
	10	70.(1.)	69.(1.)
MCH pg	0	21.(1.)	20.(1.)
	1	21.(1.)	20.(1.)
	5	22.(1.)	21.(0.)
	10	21.(1.)	21.(1.)
MCHC g/dl	0	30.(1.)	30.(1.)
	1	31.(1.)	29.(0.)
	5	31.(0.)	30.(0.)
	10	31.(1.)	30.(1.)
PLAT x10 ³ /ul	0	1144.(326.)	1151.(363.)
	1	1127.(221.)	1028.(258.)
	5	1115.(261.)	983.(161.)
	10	1146.(246.)	843.(74.)

^a Group means and standard deviations(SD)

No statistically significant differences found at 5% level by Dunnett or
Mann-Whitney U criteria

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

TABLE 2 (continued)

SUMMARY OF HEMATOLOGIC FINDINGS FOR MALE RATS

TESTS	CONCENTRATION (mg/m ³)	SAMPLING TIME	
		12 DAYS ON TEST	26 DAYS ON TEST
WBC x10 ³ /ul	0	14.6(1.6) ^a	15.0(2.4)
	1	14.3(2.5)	14.3(0.8)
	5	14.4(1.8)	12.8(1.6)
	10	12.7(2.0)	12.3(1.5)
Neut WBCx%	0	2250.(1004.)	2793.(1431.)
	1	2806.(1404.)	3448.(1390.)
	5	2423.(1085.)	3089.(1186.)
	10	2578.(1000.)	2452.(1017.)
Band WBCx%	0	0.(0.)	0.(0.)
	1	0.(0.)	0.(0.)
	5	0.(0.)	0.(0.)
	10	0.(0.)	0.(0.)
Lymph WBCx%	0	11499.(1892.)	10753.(1824.)
	1	10856.(1827.)	9943.(772.)
	5	11081.(1769.)	8721.(820.)*
	10	9453.(1649.)	8979.(872.)

^a Group means and standard deviations(SD)

* Significantly different from control at 5% level by Dunnett criteria

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

TABLE 2 (continued)

SUMMARY OF HEMATOLOGIC FINDINGS FOR MALE RATS

TESTS	CONCENTRATION (mg/m ³)	SAMPLING TIME	
		12 DAYS ON TEST	26 DAYS ON TEST
Alym WBCx%	0	147.(203.) ^a	38.(85.)
	1	103.(229.)	0.(0.)
	5	136.(199.)	29.(65.)
	10	172.(161.)	95.(130.)
Mono WBCx%	0	626.(409.)	1362.(393.)
	1	481.(301.)	889.(252.)
	5	767.(383.)	916.(311.)
	10	432.(267.)	728.(526.)
Eosin WBCx%	0	58.(77.)	54.(73.)
	1	15.(47.)	0.(0.)
	5	25.(78.)	66.(96.)
	10	65.(86.)	26.(58.)
Baso WBCx%	0	0.(0.)	0.(0.)
	1	0.(0.)	0.(0.)
	5	0.(0.)	0.(0.)
	10	0.(0.)	0.(0.)

^a Group means and standard deviations(SD)

No statistically significant differences found at 5% level by Dunnett or Mann-Whitney U criteria

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SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

TABLE 3

SUMMARY OF CLINICAL CHEMICAL FINDINGS FOR MALE RATS

TESTS	CONCENTRATION (mg/m ³)	SAMPLING TIME	
		12 DAYS ON TEST	26 DAYS ON TEST
ALP U/L	0	468.(97.) ^a	466.(92.)
	1	394.(85.)	391.(65.)
	5	454.(108.)	494.(119.)
	10	428.(47.)	464.(101.)
ALT U/L	0	45.(6.)	41.(5.)
	1	53.(23.)	38.(7.)
	5	56.(33.)	39.(6.)
	10	51.(10.)	41.(5.)
AST U/L	0	75.(13.)	66.(4.)
	1	82.(29.)	66.(4.)
	5	77.(41.)	61.(8.)
	10	72.(9.)	70.(5.)
BUN mg/dl	0	16.(2.)	17.(2.)
	1	19.(4.)	15.(3.)
	5	16.(2.)	19.(2.)
	10	16.(2.)	17.(3.)
CREAT mg/dl	0	0.6(0.1)	0.6(0.0)
	1	0.5(0.1)	0.5(0.1)*
	5	0.5(0.1)	0.6(0.0)
	10	0.5(0.0)	0.6(0.0)
TPROT g/dl	0	6.0(0.3)	6.5(0.3)
	1	6.2(0.4)	6.2(0.2)
	5	5.8(0.2)	6.3(0.1)
	10	5.6(0.3)*	6.0(0.2)
CHOL mg/dl	0	67.(15.)	76.(16.)
	1	55.(9.)	63.(7.)
	5	60.(6.)	63.(10.)
	10	55.(5.)#	62.(14.)

^a Group means and standard deviations(SD)

* Significantly different from control at 5% level by Dunnett criteria

Significantly different from control at 5% level by Mann-Whitney U criteria

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SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

TABLE 4

SUMMARY OF CLINICAL URINALYSIS FINDINGS FOR MALE RATS

TESTS	CONCENTRATION (mg/m ³)	SAMPLING TIME	
		12 DAYS ON TEST	26 DAYS ON TEST
VOL ml	0	12.7(3.0) ^a	13.9(4.1)
	1	7.5(2.2)*	18.4(10.1)
	5	8.7(1.3)*	13.0(3.2)
	10	8.4(2.0)*	14.3(3.3)
OSMOL mOs	0	1368.(208.)	1506.(407.)
	1	1916.(304.)*	1296.(627.)
	5	1783.(198.)*	1558.(316.)
	10	1797.(337.)*	1323.(473.)
pH	0	7.4(0.3)	7.4(0.4)
	1	7.3(0.4)	7.7(0.3)
	5	7.2(0.4)	7.6(0.2)
	10	7.3(0.4)	7.9(0.2)
UROBL mg/dl	0	0.1(0.0)	0.1(0.0)
	1	0.1(0.0)	0.1(0.0)
	5	0.1(0.0)	0.1(0.0)
	10	0.1(0.0)	0.1(0.0)

^a Group means and standard deviations(SD)

* Significantly different from control at 5% level by Dunnett criteria

H-17375

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

TABLE 4 (continued)

SUMMARY OF CLINICAL URINALYSIS FINDINGS FOR MALE RATS

Measurement	Concentration (mg/m ³)	Sampling Time	
		12 DAYS ON TEST	26 DAYS ON TEST
Blood	0	1/10++	3/5
Number Positive	1	2/10	1/5
	5	1/10	0/5
	10	2/10	1/5
Glucose	0	0/10	0/5
Number Positive	1	0/10	0/5
	5	0/10	0/5
	10	0/10	1/5
Protein	0	0/10	0/5
Number Abnormal ≥ + 3	1	0/10	0/5
	5	0/10	0/5
	10	0/10	0/5
Bilirubin	0	0/10	0/5
Number Positive	1	0/10	0/5
	5	0/10	0/5
	10	0/10	0/5
Ketone	0	10/10	5/5
Number Positive	1	10/10	5/5
	5	10/10	5/5
	10	10/10	5/5
Appearance (Color and Transparency)	0	0/10	0/5
	1	0/10	0/5
	5	0/10	0/5
	10	0/10	0/5
Microscopic	0	6/10	5/5
Number Abnormal	1	7/10	5/5
	5	5/10	5/5
	10	7/10	5/5

++ Number of abnormal or positive findings/number of individual specimens examined

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SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A

H-17375, [REDACTED]

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APPENDIX A - EXPLANATORY NOTESTERMS AND CRITERIA USED IN URINALYSES

Abbreviations for Descriptive Terms Normally Used for Gross Evaluation of Urine (other Abbreviations and Descriptive Terms may be used if they are more applicable)

Y = Yellow
 LY = Light Yellow
 DY = Dark Yellow
 A = Amber
 DA = Dark Amber
 G = Green
 BL = Bloody
 R = Red
 C = Clear
 CL = Cloudy
 P/PPT = Precipitate
 F = Feed
 FEC = Feces
 QNS = Quantity not sufficient

Abbreviations for Descriptive Terms Used for Microscopic Evaluation of Urine

Epith = Epithelial Cells
 hpf = high power field
 lpf = low power field
 RBC = Red Blood Cells
 WBC = White Blood Cells
 TNTC (99-99) = Too Numerous to Count

Definition of "Normal" and "Abnormal" Designations Used for Gross and Microscopic Appearance of Urine

<u>Appearance</u>	<u>Normal</u>	<u>Abnormal</u>
Color	Light to dark yellow or amber	Color other than yellow or amber
<u>Microscopic</u>		
Red Blood Cells	Average of 0 to 4 red blood cells per high power field	Average of more than 4 red blood cells per high power field
Casts	None observed	Average of more than 0 per low power field
Epithelial Cells	Average of 0 to 9 per high power field	Average of more than 9 per high power field
White Blood Cells	Average of 0 to 9 per high power field	Average of more than 9 per high power field

H-17375
[REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A

ANIMALS WITH MISSING CLINICAL DATA

<u>Animal Number</u>	<u>Group Designation</u>	<u>Sampling Time</u>	<u>Test(s) Omitted</u>	<u>Reason for Omission</u>
447150	VII	12 DAYS ON TEST	Serum TPROT	Invalid results-data not used

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A

INDIVIDUAL HEMATOLOGIC FINDINGS FOR MALE RATS
AT 12 DAYS ON TEST

GROUP: I

SAMPLE DATE: 10/28/88

CONCENTRATION: 0 mg/m³

BIRTH DATE: 08/22/88

	RBC	Hb	Ht	MCV	MCH	MCHC	PLAT
ANIMAL#:	x10 ⁶ /ul	g/dl	%	fl	pg	g/dl	x10 ³ /ul
447112	7.13	14.5	49.	68.	20.	30.	680.
447113	6.84	14.7	48.	70.	22.	31.	1102.
447114	6.29	12.8	43.	69.	20.	30.	1031.
447115	6.97	14.3	48.	69.	21.	30.	1300.
447116	6.93	15.3	49.	70.	22.	31.	1484.
447117	6.86	14.2	47.	69.	21.	30.	1599.
447118	7.23	14.9	50.	69.	21.	30.	1500.
447119	7.12	14.5	49.	68.	20.	30.	1026.
447120	7.50	15.0	52.	69.	20.	29.	665.
447121	7.45	15.7	52.	69.	21.	31.	1051.
AVG.	7.03	14.6	49.	69.	21.	30.	1144.
S. D.	0.35	0.8	2.	1.	1.	1.	326.
S. E.	0.11	0.2	1.	0.	0.	0.	103.

GROUP: III

SAMPLE DATE: 10/28/88

CONCENTRATION: 1 mg/m³

BIRTH DATE: 08/22/88

	RBC	Hb	Ht	MCV	MCH	MCHC	PLAT
ANIMAL#:	x10 ⁶ /ul	g/dl	%	fl	pg	g/dl	x10 ³ /ul
447122	7.55	16.7	53.	70.	22.	32.	1020.
447123	6.83	14.6	48.	70.	21.	31.	1547.
447124	6.89	15.0	49.	71.	22.	31.	858.
447125	6.79	15.2	48.	71.	22.	32.	1079.
447126	6.74	14.4	47.	70.	21.	31.	971.
447127	7.12	14.9	49.	69.	21.	30.	1295.
447128	7.04	14.8	49.	69.	21.	31.	1389.
447129	7.21	15.4	50.	70.	21.	31.	1154.
447130	6.86	14.0	47.	69.	20.	30.	903.
447131	7.92	16.3	54.	68.	21.	30.	1056.
AVG.	7.09	15.1	49.	70.	21.	31.	1127.
S. D.	0.38	0.8	2.	1.	1.	1.	221.
S. E.	0.12	0.3	1.	0.	0.	0.	70.

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL HEMATOLOGIC FINDINGS FOR MALE RATS
AT 12 DAYS ON TESTGROUP: V
SAMPLE DATE: 10/28/88CONCENTRATION: 5 mg/m³
BIRTH DATE: 08/22/88

	RBC	Hb	Ht	MCV	MCH	MCHC	PLAT
ANIMAL#:	x10 ⁶ /ul	g/dl	%	fl	pg	g/dl	x10 ³ /ul
447132	6.39	13.7	45.	71.	21.	30.	1622.
447133	7.03	15.0	49.	70.	21.	31.	1280.
447134	6.77	14.7	47.	70.	22.	31.	941.
447135	6.89	14.7	48.	70.	21.	31.	1351.
447136	7.29	15.9	51.	70.	22.	31.	804.
447137	6.76	14.9	48.	70.	22.	31.	1113.
447138	6.72	13.8	45.	67.	21.	31.	797.
447139	6.97	15.3	49.	70.	22.	31.	1036.
447140	7.23	15.1	50.	69.	21.	30.	964.
447141	6.33	14.0	45.	72.	22.	31.	1246.
AVG.	6.84	14.7	48.	70.	22.	31.	1115.
S. D.	0.32	0.7	2.	1.	1.	0.	261.
S. E.	0.10	0.2	1.	0.	0.	0.	83.

GROUP: VII
SAMPLE DATE: 10/28/88CONCENTRATION: 10 mg/m³
BIRTH DATE: 08/22/88

	RBC	Hb	Ht	MCV	MCH	MCHC	PLAT
ANIMAL#:	x10 ⁶ /ul	g/dl	%	fl	pg	g/dl	x10 ³ /ul
447142	6.88	14.6	48.	70.	21.	30.	1422.
447143	6.63	15.1	48.	72.	23.	32.	822.
447144	6.73	13.9	46.	68.	21.	30.	1050.
447145	7.12	15.5	50.	70.	22.	31.	920.
447146	6.75	15.1	48.	71.	22.	32.	1138.
447147	6.62	13.6	46.	69.	21.	30.	1359.
447148	6.63	13.5	46.	70.	20.	29.	758.
447149	6.86	14.5	48.	69.	21.	31.	1377.
447150	6.83	14.1	47.	69.	21.	30.	1272.
447151	6.43	14.1	46.	71.	22.	31.	1340.
AVG.	6.75	14.4	47.	70.	21.	31.	1146.
S. D.	0.19	0.7	1.	1.	1.	1.	246.
S. E.	0.06	0.2	0.	0.	0.	0.	78.

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL HEMATOLOGIC FINDINGS FOR MALE RATS
AT 12 DAYS ON TEST

GROUP: I

SAMPLE DATE: 10/28/88

CONCENTRATION: 0 mg/m³

BIRTH DATE: 08/22/88

	WBC	Neut	Band	Lymph	Alym	Mono	Eosin	Baso
ANIMAL#:	x10 ³ /ul	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%
447112	17.1	2907.	0.	12654.	0.	1368.	171.	0.
447113	14.8	2220.	0.	11100.	296.	1184.	0.	0.
447114	11.5	3105.	0.	7935.	0.	345.	115.	0.
447115	15.6	3120.	0.	12012.	312.	156.	0.	0.
447116	12.9	1032.	0.	11481.	0.	387.	0.	0.
447117	13.8	2622.	0.	10212.	552.	414.	0.	0.
447118	15.7	1727.	0.	12560.	314.	942.	157.	0.
447119	14.1	3666.	0.	9588.	0.	705.	141.	0.
447120	15.5	620.	0.	14570.	0.	310.	0.	0.
447121	14.8	1480.	0.	12876.	0.	444.	0.	0.
AVG.	14.6	2250.	0.	11499.	147.	626.	58.	0.
S. D.	1.6	1004.	0.	1892.	203.	409.	77.	0.
S. E.	0.5	317.	0.	598.	64.	129.	24.	0.

GROUP: III

SAMPLE DATE: 10/28/88

CONCENTRATION: 1 mg/m³

BIRTH DATE: 08/22/88

	WBC	Neut	Band	Lymph	Alym	Mono	Eosin	Baso
ANIMAL#:	x10 ³ /ul	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%
447122	16.3	2934.	0.	12388.	0.	978.	0.	0.
447123	14.2	2414.	0.	11218.	0.	568.	0.	0.
447124	15.5	2015.	0.	12710.	0.	775.	0.	0.
447125	11.8	1652.	0.	9440.	354.	354.	0.	0.
447126	10.6	530.	0.	9964.	0.	106.	0.	0.
447127	16.8	3192.	0.	12768.	672.	168.	0.	0.
447128	16.7	3507.	0.	12859.	0.	334.	0.	0.
447129	10.4	1976.	0.	7800.	0.	624.	0.	0.
447130	15.4	4620.	0.	10626.	0.	154.	0.	0.
447131	14.9	5215.	0.	8791.	0.	745.	149.	0.
AVG.	14.3	2806.	0.	10856.	103.	481.	15.	0.
S. D.	2.5	1404.	0.	1827.	229.	301.	47.	0.
S. E.	0.8	444.	0.	578.	72.	95.	15.	0.

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL HEMATOLOGIC FINDINGS FOR MALE RATS
AT 12 DAYS ON TESTGROUP: V
SAMPLE DATE: 10/28/88CONCENTRATION: 5 mg/m³
BIRTH DATE: 08/22/88

	WBC	Neut	Band	Lymph	Alym	Mono	Eosin	Baso
ANIMAL#:	x10 ³ /ul	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%
447132	13.3	798.	0.	11704.	133.	665.	0.	0.
447133	14.1	2538.	0.	10716.	423.	423.	0.	0.
447134	15.4	2464.	0.	12012.	0.	924.	0.	0.
447135	12.0	1800.	0.	8640.	0.	1560.	0.	0.
447136	12.3	1968.	0.	8856.	0.	1230.	246.	0.
447137	16.3	3260.	0.	12388.	0.	652.	0.	0.
447138	17.0	4590.	0.	11730.	0.	680.	0.	0.
447139	12.8	2816.	0.	8704.	512.	768.	0.	0.
447140	16.7	2839.	0.	13527.	0.	334.	0.	0.
447141	14.4	1152.	0.	12528.	288.	432.	0.	0.
AVG.	14.4	2423.	0.	11081.	136.	767.	25.	0.
S. D.	1.8	1085.	0.	1769.	199.	383.	78.	0.
S. E.	0.6	343.	0.	559.	63.	121.	25.	0.

GROUP: VII
SAMPLE DATE: 10/28/88CONCENTRATION: 10 mg/m³
BIRTH DATE: 08/22/88

	WBC	Neut	Band	Lymph	Alym	Mono	Eosin	Baso
ANIMAL#:	x10 ³ /ul	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%
447142	10.7	2461.	0.	7490.	214.	321.	214.	0.
447143	13.9	3475.	0.	10008.	0.	278.	139.	0.
447144	11.9	1190.	0.	10353.	238.	119.	0.	0.
447145	16.1	4347.	0.	11109.	0.	483.	161.	0.
447146	9.8	1470.	0.	7742.	196.	392.	0.	0.
447147	13.2	3564.	0.	8712.	0.	792.	132.	0.
447148	10.6	2014.	0.	7950.	0.	636.	0.	0.
447149	12.3	2337.	0.	9102.	369.	492.	0.	0.
447150	15.0	1950.	0.	12750.	300.	0.	0.	0.
447151	13.5	2970.	0.	9315.	405.	810.	0.	0.
AVG.	12.7	2578.	0.	9453.	172.	432.	65.	0.
S. D.	2.0	1000.	0.	1649.	161.	267.	86.	0.
S. E.	0.6	316.	0.	521.	51.	84.	27.	0.

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL CLINICAL CHEMICAL FINDINGS FOR MALE RATS
AT 12 DAYS ON TEST

GROUP: I

SAMPLE DATE: 10/28/88

CONCENTRATION: 0 mg/m³

BIRTH DATE: 08/22/88

	ALP	ALT	AST	BUN	CREAT	TPROT	CHOL
ANIMAL#:	U/L	U/L	U/L	mg/dl	mg/dl	g/dl	mg/dl
447112	457.	51.	69.	21.	0.5	6.1	72.
447113	539.	43.	67.	16.	0.5	5.8	61.
447114	425.	48.	72.	15.	0.6	6.4	56.
447115	539.	43.	68.	15.	0.5	5.7	64.
447116	630.	48.	75.	14.	0.5	5.4	50.
447117	353.	53.	100.	15.	0.6	5.8	79.
447118	526.	51.	74.	17.	0.6	6.3	73.
447119	410.	39.	67.	15.	0.5	6.0	61.
447120	492.	37.	95.	16.	0.6	6.1	101.
447121	307.	40.	60.	14.	0.6	6.1	56.
AVG.	468.	45.	75.	16.	0.6	6.0	67.
S. D.	97.	6.	13.	2.	0.1	0.3	15.
S. E.	31.	2.	4.	1.	0.0	0.1	5.

GROUP: III

SAMPLE DATE: 10/28/88

CONCENTRATION: 1 mg/m³

BIRTH DATE: 08/22/88

	ALP	ALT	AST	BUN	CREAT	TPROT	CHOL
ANIMAL#:	U/L	U/L	U/L	mg/dl	mg/dl	g/dl	mg/dl
447122	307.	28.	57.	21.	0.6	6.4	37.
447123	413.	37.	56.	16.	0.6	5.9	64.
447124	396.	66.	97.	15.	0.4	6.0	58.
447125	457.	42.	64.	20.	0.5	6.3	61.
447126	536.	41.	68.	13.	0.5	5.8	44.
447127	326.	30.	65.	24.	0.5	6.1	66.
447128	394.	48.	65.	15.	0.5	6.3	55.
447129	471.	68.	100.	19.	0.5	6.1	53.
447130	395.	106.	149.	16.	0.5	5.7	60.
447131	242.	61.	96.	27.	0.6	7.0	52.
AVG.	394.	53.	82.	19.	0.5	6.2	55.
S. D.	85.	23.	29.	4.	0.1	0.4	9.
S. E.	27.	7.	9.	1.	0.0	0.1	3.

Company Sanitized. Does not contain TSCA CBI

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL CLINICAL CHEMICAL FINDINGS FOR MALE RATS
AT 12 DAYS ON TEST

GROUP: V

SAMPLE DATE: 10/28/88

CONCENTRATION: 5 mg/m³

BIRTH DATE: 08/22/88

	ALP	ALT	AST	BUN	CREAT	TPROT	CHOL
ANIMAL#:	U/L	U/L	U/L	mg/dl	mg/dl	g/dl	mg/dl
447132	641.	40.	55.	13.	0.5	5.8	63.
447133	498.	37.	67.	15.	0.6	5.8	55.
447134	607.	147.	193.	17.	0.6	5.7	59.
447135	495.	55.	60.	18.	0.5	5.9	51.
447136	460.	40.	58.	17.	0.6	6.2	52.
447137	317.	57.	67.	17.	0.6	5.7	67.
447138	357.	53.	72.	14.	0.5	5.9	60.
447139	409.	34.	56.	15.	0.5	6.0	69.
447140	374.	41.	65.	16.	0.5	5.7	62.
447141	377.	51.	75.	16.	0.5	5.8	60.
AVG.	454.	56.	77.	16.	0.5	5.8	60.
S. D.	108.	33.	41.	2.	0.1	0.2	6.
S. E.	34.	10.	13.	0.	0.0	0.1	2.

GROUP: VII

SAMPLE DATE: 10/28/88

CONCENTRATION: 10 mg/m³

BIRTH DATE: 08/22/88

	ALP	ALT	AST	BUN	CREAT	TPROT	CHOL
ANIMAL#:	U/L	U/L	U/L	mg/dl	mg/dl	g/dl	mg/dl
447142	434.	46.	69.	17.	0.5	5.8	61.
447143	506.	66.	82.	17.	0.5	5.7	60.
447144	418.	48.	84.	15.	0.5	5.3	50.
447145	386.	48.	67.	16.	0.5	6.1	50.
447146	466.	46.	72.	17.	0.5	5.7	49.
447147	457.	48.	64.	15.	0.5	5.2	57.
447148	417.	47.	72.	12.	0.5	5.5	55.
447149	439.	61.	79.	16.	0.4	5.8	58.
447150	330.	34.	55.	17.	0.6		58.
447151	427.	63.	73.	16.	0.5	5.7	50.
AVG.	428.	51.	72.	16.	0.5	5.6	55.
S. D.	47.	10.	9.	2.	0.0	0.3	5.
S. E.	15.	3.	3.	0.	0.0	0.1	1.

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL CLINICAL URINALYSIS FINDINGS FOR MALE RATS
AT 12 DAYS ON TESTGROUP: I
SAMPLE DATE: 10/28/88CONCENTRATION: 0 mg/m³
BIRTH DATE: 08/22/88

ANIMAL#:	VOL ml	OSMOL mOs	BLOOD	GLUCOSE	PRO- TEIN	pH	BILI- RUBIN	UROBL mg/dl	Ke- tone
447112	15.0	1280.	+	-	+1	7.5	-	0.1	+
447113	10.0	1553.	-	-	+2	7.5	-	0.1	+
447114	16.0	1220.	-	-	+	7.5	-	0.1	+
447115	10.0	1554.	-	-	+1	7.5	-	0.1	+1
447116	18.0	969.	-	-	+1	8.0	-	0.1	+
447117	15.0	1159.	-	-	+	7.5	-	0.1	+
447118	11.0	1579.	-	-	+1	7.0	-	0.1	+
447119	11.0	1358.	-	-	+2	7.0	-	0.1	+
447120	11.0	1445.	-	-	+1	7.0	-	0.1	+
447121	10.0	1558.	-	-	+2	7.5	-	0.1	+
AVG.	12.7	1368.				7.4		0.1	
S. D.	3.0	208.				0.3		0.0	
S. E.	0.9	66.				0.1		0.0	

GROUP: III
SAMPLE DATE: 10/28/88CONCENTRATION: 1 mg/m³
BIRTH DATE: 08/22/88

ANIMAL#:	VOL ml	OSMOL mOs	BLOOD	GLUCOSE	PRO- TEIN	pH	BILI- RUBIN	UROBL mg/dl	Ke- tone
447122	6.0	2035.	-	-	+2	7.0	-	0.1	+
447123	5.2	2278.	-	-	+2	6.5	-	0.1	+
447124	8.0	1889.	+	-	+2	8.0	-	0.1	+
447125	6.5	2017.	-	-	+2	7.5	-	0.1	+
447126	11.0	1475.	-	-	+1	7.5	-	0.1	+
447127	5.2	2094.	-	-	+2	7.5	-	0.1	+
447128	8.0	1775.	+	-	+2	7.5	-	0.1	+
447129	10.0	1419.	-	-	+2	7.0	-	0.1	+
447130	10.0	1844.	-	-	+2	7.0	-	0.1	+1
447131	5.0	2338.	-	-	+2	7.0	-	0.1	+
AVG.	7.5	1916.				7.3		0.1	
S. D.	2.2	304.				0.4		0.0	
S. E.	0.7	96.				0.1		0.0	

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL CLINICAL URINALYSIS FINDINGS FOR MALE RATS
AT 12 DAYS ON TEST

GROUP: V

CONCENTRATION: 5 mg/m³

SAMPLE DATE: 10/28/88

BIRTH DATE: 08/22/88

ANIMAL#:	VOL ml	OSMOL mOs	BLOOD	GLUCOSE	PRO- TEIN	pH	BILI- RUBIN	UROBL mg/dl	Ke- tone
447132	11.0	1464.	-	-	+1	7.5	-	0.1	+
447133	7.0	1778.	-	-	+1	7.0	-	0.1	+
447134	10.0	1523.	-	-	+1	8.0	-	0.1	+
447135	9.0	1743.	-	-	+2	7.0	-	0.1	+
447136	8.0	1971.	-	-	+2	7.5	-	0.1	+1
447137	8.0	2001.	-	-	+2	7.0	-	0.1	+
447138	10.0	1865.	-	-	+2	7.0	-	0.1	+
447139	7.0	2057.	+	-	+2	7.5	-	0.1	+
447140	9.0	1784.	-	-	+1	6.5	-	0.1	+
447141	8.0	1646.	-	-	+1	7.0	-	0.1	+1
AVG.	8.7	1783.				7.2		0.1	
S. D.	1.3	198.				0.4		0.0	
S. E.	0.4	63.				0.1		0.0	

GROUP: VII

CONCENTRATION: 10 mg/m³

SAMPLE DATE: 10/28/88

BIRTH DATE: 08/22/88

ANIMAL#:	VOL ml	OSMOL mOs	BLOOD	GLUCOSE	PRO- TEIN	pH	BILI- RUBIN	UROBL mg/dl	Ke- tone
447142	5.0	2403.	-	-	+2	6.5	-	0.1	+
447143	6.0	2261.	-	-	+2	7.0	-	0.1	+
447144	10.0	1484.	-	-	+1	7.5	-	0.1	+
447145	9.0	1641.	-	-	+2	7.0	-	0.1	+
447146	9.0	1639.	-	-	+2	7.5	-	0.1	+
447147	11.0	1383.	-	-	+2	7.5	-	0.1	+
447148	6.6	2025.	-	-	+2	7.5	-	0.1	+
447149	7.8	1871.	+	-	+2	8.0	-	0.1	+
447150	10.0	1705.	-	-	+1	7.0	-	0.1	+
447151	10.0	1561.	+	-	+2	7.5	-	0.1	+
AVG.	8.4	1797.				7.3		0.1	
S. D.	2.0	337.				0.4		0.0	
S. E.	0.6	107.				0.1		0.0	

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL CLINICAL URINALYSIS FINDINGS FOR MALE RATS
AT 12 DAYS ON TESTGROUP: I
SAMPLE DATE: 10/28/88CONCENTRATION: 0 mg/m³
BIRTH DATE: 08/22/88

ANIMAL#:	RBC /hpf	WBC /hpf	Epith /hpf	Cast /lpf	APPEARANCE
447112	0-2	1-2	2-3	0-0	DY CL PPT FEED FECES
447113	15-20	0-2	3-4	0-0	LY CL PPT FEED
447114	1-2	0-1	1-2	0-0	LY CL PPT FEED
447115	2-3	0-1	1-2	0-0	Y CL PPT
447116	8-10	0-1	4-5	0-0	LY CL PPT FEED
447117	6-8	0-1	3-4	0-0	Y CL PPT
447118	5-6	1-2	2-3	0-1	Y CL PPT
447119	2-3	0-1	1-2	0-0	Y CL PPT FEED FECES
447120	5-6	2-3	1-2	0-0	Y CL PPT
447121	6-8	1-2	1-2	0-0	Y CL PPT FEED

GROUP: III
SAMPLE DATE: 10/28/88CONCENTRATION: 1 mg/m³
BIRTH DATE: 08/22/88

ANIMAL#:	RBC /hpf	WBC /hpf	Epith /hpf	Cast /lpf	APPEARANCE
447122	6-8	0-2	1-2	0-0	LY CL PPT FEED
447123	3-4	0-0	0-2	0-0	Y CL PPT FEED
447124	1-2	0-1	2-3	0-0	DY CL PPT FEED
447125	6-8	0-2	3-4	0-0	Y CL PPT
447126	2-3	0-0	0-1	0-1	Y CL PPT
447127	4-5	0-2	1-2	0-0	Y CL PPT
447128	5-6	0-1	4-5	0-0	Y CL PPT FEED
447129	3-4	0-0	4-5	0-0	LY CL PPT FEED
447130	5-6	1-2	3-4	0-0	Y CL PPT FEED FECES
447131	8-10	1-2	4-5	0-0	Y CL PPT

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL CLINICAL URINALYSIS FINDINGS FOR MALE RATS
AT 12 DAYS ON TESTGROUP: V
SAMPLE DATE: 10/28/88CONCENTRATION: 5 mg/m³
BIRTH DATE: 08/22/88

ANIMAL#:	RBC /hpf	WBC /hpf	Epith /hpf	Cast /lpf	APPEARANCE
447132	4-5	8-10	0-1	0-0	Y CL PPT
447133	3-4	3-4	0-0	0-0	Y CL PPT
447134	1-2	4-6	0-0	0-0	Y CL PPT
447135	6-8	4-6	0-0	0-0	Y CL PPT
447136	8-10	8-10	0-1	0-0	Y CL PPT
447137	3-4	4-6	0-0	0-0	Y CL PPT
447138	4-6	4-6	0-0	0-0	Y CL PPT
447139	4-6	6-8	0-1	0-0	DY CL PPT FEED
447140	2-3	2-3	0-0	0-0	Y CL PPT
447141	3-4	4-6	0-0	0-0	Y CL PPT

GROUP: VII
SAMPLE DATE: 10/28/88CONCENTRATION: 10 mg/m³
BIRTH DATE: 08/22/88

ANIMAL#:	RBC /hpf	WBC /hpf	Epith /hpf	Cast /lpf	APPEARANCE
447142	3-4	4-6	0-1	0-0	Y CL PPT
447143	3-4	4-6	0-0	0-0	Y CL PPT
447144	10-15	8-10	1-2	0-0	LY CL PPT
447145	8-10	12-14	2-3	0-0	Y CL PPT
447146	8-10	8-10	0-0	0-0	Y CL PPT
447147	4-6	16-18	2-3	0-0	Y CL PPT FEED
447148	3-4	6-8	1-2	0-0	Y CL PPT FEED
447149	6-8	6-8	0-0	0-0	DY CL PPT FEED FECES
447150	3-4	3-4	0-0	0-1	Y CL PPT
447151	5-6	6-8	0-1	0-0	Y CL PPT FEED

Company Sanitized. Does not contain TSCA CB1

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A

INDIVIDUAL HEMATOLOGIC FINDINGS FOR MALE RATS
AT 26 DAYS ON TESTGROUP: I
SAMPLE DATE: 11/11/88CONCENTRATION: 0 mg/m³
BIRTH DATE: 08/22/88

	RBC	Hb	Ht	MCV	MCH	MCHC	PLAT
ANIMAL#:	x10 ⁶ /ul	g/dl	%	fl	pg	g/dl	x10 ³ /ul
447112	7.08	14.4	48.	67.	20.	30.	1089.
447113	7.37	15.2	51.	69.	21.	30.	1385.
447115	7.09	13.9	49.	68.	20.	29.	1645.
447119	7.69	15.1	51.	67.	20.	29.	869.
447120	7.81	16.3	54.	69.	21.	30.	769.
AVG.	7.41	15.0	50.	68.	20.	30.	1151.
S. D.	0.34	0.9	2.	1.	1.	1.	363.
S. E.	0.15	0.4	1.	0.	0.	0.	162.

GROUP: III
SAMPLE DATE: 11/11/88CONCENTRATION: 1 mg/m³
BIRTH DATE: 08/22/88

	RBC	Hb	Ht	MCV	MCH	MCHC	PLAT
ANIMAL#:	x10 ⁶ /ul	g/dl	%	fl	pg	g/dl	x10 ³ /ul
447124	6.96	14.4	49.	70.	21.	29.	872.
447126	6.84	14.1	47.	69.	21.	30.	910.
447127	7.12	13.9	48.	68.	20.	29.	1412.
447130	7.28	14.6	49.	67.	20.	30.	1166.
447131	7.61	15.0	51.	67.	20.	29.	782.
AVG.	7.16	14.4	49.	68.	20.	29.	1028.
S. D.	0.30	0.4	1.	1.	1.	0.	258.
S. E.	0.13	0.2	1.	1.	0.	0.	115.

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL HEMATOLOGIC FINDINGS FOR MALE RATS
AT 26 DAYS ON TESTGROUP: V
SAMPLE DATE: 11/11/88CONCENTRATION: 5 mg/m³
BIRTH DATE: 08/22/88

	RBC	Hb	Ht	MCV	MCH	MCHC	PLAT
ANIMAL#:	x10 ⁶ /ul	g/dl	%	fl	pg	g/dl	x10 ³ /ul
447133	7.55	15.6	52.	68.	21.	30.	830.
447135	6.83	14.2	48.	70.	21.	30.	1105.
447136	7.44	15.4	52.	69.	21.	30.	793.
447137	7.44	15.6	52.	69.	21.	30.	1143.
447139	6.97	14.3	49.	70.	21.	29.	1042.
AVG.	7.25	15.0	50.	69.	21.	30.	983.
S. D.	0.32	0.7	2.	1.	0.	0.	161.
S. E.	0.14	0.3	1.	0.	0.	0.	72.

GROUP: VII
SAMPLE DATE: 11/11/88CONCENTRATION: 10 mg/m³
BIRTH DATE: 08/22/88

	RBC	Hb	Ht	MCV	MCH	MCHC	PLAT
ANIMAL#:	x10 ⁶ /ul	g/dl	%	fl	pg	g/dl	x10 ³ /ul
447142	7.59	15.3	52.	68.	20.	30.	723.
447143	7.26	16.0	52.	71.	22.	31.	817.
447146	7.25	15.2	51.	70.	21.	30.	889.
447148	6.96	13.9	48.	69.	20.	29.	896.
447149	7.84	15.7	54.	68.	20.	29.	888.
AVG.	7.38	15.2	51.	69.	21.	30.	843.
S. D.	0.34	0.8	2.	1.	1.	1.	74.
S. E.	0.15	0.4	1.	1.	0.	0.	33.

Company Sanitized. Does not contain TSCA CBI

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL HEMATOLOGIC FINDINGS FOR MALE RATS
AT 26 DAYS ON TESTGROUP: I
SAMPLE DATE: 11/11/88CONCENTRATION: 0 mg/m³
BIRTH DATE: 08/22/88

	WBC	Neut	Band	Lymph	Alym	Mono	Eosin	Baso
ANIMAL#:	x10 ³ /ul	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%
447112	13.3	3857.	0.	8379.	0.	931.	133.	0.
447113	13.5	1080.	0.	10935.	0.	1350.	135.	0.
447115	13.8	1380.	0.	10488.	0.	1932.	0.	0.
447119	15.4	3850.	0.	10472.	0.	1078.	0.	0.
447120	19.0	3800.	0.	13490.	190.	1520.	0.	0.
AVG.	15.0	2793.	0.	10753.	38.	1362.	54.	0.
S. D.	2.4	1431.	0.	1824.	85.	393.	73.	0.
S. E.	1.1	640.	0.	816.	38.	176.	33.	0.

GROUP: III
SAMPLE DATE: 11/11/88CONCENTRATION: 1 mg/m³
BIRTH DATE: 08/22/88

	WBC	Neut	Band	Lymph	Alym	Mono	Eosin	Baso
ANIMAL#:	x10 ³ /ul	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%
447124	13.8	2898.	0.	9936.	0.	966.	0.	0.
447126	13.6	2176.	0.	10880.	0.	544.	0.	0.
447127	14.3	3575.	0.	10010.	0.	715.	0.	0.
447130	14.1	2820.	0.	10152.	0.	1128.	0.	0.
447131	15.6	5772.	0.	8736.	0.	1092.	0.	0.
AVG.	14.3	3448.	0.	9943.	0.	889.	0.	0.
S. D.	0.8	1390.	0.	772.	0.	252.	0.	0.
S. E.	0.4	622.	0.	345.	0.	113.	0.	0.

Company Sanitized. Does not contain TSCA cas

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL HEMATOLOGIC FINDINGS FOR MALE RATS
AT 26 DAYS ON TESTGROUP: V
SAMPLE DATE: 11/11/88CONCENTRATION: 5 mg/m³
BIRTH DATE: 08/22/88

	WBC	Neut	Band	Lymph	Alym	Mono	Eosin	Baso
ANIMAL#:	x10 ³ /ul	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%
447133	10.6	1590.	0.	8056.	0.	742.	212.	0.
447135	11.6	2320.	0.	8004.	0.	1160.	116.	0.
447136	13.6	4488.	0.	8568.	0.	544.	0.	0.
447137	14.5	3045.	0.	10005.	145.	1305.	0.	0.
447139	13.8	4002.	0.	8970.	0.	828.	0.	0.
AVG.	12.8	3089.	0.	8721.	29.	916.	66.	0.
S. D.	1.6	1186.	0.	820.	65.	311.	96.	0.
S. E.	0.7	531.	0.	367.	29.	139.	43.	0.

GROUP: VII
SAMPLE DATE: 11/11/88CONCENTRATION: 10 mg/m³
BIRTH DATE: 08/22/88

	WBC	Neut	Band	Lymph	Alym	Mono	Eosin	Baso
ANIMAL#:	x10 ³ /ul	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%	WBCx%
447142	12.9	2838.	0.	9159.	0.	774.	129.	0.
447143	14.5	3770.	0.	10005.	0.	725.	0.	0.
447146	11.9	2618.	0.	8568.	238.	476.	0.	0.
447148	11.8	2006.	0.	9440.	236.	118.	0.	0.
447149	10.3	1030.	0.	7725.	0.	1545.	0.	0.
AVG.	12.3	2452.	0.	8979.	95.	728.	26.	0.
S. D.	1.5	1017.	0.	872.	130.	526.	58.	0.
S. E.	0.7	455.	0.	390.	58.	235.	26.	0.

Company Sanitized. Does not contain TSCA CBI

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL CLINICAL CHEMICAL FINDINGS FOR MALE RATS
AT 26 DAYS ON TESTGROUP: I
SAMPLE DATE: 11/11/88CONCENTRATION: 0 mg/m³
BIRTH DATE: 08/22/88

	ALP	ALT	AST	BUN	CREAT	TPROT	CHOL
ANIMAL#:	U/L	U/L	U/L	mg/dl	mg/dl	g/dl	mg/dl
447112	384.	46.	63.	18.	0.7	6.4	69.
447113	530.	41.	68.	16.	0.6	6.6	59.
447115	590.	42.	62.	17.	0.6	6.3	72.
447119	446.	42.	66.	20.	0.6	6.9	79.
447120	382.	33.	71.	16.	0.6	6.1	102.
AVG.	466.	41.	66.	17.	0.6	6.5	76.
S. D.	92.	5.	4.	2.	0.0	0.3	16.
S. E.	41.	2.	2.	1.	0.0	0.1	7.

GROUP: III
SAMPLE DATE: 11/11/88CONCENTRATION: 1 mg/m³
BIRTH DATE: 08/22/88

	ALP	ALT	AST	BUN	CREAT	TPROT	CHOL
ANIMAL#:	U/L	U/L	U/L	mg/dl	mg/dl	g/dl	mg/dl
447124	414.	35.	65.	16.	0.6	6.4	63.
447126	490.	35.	70.	13.	0.5	6.0	53.
447127	360.	31.	65.	15.	0.5	6.0	70.
447130	319.	41.	70.	13.	0.5	6.3	69.
447131	371.	48.	62.	20.	0.6	6.5	62.
AVG.	391.	38.	66.	15.	0.5	6.2	63.
S. D.	65.	7.	4.	3.	0.1	0.2	7.
S. E.	29.	3.	2.	1.	0.0	0.1	3.

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL CLINICAL CHEMICAL FINDINGS FOR MALE RATS
AT 26 DAYS ON TEST

GROUP: V

SAMPLE DATE: 11/11/88

CONCENTRATION: 5 mg/m³

BIRTH DATE: 08/22/88

	ALP	ALT	AST	BUN	CREAT	TPROT	CHOL
ANIMAL#:	U/L	U/L	U/L	mg/dl	mg/dl	g/dl	mg/dl
447133	583.	37.	75.	16.	0.6	6.4	59.
447135	617.	48.	61.	22.	0.6	6.3	61.
447136	404.	34.	56.	17.	0.6	6.1	50.
447137	337.	44.	58.	20.	0.6	6.4	78.
447139	528.	34.	54.	19.	0.6	6.2	66.
AVG.	494.	39.	61.	19.	0.6	6.3	63.
S. D.	119.	6.	8.	2.	0.0	0.1	10.
S. E.	53.	3.	4.	1.	0.0	0.1	5.

GROUP: VII

SAMPLE DATE: 11/11/88

CONCENTRATION: 10 mg/m³

BIRTH DATE: 08/22/88

	ALP	ALT	AST	BUN	CREAT	TPROT	CHOL
ANIMAL#:	U/L	U/L	U/L	mg/dl	mg/dl	g/dl	mg/dl
447142	371.	36.	67.	15.	0.6	6.0	68.
447143	526.	43.	76.	21.	0.6	6.0	67.
447146	360.	38.	72.	15.	0.6	6.0	41.
447148	466.	39.	63.	18.	0.6	5.9	57.
447149	595.	49.	71.	16.	0.6	6.3	78.
AVG.	464.	41.	70.	17.	0.6	6.0	62.
S. D.	101.	5.	5.	3.	0.0	0.2	14.
S. E.	45.	2.	2.	1.	0.0	0.1	6.

Company Sanitized. Does not contain TSCA CSI

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL CLINICAL URINALYSIS FINDINGS FOR MALE RATS
AT 26 DAYS ON TEST

GROUP: I

CONCENTRATION: 0 mg/m³

SAMPLE DATE: 11/11/88

BIRTH DATE: 08/22/88

ANIMAL#:	VOL ml	OSMOL mOs	BLOOD	GLUCOSE	PRO- TEIN	pH	BILI- RUBIN	UROBL mg/dl	Ke- tone
447112	19.0	1021.	-	-	+1	8.0	-	0.1	+
447113	12.4	1792.	-	-	+2	7.0	-	0.1	+1
447115	8.0	1923.	+	-	+2	7.0	-	0.1	+1
447119	16.0	1669.	+3	-	+2	7.5	-	0.1	+
447120	14.2	1125.	+1	-	+1	7.5	-	0.1	+1
AVG.	13.9	1506.				7.4		0.1	
S. D.	4.1	407.				0.4		0.0	
S. E.	1.8	182.				0.2		0.0	

GROUP: III

CONCENTRATION: 1 mg/m³

SAMPLE DATE: 11/11/88

BIRTH DATE: 08/22/88

ANIMAL#:	VOL ml	OSMOL mOs	BLOOD	GLUCOSE	PRO- TEIN	pH	BILI- RUBIN	UROBL mg/dl	Ke- tone
447124	9.2	2075.	-	-	+2	8.0	-	0.1	+1
447126	35.0	526.	-	-	+1	8.0	-	0.1	+
447127	17.0	993.	-	-	+1	7.5	-	0.1	+
447130	18.8	1101.	-	-	+2	7.5	-	0.1	+1
447131	11.8	1787.	+	-	+2	7.5	-	0.1	+
AVG.	18.4	1296.				7.7		0.1	
S. D.	10.1	627.				0.3		0.0	
S. E.	4.5	280.				0.1		0.0	

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL CLINICAL URINALYSIS FINDINGS FOR MALE RATS
AT 26 DAYS ON TEST

GROUP: V

SAMPLE DATE: 11/11/88

CONCENTRATION: 5 mg/m³

BIRTH DATE: 08/22/88

ANIMAL#:	VOL ml	OSMOL mOs	BLOOD	GLUCOSE	PRO- TEIN	pH	BILI- RUBIN	UROBL mg/dl	Ke- tone
447133	9.0	1828.	-	-	+2	7.5	-	0.1	+1
447135	16.6	1290.	-	-	+2	7.5	-	0.1	+1
447136	16.0	1225.	-	-	+2	8.0	-	0.1	+1
447137	11.2	1934.	-	-	+2	7.5	-	0.1	+1
447139	12.4	1513.	-	-	+2	7.5	-	0.1	+
AVG.	13.0	1558.				7.6		0.1	
S. D.	3.2	316.				0.2		0.0	
S. E.	1.4	141.				0.1		0.0	

GROUP: VII

SAMPLE DATE: 11/11/88

CONCENTRATION: 10 mg/m³

BIRTH DATE: 08/22/88

ANIMAL#:	VOL ml	OSMOL mOs	BLOOD	GLUCOSE	PRO- TEIN	pH	BILI- RUBIN	UROBL mg/dl	Ke- tone
447142	16.4	863.	-	-	+1	7.5	-	0.1	+1
447143	11.2	1316.	-	-	+1	8.0	-	0.1	+1
447146	19.0	857.	-	-	+2	8.0	-	0.1	+1
447148	12.0	1911.	-	-	+2	8.0	-	0.1	+1
447149	12.8	1668.	+	+	+2	8.0	-	0.1	+1
AVG.	14.3	1323.				7.9		0.1	
S. D.	3.3	473.				0.2		0.0	
S. E.	1.5	211.				0.1		0.0	

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL CLINICAL URINALYSIS FINDINGS FOR MALE RATS
AT 26 DAYS ON TESTGROUP: I
SAMPLE DATE: 11/11/88CONCENTRATION: 0 mg/m³
BIRTH DATE: 08/22/88

ANIMAL#:	RBC /hpf	WBC /hpf	Epith /hpf	Cast /lpf	APPEARANCE
447112	25-30	TNTC	4-5	0-0	Y CL PPT FEED FECES
447113	50-60	20-25	2-3	0-0	Y CL PPT FEED
447115	8-10	8-10	2-3	0-0	DY CL PPT FEED FECES
447119	TNTC	20-25	2-3	0-0	DY CL PPT FEED FECES
447120	8-10	10-15	1-2	0-0	DY CL PPT FEED FECES

GROUP: III
SAMPLE DATE: 11/11/88CONCENTRATION: 1 mg/m³
BIRTH DATE: 08/22/88

ANIMAL#:	RBC /hpf	WBC /hpf	Epith /hpf	Cast /lpf	APPEARANCE
447124	15-20	10-15	3-4	0-0	Y CL PPT
447126	6-8	6-8	0-1	0-0	LY CL PPT
447127	8-10	4-6	1-2	0-0	Y CL PPT
447130	15-20	8-10	2-3	0-0	Y CL PPT
447131	TNTC	50-60	4-5	0-0	DY CL PPT FEED FECES

Company Sanitized. Does not contain TSCA CBI

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

H-17375
[REDACTED]

APPENDIX A (continued)

INDIVIDUAL CLINICAL URINALYSIS FINDINGS FOR MALE RATS
AT 26 DAYS ON TESTGROUP: V
SAMPLE DATE: 11/11/88CONCENTRATION: 5 mg/m³
BIRTH DATE: 08/22/88

ANIMAL#:	RBC /hpf	WBC /hpf	Epith /hpf	Cast /lpf	APPEARANCE
447133	25-30	10-15	2-3	0-0	Y CL PPT
447135	TNTC	25-30	6-8	0-0	Y CL PPT FEED
447136	10-15	8-10	3-4	0-0	Y CL PPT
447137	25-30	15-20	2-3	0-0	Y CL PPT
447139	15-20	10-15	2-3	0-0	Y CL PPT

GROUP: VII
SAMPLE DATE: 11/11/88CONCENTRATION: 10 mg/m³
BIRTH DATE: 08/22/88

ANIMAL#:	RBC /hpf	WBC /hpf	Epith /hpf	Cast /lpf	APPEARANCE
447142	6-10	4-6	0-1	0-0	Y CL PPT
447143	10-15	4-6	1-2	2-3	Y CL PPT
447146	20-25	8-10	1-2	0-1	LY CL PPT
447148	50-60	50-60	2-3	4-5	Y CL PPT
447149	TNTC	45-50	1-2	0-0	DY CL PPT FEED FECES

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Subchronic Inhalation Toxicity Study with [REDACTED]

APPENDIX F

Pathology Report No. 6-89

PATHOLOGY REPORT NO. 6-89

SUBCHRONIC INHALATION TOXICITY STUDY WITH ([REDACTED]) IN RATS

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SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED] IN RATSSUMMARY

Groups of 10 male Crl:CD®BR rats were exposed by inhalation to [REDACTED] at concentrations of 0, 1, 5, and 10 mg/m³ for 6 hours/day, Monday through Friday for 2 weeks. At study termination, all animals were necropsied, examined grossly, and selected tissues were weighed and/or examined microscopically.

There were no compound-related effects detected. There was a statistically significant difference in absolute lung weights between the control group and a treated group that was considered to be a spurious occurrence without biological significance. Under the conditions of this study the no-observable-effect level, based upon final body and organ weights and gross and microscopic pathology, was the high-dose level (10 mg/m³) for male rats.

Report by:

G. Tracy Makovec
G. Tracy Makovec, D.V.M.
Diplomate, A.C.V.P.
Staff Pathologist

12/20/94

Approved by:

Paul E. Ross
Paul E. Ross, D.V.M.
Diplomate, A.C.V.P.
Pathology

12/20/94

GTM/PER/wfd
WPSP/MAKOVEC

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INTRODUCTION AND METHODS

Body and organ weight data and gross and microscopic findings from male Crl:CD®BR rats exposed via inhalation to [REDACTED] vapor or air alone are summarized in this report. Exposure groups were as follows:

GROUP	RATS/GROUP	CONCENTRATION OF [REDACTED] (mg/m ³)
I	10	0 (air-exposed control)
III	10	1 (low)
V	10	5 (intermediate)
VII	10	10 (high)

Animals were exposed to their respective concentrations of [REDACTED] vapor for 6 hours/day, Monday through Friday for two weeks. At the end of the exposure period, 5 rats/group were sacrificed for pathologic evaluation and the remaining 5 rats/group were sacrificed following a 14-day recovery period.

Following euthanasia by sodium pentobarbital anesthesia and exsanguination, all animals were examined for gross alterations. The following organs were collected for weighing: spleen, lungs, liver, kidneys, and testes. Representative samples of the following organs and tissues were collected from all rats for microscopic evaluation: liver, kidneys, urinary bladder, lungs, heart, spleen, thymus, pancreas, adrenals, thyroid, trachea, esophagus, brain, stomach, duodenum, jejunum, ileum, cecum, colon, rectum, mesenteric lymph node, testes, epididymides, sternum (bone and marrow), eyes, nose, and any gross lesions. Testes, epididymides, sternum, and eyes were fixed in Bouin's solution. Remaining tissues were fixed in 10% neutral buffered formalin. Processed tissues were embedded in paraffin, sectioned at a nominal thickness of 5 micrometers, and stained with hematoxylin and eosin.

Mean body weights, mean absolute organ weights, and mean relative organ weights (organ-to-body weight ratios) were analyzed using a one-way analysis of variance (ANOVA). When the F-test from the ANOVA was significant, the Least Significant Difference (LSD) test and Dunnett's test were used to compare means from the control group with the test group. Significance was judged at the 0.05 probability level.

RESULTS AND DISCUSSION

Table 1 summarizes mean final body and organ weights. Incidences of gross observations are listed in Table 2. Table 3 contains incidences of microscopic observations. Appendix A lists body weights and absolute and

relative organ weights for individual animals. Appendix B contains individual animal gross and microscopic pathology data.

There were no compound-related effects detected. Lung weights were statistically significantly decreased in the 1 mg/m³ zero-day recovery group when compared to the control group. This finding was considered to be a spurious occurrence without biological significance.

There were no compound-related changes grossly or microscopically. The gross observations and microscopic diagnoses noted in these animals were incidental occurrences of spontaneous lesions common to rats of this strain and age.

CONCLUSION

Under the conditions of this study the no-observable-effect level, based upon final body and organ weights and gross and microscopic pathology, was the high-dose level (10 mg/m³) for male rats.

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

TABLE 1
MEAN FINAL BODY AND ORGAN WEIGHTS FROM MALE RAT
(ANIMALS NECROPSIED ON DAY 12)

MEAN FINAL BODY WEIGHTS (grams)

GROUP	CONC. (MG/M3)	FINAL BODY
I	0.0	309.9 (13.9)
III	1.0	288.3 (12.3)
V	5.0	304.7 (19.5)
VII	10.0	300.9 (19.0)

MEAN ABSOLUTE ORGAN WEIGHTS (grams)

GROUP	CONC. (MG/M3)	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
I	0.0	1.443 (0.044)	11.168 (1.347)	2.527 (0.101)	0.632 (0.062)	3.147 (0.174)
III	1.0	1.304 (0.071) #	10.531 (1.265)	2.399 (0.146)	0.575 (0.064)	3.116 (0.230)
V	5.0	1.403 (0.066)	10.792 (1.471)	2.481 (0.291)	0.632 (0.072)	3.052 (0.230)
VII	10.0	1.385 (0.096)	11.081 (1.214)	2.324 (0.167)	0.701 (0.144)	3.245 (0.437)

MEAN RELATIVE ORGAN WEIGHTS (% of body weight)

GROUP	CONC. (MG/M3)	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
I	0.0	0.4667 (.0314)	3.5997 (.3655)	0.8172 (.0592)	0.2036 (.0130)	1.0170 (.0713)
III	1.0	0.4526 (.0183)	3.6531 (.3983)	0.8332 (.0588)	0.1998 (.0230)	1.0836 (.1071)
V	5.0	0.4618 (.0321)	3.5308 (.2984)	0.8135 (.0725)	0.2078 (.0219)	1.0045 (.0915)
VII	10.0	0.4604 (.0139)	3.6753 (.2156)	0.7724 (.0265)	0.2332 (.0450)	1.0794 (.1410)

STANDARD DEVIATION IN PARENTHESES

+ - SIGNIFICANTLY DIFFERENT (P<0.05) FROM CONTROL GROUP BY LSD
- SIGNIFICANTLY DIFFERENT (P<0.05) FROM CONTROL GROUP BY LSD AND DUNNETT'S TEST

H# 17,375

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

TABLE 1 (continued)
MEAN FINAL BODY AND ORGAN WEIGHTS FROM MALE RAT
(ANIMALS NECROPSIED ON DAY 26)

MEAN FINAL BODY WEIGHTS (grams)

GROUP	CONC. (MG/M3)	FINAL BODY
I	0.0	388.5 (9.4)
III	1.0	388.7 (28.6)
V	5.0	364.3 (21.8)
VII	10.0	375.1 (26.0)

MEAN ABSOLUTE ORGAN WEIGHTS (grams)

GROUP	CONC. (MG/M3)	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
I	0.0	1.719 (0.125)	14.277 (2.226)	2.995 (0.307)	0.794 (0.087)	3.355 (0.260)
III	1.0	1.843 (0.220)	14.501 (1.562)	3.154 (0.361)	0.845 (0.077)	3.480 (0.249)
V	5.0	1.608 (0.195)	13.841 (1.018)	2.984 (0.115)	0.789 (0.149)	3.203 (0.399)
VII	10.0	1.609 (0.144)	13.763 (1.112)	3.111 (0.451)	0.732 (0.058)	3.535 (0.230)

MEAN RELATIVE ORGAN WEIGHTS (% of body weight)

GROUP	CONC. (MG/M3)	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
I	0.0	0.4430 (.0398)	3.6719 (.5443)	0.7709 (.0762)	0.2042 (.0187)	0.8632 (.0567)
III	1.0	0.4731 (.0262)	3.7364 (.3709)	0.8108 (.0603)	0.2179 (.0209)	0.8961 (.0458)
V	5.0	0.4420 (.0236)	3.7983 (.1097)	0.8211 (.0503)	0.2168 (.0410)	0.8780 (.0821)
VII	10.0	0.4297 (.0356)	3.6690 (.1625)	0.8276 (.0938)	0.1956 (.0148)	0.9444 (.0654)

STANDARD DEVIATION IN PARENTHESES

+ - SIGNIFICANTLY DIFFERENT (P<0.05) FROM CONTROL GROUP BY LSD

- SIGNIFICANTLY DIFFERENT (P<0.05) FROM CONTROL GROUP BY LSD AND DUNNETT'S TEST

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

HN-17375 [REDACTED]

TABLE 2

INCIDENCES OF GROSS OBSERVATIONS IN MALE RAT
(ANIMALS NECROPSIED ON DAY 12)

	I	III	V	VII
GROUP DESIGNATION:	0 MG/M3	1.0 MG/M3	5.0 MG/M3	10.0 MG/M3
DOSE (UNITS):	5	5	5	5
NUMBER IN GROUP:	5	5	5	5
SITE/LESION:				
LUNGS				
FOCI	0	1	0	0
DISCOLORATION	1	0	0	0
RENAL PELVIS				
DILATATION	2	0	0	1
EPIDIDYMIDES				
SMALL	0	0	1	0
ADRENALS				
DEFORMITY	0	0	1	0

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

HN-17375 [REDACTED]

TABLE 2 (continued)
INCIDENCES OF GROSS OBSERVATIONS IN MALE RAT
(ANIMALS NECROPSIED ON DAY 26)

	GROUP DESIGNATION:		III		V		VII	
	DOSE (UNITS):		1.0 MG/M3		5.0 MG/M3		10.0 MG/M3	
	NUMBER IN GROUP:		5		5		5	
SITE/LESION:	I	0	1	1	0	0	0	0
LUNGS								
FOCI		0	1	1	0	0	0	0
RENAL PELVIS								
DILATATION		1	1	1	0	0	0	0
EPIDIDYMIDES								
NODULE		0	1	1	0	0	0	0

HN-17375

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

TABLE 3

INCIDENCES OF MICROSCOPIC OBSERVATIONS IN MALE RATS

(ANIMALS NECROPSIED ON DAY 12)

TISSUE/LESION	GROUP DESIGNATION: DOSE (MG/M3): NUMBER IN GROUP:	I 0.0 5	III 1.0 5	V 5.0 5	VII 10.0 5
LIVER		5 5	5 2	5 3	5 3
INFLAMMATION, SUBACUTE					
KIDNEYS		5 2	5 2	5 2	5 1
DILATATION, RENAL PELVIS					
URINARY BLADDER		5 5	5 5	5 5	5 5
LUNGS		5 1	5 1	5 1	5 1
HEMORRHAGE, ACUTE					
HEART		5 5	5 5	5 5	5 5
SPLEEN		5 5	5 5	5 5	5 5
THYMUS		5 5	5 5	5 5	5 5
PANCREAS		5 5	5 5	5 5	5 5
ADRENALS		5 5	5 5	5 5	5 5
THYROID		5 5	5 5	5 5	5 5
TRACHEA		5 5	5 5	5 5	5 5
ESOPHAGUS		5 5	5 5	5 5	5 5
BRAIN		5 5	5 5	5 5	5 5
STOMACH		5 5	5 5	5 5	5 5
DUODENUM		5 5	5 5	5 5	5 5
JEJUNUM		5 5	5 5	5 5	5 5
ILEUM		5 5	5 5	5 5	5 5
CECUM		5 5	5 5	5 5	5 5

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

 TABLE 3 (continued)
 INCIDENCES OF MICROSCOPIC OBSERVATIONS IN MALE RATS

(ANIMALS NECROPSIED ON DAY 12)

TISSUE/LESION	GROUP DESIGNATION: DOSE (MG/M3): NUMBER IN GROUP:	I 0.0 5	III 1.0 5	V 5.0 5	VII 10.0 5
COLON		5	5	5	5
RECTUM		5	5	5	5
MESENTERIC LYMPH NODE		5	5	5	5
TESTES		5	5	5	5
EPIDIDYMIDES SPERM GRANULOMA		5	5	5	5
STERNUM		5	5	5	5
EYES		5	5	5	5
NOSE		5	5	5	5
OTHER		0	0	0	0

 NOTES:
 o THE NUMBER OF ORGANS EXAMINED FOR EACH GROUP IS UNDERLINED.

HN-17375
[REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

TABLE 3 (continued)
INCIDENCES OF MICROSCOPIC OBSERVATIONS IN MALE RATS
(ANIMALS NECROPSIED ON DAY 28)

TISSUE/LESION	GROUP DESIGNATION: DOSE (MG/M3): NUMBER IN GROUP:	I 0.0 5	III 1.0 5	V 5.0 5	VII 10.0 5
LIVER		5	5	5	5
INFLAMMATION, SUBACUTE		2	4	2	1
KIDNEYS		5	5	5	5
DILATATION, RENAL PELVIS		1	-	-	-
URINARY BLADDER		5	5	5	5
LUNGS		5	5	5	5
HEART		5	5	5	5
SPLEEN		5	5	5	5
THYMUS		5	5	5	5
PANCREAS		5	5	5	5
ACINAR CELL ATROPHY		1	-	-	-
ADRENALS		5	5	5	5
THYROID		5	5	5	5
TRACHEA		5	5	5	5
ESOPHAGUS		5	5	5	5
BRAIN		5	5	5	5
STOMACH		5	5	5	5
DUODENUM		5	5	5	5
JEJUNUM		5	5	5	5
ILEUM		4	5	5	5
CECUM		4	5	5	5

HN-17375

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

TABLE 3 (continued)
INCIDENCES OF MICROSCOPIC OBSERVATIONS IN MALE RATS
(ANIMALS NECROPSIED ON DAY 26)

TISSUE/LESION	GROUP DESIGNATION: DOSE (MG/M3): NUMBER IN GROUP:	I 0.0 5	III 1.0 5	V 5.0 5	VII 10.0 5
COLON		5	5	5	5
RECTUM		5	5	5	5
MESENTERIC LYMPH NODE		5	5	5	5
TESTES		5	5	5	5
EPIDIDYMIDES SPERM GRANULOMA		5 1	5 1	5 1	5 1
STERNUM		5	5	5	5
EYES		5	5	5	5
INFLAMMATION, CHRONIC, CORNEA		5	5	5	5
NOSE		5	5	5	5
OTHER		0	0	0	0

NOTES:
o THE NUMBER OF ORGANS EXAMINED FOR EACH GROUP IS UNDERLINED.

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A
INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
(ANIMALS NECROPSIED ON DAY 12)

H# 17,375 [REDACTED]

FINAL BODY AND ABSOLUTE ORGAN WEIGHTS (grams) FROM MALE RAT

GROUP : I - 0 MG/M3

ANIMAL NUMBER	FINAL BODY	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
447114	329.3	1.442	11.637	2.450	0.720	3.292
447116	296.6	1.491	10.588	2.605	0.547	3.366
447117	312.5	1.377	13.116	2.649	0.621	2.961
447118	315.1	1.431	11.033	2.408	0.645	3.091
447121	296.2	1.475	9.468	2.523	0.626	3.027
GROUP MEAN	309.9	1.443	11.168	2.527	0.632	3.147
STD. DEV.	13.9	0.044	1.347	0.101	0.062	0.174

Company Sanitized. Does not contain TSCA CBI

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A (continued)
INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
(ANIMALS NECROPSIED ON DAY 12)

FINAL BODY AND ABSOLUTE ORGAN WEIGHTS (grams) FROM MALE RAT

GROUP : III - 1.0 MG/M3

ANIMAL NUMBER	FINAL BODY	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
447122	270.3	1.241	9.947	2.439	0.594	3.308
447123	280.7	1.273	10.109	2.256	0.542	3.084
447125	295.9	1.315	12.096	2.285	0.481	3.076
447128	297.9	1.423	11.532	2.393	0.635	3.344
447129	296.6	1.270	8.972	2.624	0.624	2.769
GROUP MEAN	288.3	1.304	10.531	2.399	0.575	3.116
STD. DEV.	12.3	0.071	1.265	0.146	0.064	0.230

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A (continued)

INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
(ANIMALS NECROPSIED ON DAY 12)

FINAL BODY AND ABSOLUTE ORGAN WEIGHTS (grams) FROM MALE RAT

GROUP: 11 V - 5.0 MG/M3

ANIMAL NUMBER	FINAL BODY	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
447132	310.5	1.342	12.050	2.900	0.710	2.841
447134	326.3	1.511	12.439	2.461	0.688	3.419
447138	299.8	1.362	10.258	2.337	0.638	2.936
447140	274.1	1.413	8.811	2.118	0.592	3.128
447141	312.8	1.389	10.400	2.587	0.534	2.938
GROUP MEAN	304.7	1.403	10.792	2.481	0.632	3.052
STD. DEV.	19.5	0.066	1.471	0.291	0.072	0.230

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H# 17,375

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A (continued)
INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
(ANIMALS NECROPSIED ON DAY 12)

FINAL BODY AND ABSOLUTE ORGAN WEIGHTS (grams) FROM MALE RAT

GROUP: VII - 10.0 MG/M3

ANIMAL NUMBER	FINAL BODY	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
447144	295.7	1.419	10.945	2.384	0.526	3.624
447145	318.6	1.467	11.502	2.396	0.640	2.859
447147	294.8	1.299	11.206	2.331	0.688	3.535
447150	320.5	1.474	12.550	2.471	0.917	3.518
447151	274.9	1.268	9.203	2.040	0.736	2.687
GROUP MEAN	300.9	1.385	11.081	2.324	0.701	3.245
STD. DEV.	19.0	0.096	1.214	0.167	0.144	0.437

H# 17.375 [REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A (continued)

INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
(ANIMALS NECROPSIED ON DAY 12)

RELATIVE ORGAN WEIGHTS (% of body weight) FROM MALE RAT

GROUP : I - 0 MG/M3

ANIMAL NUMBER	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
447114	0.4379	3.5339	0.7440	0.2186	0.9997
447116	0.5027	3.5698	0.8783	0.1844	1.1349
447117	0.4406	4.1971	0.8477	0.1987	0.9475
447118	0.4541	3.5014	0.7642	0.2047	0.9810
447121	0.4980	3.1965	0.8518	0.2113	1.0219
GROUP MEAN	0.4667	3.5997	0.8172	0.2036	1.0170
STD. DEV.	0.0314	0.3655	0.0592	0.0130	0.0713

H# 17,375

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A (continued)
INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
(ANIMALS NECROPSIED ON DAY 12)

RELATIVE ORGAN WEIGHTS (% of body weight) FROM MALE RAT

GROUP : III - 1.0 MG/M3

ANIMAL NUMBER	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
447122	0.4591	3.6800	0.9023	0.2198	1.2238
447123	0.4535	3.6014	0.8037	0.1931	1.0987
447125	0.4444	4.0879	0.7722	0.1626	1.0395
447128	0.4777	3.8711	0.8033	0.2132	1.1225
447129	0.4282	3.0249	0.8847	0.2104	0.9336
GROUP MEAN	0.4526	3.6531	0.8332	0.1998	1.0836
STD. DEV.	0.0183	0.3983	0.0568	0.0230	0.1071

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A (continued)
INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
(ANIMALS NECROPSIED ON DAY 12)

H# 17,375 [REDACTED]

RELATIVE ORGAN WEIGHTS (% of body weight) FROM MALE RAT

GROUP : V - 5.0 MG/M3

ANIMAL NUMBER	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
447132	0.4322	3.8808	0.9340	0.2287	0.9150
447134	0.4631	3.8121	0.7542	0.2108	1.0478
447138	0.4543	3.4216	0.7795	0.2128	0.9793
447140	0.5155	3.2145	0.7727	0.2160	1.1412
447141	0.4441	3.3248	0.8270	0.1707	0.9393
GROUP MEAN	0.4618	3.5308	0.8135	0.2078	1.0045
STD. DEV.	0.0321	0.2984	0.0725	0.0219	0.0915

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SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A (continued)

INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
(ANIMALS NECROPSIED ON DAY 12)

RELATIVE ORGAN WEIGHTS (% of body weight) FROM MALE RAT

GROUP : VII - 10.0 MG/M3

ANIMAL NUMBER	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
447144	0.4799	3.7014	0.8062	0.1779	1.2256
447145	0.4605	3.6102	0.7520	0.2009	0.8974
447147	0.4406	3.8012	0.7907	0.2334	1.1991
447150	0.4599	3.9158	0.7710	0.2861	1.0977
447151	0.4613	3.3478	0.7421	0.2677	0.9774
GROUP MEAN	0.4604	3.6753	0.7724	0.2332	1.0794
STD. DEV.	0.0139	0.2156	0.0265	0.0450	0.1410

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A (continued)

INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
(ANIMALS NECROPSIED ON DAY 26)

FINAL BODY AND ABSOLUTE ORGAN WEIGHTS (grams) FROM MALE RAT

GROUP :		I - 0 MG/M3				
ANIMAL NUMBER	FINAL BODY	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
447112	378.1	1.684	12.978	2.750	0.763	3.215
447113	382.2	1.843	16.033	3.250	0.733	2.988
447115	400.0	1.559	14.725	2.807	0.948	3.397
447119	396.7	1.658	16.512	3.400	0.777	3.636
447120	385.6	1.849	11.139	2.768	0.751	3.541
GROUP MEAN	388.5	1.719	14.277	2.995	0.794	3.355
STD. DEV.	9.4	0.125	2.226	0.307	0.087	0.260

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A (continued)

INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
(ANIMALS NECROPSIED ON DAY 26)

FINAL BODY AND ABSOLUTE ORGAN WEIGHTS (grams) FROM MALE RAT						
GROUP :		III - 1.0 MG/M3				
ANIMAL NUMBER	FINAL BODY	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
447124	398.7	1.811	17.036	3.324	0.874	3.689
447126	384.3	1.800	12.907	2.848	0.751	3.319
447127	360.8	1.743	13.820	3.174	0.777	3.136
447130	432.5	2.218	14.754	3.656	0.899	3.719
447131	367.3	1.641	13.989	2.770	0.924	3.536
GROUP MEAN	388.7	1.843	14.501	3.154	0.845	3.480
STD. DEV.	28.6	0.220	1.562	0.361	0.077	0.249

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A (continued)
INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
(ANIMALS NECROPSIED ON DAY 26)

FINAL BODY AND ABSOLUTE ORGAN WEIGHTS (grams) FROM MALE RAT						
GROUP	V - 5.0 MG/M3					
ANIMAL NUMBER	FINAL BODY	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
447133	370.0	NW	14.114	2.994	0.693	3.613
447135	343.7	1.496	13.419	2.995	0.954	2.598
447136	353.1	1.475	13.315	3.090	0.742	3.261
447137	399.4	1.894	15.481	3.051	0.937	3.482
447139	355.2	1.566	12.878	2.791	0.620	3.062
GROUP MEAN	364.3	1.608	13.841	2.984	0.789	3.203
STD. DEV.	21.8	0.195	1.018	0.115	0.149	0.399

NW = NOT WEIGHED

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A (continued)

INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
(ANIMALS NECROPSIED ON DAY 26)

H# 17,375

FINAL BODY AND ABSOLUTE ORGAN WEIGHTS (grams) FROM MALE RAT							
VII - 10.0 MG/M3							
GROUP	ANIMAL NUMBER	FINAL BODY	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
	447142	397.8	1.743	13.870	3.124	0.782	3.450
	447143	333.2	1.558	11.909	2.407	0.668	3.221
	447146	392.6	1.779	14.177	3.472	0.736	3.648
	447148	383.9	1.450	14.896	3.019	0.679	3.517
	447149	368.1	1.516	13.962	3.532	0.797	3.838
GROUP MEAN		375.1	1.609	13.763	3.111	0.732	3.535
STD. DEV.		26.0	0.144	1.112	0.451	0.058	0.230

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A (continued)

INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
(ANIMALS NECROPSIED ON DAY 26)

RELATIVE ORGAN WEIGHTS (% of body weight) FROM MALE RAT

GROUP : I - 0. MG/M3

ANIMAL NUMBER	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
447112	0.4454	3.4324	0.7273	0.2018	0.8503
447113	0.4822	4.1949	0.8503	0.1918	0.7818
447115	0.3898	3.6812	0.7017	0.2370	0.8493
447119	0.4179	4.1623	0.8571	0.1959	0.9166
447120	0.4795	2.8887	0.7178	0.1948	0.9183
GROUP MEAN	0.4430	3.6719	0.7709	0.2042	0.8632
STD. DEV.	0.0398	0.5443	0.0762	0.0187	0.0567

Company Sanitized. Does not contain TSCA CBI

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]
 APPENDIX A (continued)
 INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
 (ANIMALS NECROPSIED ON DAY 28)

RELATIVE ORGAN WEIGHTS (% of body weight) FROM MALE RAT

GROUP : III - 1.0 MG/M3

ANIMAL NUMBER	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
447124	0.4542	4.2729	0.8337	0.2192	0.9253
447126	0.4684	3.3586	0.7411	0.1954	0.8636
447127	0.4831	3.8304	0.8797	0.2154	0.8692
447130	0.5128	3.4113	0.8453	0.2079	0.8599
447131	0.4468	3.8086	0.7542	0.2516	0.9627
GROUP MEAN	0.4731	3.7364	0.8108	0.2179	0.8961
STD. DEV.	0.0262	0.3709	0.0603	0.0209	0.0458

Company Sanitized. Does not contain TSCA CBI

H# 17.375

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX A (continued)

INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
(ANIMALS NECROPSIED ON DAY 26)

RELATIVE ORGAN WEIGHTS (% of body weight) FROM MALE RAT

GROUP : V - 5.0 MG/M3

ANIMAL NUMBER	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES
447133	NW	3.8146	0.8092	0.1873	0.9765
447135	0.4353	3.9043	0.8714	0.2776	0.7559
447136	0.4177	3.7709	0.8751	0.2101	0.9235
447137	0.4742	3.8761	0.7639	0.2346	0.8718
447139	0.4409	3.6256	0.7858	0.1745	0.8620
GROUP MEAN	0.4420	3.7983	0.8211	0.2168	0.8780
STD. DEV.	0.0236	0.1097	0.0503	0.0410	0.0821

NW = NOT WEIGHED

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]
 APPENDIX A (continued)
 INDIVIDUAL ANIMAL FINAL BODY AND ORGAN WEIGHTS
 (ANIMALS NECROPSIED ON DAY 26)

RELATIVE ORGAN WEIGHTS (% of body weight) FROM MALE RAT

GROUP	VII	10.0 MG/M3							
ANIMAL NUMBER	LUNGS	LIVER	KIDNEYS	SPLEEN	TESTES				
447142	0.4382	3.4867	0.7853	0.1966	0.8673				
447143	0.4676	3.5741	0.7224	0.2005	0.9667				
447146	0.4531	3.6111	0.8844	0.1875	0.9292				
447148	0.3777	3.8802	0.7864	0.1769	0.9161				
447149	0.4118	3.7930	0.9595	0.2165	1.0427				
GROUP MEAN	0.4297	3.6690	0.8276	0.1956	0.9444				
STD. DEV.	0.0356	0.1625	0.0938	0.0148	0.0654				

Company Sanitized. Does not contain TSCA CBI

HN-17375 [REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

Key to Appendix B

Mode of Death

SD = Sacrificed by Design

Lesion Codes

Histopathological changes are described according to their morphological character, distribution, and severity. The distribution (extent of tissue involvement) is indicated, where appropriate, by modifiers such as focal, multifocal, diffuse, unilateral, bilateral, etc.; a severity score, if appropriate, is also assigned as follows:

- Minimal - the amount of change present barely exceeds that which is considered to be within normal limits
- Mild - the amount of change present is easily detected
- Moderate - a large amount of change is present
- Severe - the degree of change within the affected area(s) is essentially as severe and complete as is thought possible

In terms of quantification, the terms mild and moderate represent progressive involvement/severity along a continuum. Thus, "mild" represents a change felt to be approximately one-third of the way along the continuum between minimal and marked, and "moderate" is approximately two-thirds of the way along this same continuum.

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

HN-17375 [REDACTED]

APPENDIX B
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: I DOSE: 0.0 MG/M3

ANIMAL #: 447112 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYIMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

HN-17375 [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: I DOSE: 0.0 MG/M3

ANIMAL #: 447113 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTEDMICROSCOPIC OBSERVATIONS:
PANCREAS

- ACINAR CELL ATROPHY, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES:
NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES:
NONE

HN-17375 [REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: I DOSE: 0.0 MG/M3

ANIMAL #: 447114 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS:

LIVER: - INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

HN-17375 [REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: I DOSE: 0.0 MG/M3

ANIMAL #: 447115 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, COLON, DUODENUM, EPIDIDYIMIDES, ESOPHAGUS, EYES, HEART, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: CECUM, ILEUM

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

HN-17375

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: I DOSE: 0.0 MG/M3

ANIMAL #: 447116 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
LUNGS

- DISCOLORATION, DARK RED PATCHY AREAS, DIFFUSE, (< 1 CM)

MICROSCOPIC OBSERVATIONS:

- INFLAMMATION, SUBACUTE, MINIMAL
- HEMORRHAGE, ACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: I DOSE: 0.0 MG/M3

ANIMAL #: 447117 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
RENAL PELVIS

- DILATATION, RIGHT, MODERATE

MICROSCOPIC OBSERVATIONS:

KIDNEYS
LIVER
- DILATATION, RENAL PELVIS, MILD
- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES:
NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES:
NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

HN-17375 [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: I DOSE: 0.0 MG/M3

ANIMAL #: 447118 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTEDMICROSCOPIC OBSERVATIONS:
LIVER

- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

HN-17375 [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: I DOSE: 0.0 MG/M3

ANIMAL #: 447119 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
RENAL PELVIS

DILATATION, SEVERE, RIGHT

MICROSCOPIC OBSERVATIONS:

KIDNEYS
LIVER
- DILATATION, RENAL PELVIS, MILD
- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES:
NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES:
NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: I DOSE: 0.0 MG/M3

ANIMAL #: 447120 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTEDMICROSCOPIC OBSERVATIONS:
LIVER

- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITIS, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES:
NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES:
NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)

INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: I DOSE: 0.0 MG/M3

ANIMAL #: 447121 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
RENAL PELVIS

- DILATATION, RIGHT; MODERATE

MICROSCOPIC OBSERVATIONS:

KIDNEYS
LIVER
- DILATATION, RENAL PELVIS, MILD
- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYIMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

HN-17375 [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: III DOSE: 1.0 MG/M3

ANIMAL #: 447122

DAYS ON TEST: 12

MODE OF DEATH: SD

GROSS OBSERVATIONS:

NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS:

LIVER - INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

HN-17375 [REDACTED]
 SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
 INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: III DOSE: 1.0 MG/M3
 ANIMAL #: 447123 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
 NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE
 THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES:
 NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES:
 NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: III DOSE: 1.0 MG/M3

ANIMAL #: 447124 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:

- LUNGS
- EPIDIDYMIDES
- FOCI, (< 2 MM), FEW, SCATTERED
- NODULE, (5 MM IN DIAMETER), RIGHT, TAIL, TAN

MICROSCOPIC OBSERVATIONS:

- EPIDIDYMIDES
- LIVER
- SPERM GRANULOMA, MILD
- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

HN-17375 [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: III DOSE: 1.0 MG/M3

ANIMAL #: 447126 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS:
LIVER

- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

Company Sanitized. Does not contain TSCA CRI

HN-17375 [REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: III DOSE: 1.0 MG/M3

ANIMAL #: 447125 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:

LUNGS - FOCI, (1 MM IN DIAMETER), RED, LEFT LOBE

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYIMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

HN-17375 [REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: III DOSE: 1.0 MG/M3

ANIMAL #: 447127 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

Company Sanitized. Does not contain TSCA CSI

HN-17375 [REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)

INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: III DOSE: 1.0 MG/M3

ANIMAL #: 447128 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS:
LIVER

- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

HN-17375 [REDACTED]
 SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]
 APPENDIX B (continued)
 INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: III DOSE: 1.0 MG/M3
 ANIMAL #: 447129 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
 NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

HN-17375 [REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)

INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: III DOSE: 1.0 MG/M3

ANIMAL #: 447130 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
RENAL PELVIS

- DILATATION, LEFT, MILD

MICROSCOPIC OBSERVATIONS:
LIVER

- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

HN-17375 [REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)

INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: III DOSE: 1.0 MG/M3

ANIMAL #: 447131 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS:

EYES
LIVER
- INFLAMMATION, CHRONIC, CORNEA, MINIMAL
- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMIDES, ESOPHAGUS, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

HN-17375
 SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
 INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: V DOSE: 5.0 MG/M3

ANIMAL #: 447132 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
 NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

HN-17375 [REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: V DOSE: 5.0 MG/M3

ANIMAL #: 447133 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

HN-17375 [REDACTED]
 SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
 INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: V DOSE: 5.0 MG/M3

ANIMAL #: 447134 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
 NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS:
 LIVER

- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYIMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES:
 NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES:
 NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

HN-17375 [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL #: 447135 DAYS ON TEST: 26 MALE RAT GROUP: V DOSE: 5.0 MG/M3
MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

HN-17375 [REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)

INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: V DOSE: 5.0 MG/M3

ANIMAL #: 447136 DAYS ON TEST: 28 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS:
LIVER

- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: V DOSE: 5.0 MG/M3

ANIMAL #: 447137 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYIMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: V DOSE: 5.0 MG/M3

ANIMAL #: 447138 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:

EPIDIDYIMIDES
ADRENALS
- SMALL, POSTERIOR END
- DEFORMITY, LEFT, MISSING

MICROSCOPIC OBSERVATIONS:

LIVER
- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYIMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

HN-17375 [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: V DOSE: 5.0 MG/M3

ANIMAL #: 447139 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTEDMICROSCOPIC OBSERVATIONS:
LIVER

- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITIS, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

HN-17375 [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: V DOSE: 5.0 MG/M3

ANIMAL #: 447140 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITIS, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES:
NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES:
NONE

Company Sanitized. Does not contain TSCA CBI

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: V DOSE: 5.0 MG/M3

ANIMAL #: 447141 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS:
LIVER

- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: VII DOSE: 10.0 MG/M3

ANIMAL #: 447142 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES:
NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES:
NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

HN-17375 [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: VII DOSE: 10.0 MG/M3

ANIMAL #: 447143 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITIS, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

HN-17375 [REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: VII DOSE: 10.0 MG/M3

ANIMAL #: 447144 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS:
LIVER

- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITIS, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: VII DOSE: 10.0 MG/M3

ANIMAL #: 447145 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:

RENAL PELVIS

- DILATATION, MILD, RIGHT

MICROSCOPIC OBSERVATIONS:

KIDNEYS
LIVER- DILATATION, RENAL PELVIS, MILD
- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

HN-17375 [REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: VII DOSE: 10.0 MG/M3

ANIMAL #: 447146 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS:
LIVER - INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: VII DOSE: 10.0 MG/M3

ANIMAL #: 447147 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS:
EPIDIDYMITIS

- SPERM GRANULOMA, MILD

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

HN-17375 [REDACTED]

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: VII DOSE: 10.0 MG/M3

ANIMAL #: 447148 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: VII DOSE: 10.0 MG/M3

ANIMAL #: 447149 DAYS ON TEST: 26 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITIDES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES: NONE

SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: VII DOSE: 10.0 MG/M3

ANIMAL #: 447150 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
NO ABNORMALITIES DETECTEDMICROSCOPIC OBSERVATIONS:
LIVER

- INFLAMMATION, SUBACUTE, MINIMAL

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITES, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES:
NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES:
NONE

HN-17375
 SUBCHRONIC INHALATION TOXICITY STUDY WITH [REDACTED]

APPENDIX B (continued)
 INDIVIDUAL ANIMAL PATHOLOGY DATA

MALE RAT GROUP: VII DOSE: 10.0 MG/M3

ANIMAL #: 447151 DAYS ON TEST: 12 MODE OF DEATH: SD

GROSS OBSERVATIONS:
 NO ABNORMALITIES DETECTED

MICROSCOPIC OBSERVATIONS: NONE

THE FOLLOWING TISSUES WERE UNREMARKABLE MICROSCOPICALLY: ADRENALS, BRAIN, CECUM, COLON, DUODENUM, EPIDIDYMITIS, ESOPHAGUS, EYES, HEART, ILEUM, JEJUNUM, KIDNEYS, LIVER, LUNGS, MESENTERIC LYMPH NODE, NOSE, PANCREAS, RECTUM, SPLEEN, STERNUM, STOMACH, TESTES, THYMUS, THYROID, TRACHEA, URINARY BLADDER

THE FOLLOWING TISSUES WERE AUTOLYZED; DEGREE OF AUTOLYSIS DID NOT PRECLUDE MICROSCOPIC EXAMINATION: NONE

THE FOLLOWING TISSUES WERE SEVERELY AUTOLYZED; MICROSCOPIC DIAGNOSES NOT MADE, ORGAN NOT COUNTED IN INCIDENCE TABLES:
 NONE

SECTIONS OF THE FOLLOWING TISSUES WERE NOT PRESENT FOR MICROSCOPIC EXAMINATION: NONE

SECTIONS OF THE FOLLOWING TISSUES WERE INSUFFICIENT FOR MICROSCOPIC EXAMINATION; ORGAN NOT COUNTED IN INCIDENCE TABLES:
 NONE