



CHEMICAL MANUFACTURERS ASSOCIATION

November 25, 1997

Dear Vinyl Chloride Health Committee Members:

Enclosed is the Unaudited Draft Final Report on the Vinyl Chloride Combined Inhalation Two-Generation Reproduction and Developmental Toxicity Study in CD Rats. Please review it and make comments by COB December 12, 1997. If you have any questions, please call Wendy K. Sherman at 703/741-5639. Thank you.

Sincerely,

A handwritten signature in black ink that reads "Cynthia Barrett".

Cynthia Barrett
Senior Admin Asst.,
Vinyl Chloride Health Committee

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STUDY NO. 96-4080

VINYL CHLORIDE COMBINED INHALATION TWO-GENERATION
REPRODUCTION AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS

Developmental Toxicity Study

Unaudited Draft Final Report

Submitted to: Chemical Manufacturers Association
Chemstar Department
1300 Wilson Boulevard
Arlington, Virginia 22209

Attn: Hasmukh C. Shah, Ph.D.

Date: 21 November 1997

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STATEMENT OF COMPLIANCE

This study was designed to meet or exceed the guideline requirements of the EPA (Environmental Protection agency: TSCA Test Guidelines (EPA, 1985); Organisation for Economic Co-Operation and Development (OECD, Guidelines for testing of chemicals, Section 4: Health Effects, (OECD, 1981); and European Economic Community (EEC), Methods for the Determination of Toxicity (EEC, 1988). This study was conducted in compliance with the FDA (Food and Drug Administration) Good Laboratory Practices (GLP) Regulations for Nonclinical Studies (FDA, 1988 - Part 5 of 21 CFR); EPA TSCA Good Laboratory Practice Standards (EPA, 1990 - Part 160 of 40 CFR); OECD Good Laboratory Practice Procedures (OECD, 1982 - Annex 2 C [81] 30 [FINAL]); and standard operating procedures of Huntingdon Life Sciences.

Raymond E. Schroeder, M.S., DABT
Study Director

Date

SIGNATURE PAGE

SCIENTIST

The following Scientist was responsible for the overall conduct of this study. Departmental supervisory personnel are listed on the personnel page of this report (Appendix P).

Raymond E. Schroeder, M.S., DABT
Study Director

Date

SCIENTIFIC REVIEW

The following Scientist has reviewed and approved this report.

Dean E. Rodwell, M.S.
Vice President, Toxicology Operations

Date

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QUALITY ASSURANCE STATEMENT

Listed below are the dates that this study was inspected by the Quality Assurance Unit of Huntingdon Life Sciences, East Millstone, New Jersey, and the dates that findings were reported to the Study Director and Management.

<u>Type of Inspection</u>	<u>Date(s) of Inspection</u>	<u>Reported to Study Director and Management</u>
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Quality Assurance Senior Auditor

Date

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ABSTRACT

This study conducted for Chemical Manufacturers Association, was designed to assess the potential toxicity and/or developmental toxicity of vinyl chloride. The test material was administered via whole body inhalation (six hours/day) to 100 mated rats (25 per group) at dose levels of 0, 10, 100 and 1100 ppm during the Day 6-19 gestation interval. The exposures for these animals were performed concurrent with those of the on-going two-generation reproduction study. Both studies are performed under the same study number; however, only the developmental toxicity study is included in this report.

Animals were observed twice daily for mortality/morbidity and for obvious pharmacologic and/or toxicologic effects and each animal was given a detailed physical examination on Days 0 and daily on Days 6-20 of gestation. During the treatment period, these latter examinations were conducted approximately one-half hour after exposures were completed. Body weights were recorded on Days 0, 6, 9, 12, 15 and 20 of gestation and food consumption was recorded for over Days 0-6, 6-9, 9-12, 12-15 and 15-20. Animals were sacrificed on Day 20 of gestation and given a macroscopic postmortem evaluation which included weighing of the gravid uterus, kidneys and liver. The ovaries were evaluated for the presence and number of corpora lutea and uterine implantation data was recorded. Fetuses were removed from the uterus, weighted, sexed and evaluated for external abnormalities. Subsequently, one-half of the fetuses were processed for visceral examination (microdissection technique) and the remaining fetuses processed for staining of the skeletal structures with Alizarin Red S and examined for skeletal malformations and ossification variations.

Mean exposure concentrations over the course of the study as determined by infrared spectrophotometry were close to the targeted concentration levels. The mean exposure concentration levels ($\pm$ standard deviation) for the 10, 100 and 1100 ppm groups were 10.8 ($\pm$ 1.1), 102 ($\pm$ 11) and 1110 ($\pm$ 45) ppm, respectively.

No maternal or developmental toxicity was seen at the 10 ppm exposure level. At the 100 ppm exposure level, the only maternal toxicity seen was an increase in the kidney weight relative to the Day 20 gestation weight. At the 1100 ppm exposure level, the only maternal toxicity was an increase in kidney and liver weights relative to the Day 20 gestation weights. No developmental toxicity was seen at either the 100 or 1100 ppm exposure levels. Thus, the no-observed-effect level (NOEL) for maternal toxicity with vinyl chloride in the pregnant rat was 10 ppm and the NOEL for developmental toxicity was 1100 ppm.

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1. INTRODUCTION

This study conducted for Chemical Manufacturers Association, was designed to assess the potential maternal toxicity and/or developmental toxicity of vinyl chloride. The test material was administered via whole body inhalation (six hours/day) to 100 mated rats (25 per group) at dose levels of 0, 10, 100 and 1100 ppm during the Day 6-19 gestation interval. The exposures for these animals were performed concurrent with those of the on-going two-generation reproduction study. Both studies are performed under the same study number. This report only includes the methods and results of the developmental toxicity study. Species and strain of test animal, method and route of test material administration and dose levels were determined by the Sponsor.

2. MATERIAL AND METHODS

2.1. REGULATORY REFERENCES

2.1.1. TEST GUIDELINES

This study was designed to meet or exceed the guideline requirements of the following: EPA (Environmental Protection Agency): TSCA Test Guidelines (EPA, 1985); Organization for Economic Co-operation and Development (OECD, Guidelines for testing of chemicals, Section 4: Health Effects, (OECD, 1981); and European Economic Community (EEC), Methods for the Determination of Toxicity (EEC, 1988).

2.1.2. GOOD LABORATORY PRACTICES

This study was conducted in compliance with FDA (Food and Drug Administration) Good Laboratory Practice (GLP) Regulations for Nonclinical Studies (FDA, 1988 - Part 58 of 21 CFR); EPA TSCA Good Laboratory Practice Standards (EPA, 1990 - Part 160 of 40 CFR); OECD Good Laboratory Practice Procedures (OECD, 1982 - Annex 2 C [81] 30 [FINAL]); and standard operating procedures of Huntingdon Life Sciences, Princeton Research Center.

2.1.3. ANIMAL WELFARE ACT COMPLIANCE

This study complied with all appropriate parts of the Animal Welfare Act regulations: 9 CFR Parts 1 and 2 Final Rules, Federal Register, Volume 54, No. 168, August 31, 1989, pp. 36112-36163 effective October 30, 1989 and 9 CFR Part 3 Animal Welfare Standards; Final

Rule, Federal Register, Volume 56, No. 32, February 15, 1991, pp. 6426-6505 effective March 18, 1991.

2.1.4. FACILITIES MANAGEMENT/ANIMAL HUSBANDRY

Currently acceptable practices of good animal husbandry were followed e.g., Guide for the Care and Use of Laboratory Animals, National Research Council, 1996. Huntingdon Life Sciences, East Millstone, New Jersey is fully accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC).

2.2. STUDY MANAGEMENT

2.2.1. SPONSOR

Chemical Manufacturers Association
Chemstar Department
1300 Wilson Boulevard
Arlington, Virginia 22209

2.2.2. SPONSOR REPRESENTATIVE

Hasmukh C. Shah, Ph.D.

2.2.3. TESTING FACILITY

Huntingdon Life Sciences
P.O. Box 2360
Mettlers Road
East Millstone, New Jersey 08875-2360

2.2.4. STUDY DIRECTOR

Raymond E. Schroeder, M.S., DABT

2.3. EXPERIMENTAL OUTLINE

Developmental Toxicity Study:

Group	Exposure Levels (ppm)	Treatment Schedule 6 hours/day	Number of Animals				
			Mated	Sacrificed ^a	Proportion of Gestation Day 20 Fetuses/Litter Malformation/Variation Evaluations		
				Gestation Day 20	External	Soft Tissue	Skeletal
I (chamber - housed, sham air control)	0	Gestation Days 6-19	25	25	All	½	½
II	10	Gestation Days 6-19	25	25	All	½	½
III	100	Gestation Days 6-19	25	25	All	½	½
IV	1100	Gestation Days 6-19	25	25	All	½	½

^aGross postmortem examinations performed and liver and kidneys were weighed and preserved along with gross lesions.

2.4. STUDY DATES

2.4.1. STUDY INITIATION

25 October 1996 (Date the Study Director signed the Protocol)

2.4.2. DATE OF ANIMAL RECEIPT

24 February 1997

2.4.3. INITIATION OF MATING

12 March 1997

2.4.4. INITIATION OF EXPOSURES

19 March 1997

2.4.5. TERMINATION OF EXPOSURES

10 April 1997

2.4.6. TERMINAL SACRIFICE

2-11 April 1997

2.4.7. STUDY TERMINATION

Date Final Report is signed by the Study Director.

2.5. TEST MATERIAL

Vinyl Chloride

2.5.1. SUPPLIER

The GEON Company
Pedricktown, NJ 08067

2.5.2. LOT NUMBER

1

2.5.3. DATE RECEIVED

28 August 1996

2.5.4. DESCRIPTION

Colorless gas

2.5.5. PURITY

>99.9%

2.5.6. STORAGE

Room temperature

2.5.7. ANALYSIS

The purity of the lot of test material used on study was determined at the start of the program of studies, approximately 6-months into the program and at termination. These analyses were performed by the Analytical Laboratory of Huntingdon Life Sciences. Results of these analyses will be presented in the ensuing reproduction study.

2.5.8. ARCHIVAL SAMPLES

A small sample (approximately 150 mls) from the lot of test material used for this study was taken and is being stored in the Archives of Huntingdon Life Sciences.

2.5.9. DISPOSITION

At completion of the program of studies (reproductive study and developmental toxicity study), unused test material in the one ton pressurized cylinder was returned to the Supplier (The GEON Company, Pedricktown, NJ 08067). This lot of test material will be retained at GEON until issuance of the final reports.

2.6. TEST ANIMALS

Albino Rats (Outbred) VAF/Plus®

2.6.1. STRAIN

CD® (Sprague-Dawley derived) [Cri: CD® BR]

2.6.2. SUPPLIER

Charles River Laboratories
Portage, Michigan 49081

2.6.3. NUMBER OF ANIMALS

Received: 160 females
Placed on-test: 100 females

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2.6.4. AGE AT RECEIPT

Females were 57 days in age at receipt.

2.6.5. WEIGHT AT GESTATION DAY 0

Mean: 213 grams

Range: 172-252 grams

2.6.6. JUSTIFICATION FOR ANIMAL SELECTION

The rat is a rodent animal model commonly utilized in reproduction/developmental toxicity studies as recommended in the referenced guidelines. In addition, a historical data base is available at Huntingdon Life Sciences, East Millstone, New Jersey with this strain of rat for comparative evaluations.

2.6.7. ACCLIMATION PERIOD

Approximately two weeks; all animals were observed for viability twice daily. Prior to mating, all animals were examined by the technical staff to ascertain suitability for study.

2.7. SELECTION/GROUP ASSIGNMENT

More females than required for the study were purchased and acclimated. Animals considered suitable for study on the basis of pretest physical examinations were included into the mating phase of the study. Females which mated were randomly assigned to groups daily in such a way as to most nearly equalize both the Day 0 gestation mean body weights between groups and the distribution of animals into groups. This was done by ranking the animals by body weight from lightest to heaviest and randomly assigning them to groups in blocks using a random numbers table.

2.8. MATING

Females selected for mating were co-housed with male rats from an in-house breeding colony nightly in a 1:1 ratio. Vaginal smears were taken early in the morning following nightly intervals of co-housing. The females were considered to have mated if sperm was observed microscopically in the vaginal smear and/or a vaginal plug was observed. The day on which evidence of mating was observed was defined as Day 0 of gestation.

2.9. ANIMAL IDENTIFICATION

Each female was assigned a temporary identification number upon receipt. Mated females were ear-tagged with a number assigned by Huntingdon Life Sciences that was unique. This number plus the study number comprised a unique identification for each animal. Females were ear-tagged on Day 0 of gestation.

2.10. VETERINARY CARE

Animals were monitored by the technical staff daily for any conditions requiring possible veterinary care.

2.11. HUSBANDRY DURING NON-EXPOSURE PERIODS¹

2.11.1. HOUSING

Animals were housed individually, except during mating, in suspended stainless steel cages with wire mesh floors. During mating, one male and one female were co-housed overnight until evidence of mating was seen.

2.11.2. FOOD

Certified Rodent Diet, No. 5002; (Meal) (PMI Feeds, Inc., St. Louis, Missouri) without restriction, except during exposure

2.11.3. FEED ANALYSES

Analytical certification of batches of feed provided by the manufacturer were maintained on file at Huntingdon Life Sciences.

2.11.4. WATER

Facility water (supplied by Elizabethtown Water Company, Westfield, New Jersey); without restriction, provided to individual animal cages via an automated watering system.

¹ See Inhalation Report (Appendix N, page N-2) for husbandry during exposure periods.

2.11.5. MONTHLY WATER ANALYSES

Monthly water analysis, provided by the supplier, are maintained on file at Huntingdon Life Sciences.

2.11.6. BIENNIAL WATER ANALYSES

Biannual chemical and microbiological analyses of water samples collected from representative rooms in this facility were conducted to assure that water met standards specified under EPA National Primary Drinking Water Regulations (40 CFR Part 141). Results are maintained on file.

2.11.7. CONTAMINANTS

There were no known contaminants in the feed or water which were expected to interfere with the results of this study.

2.11.8. ENVIRONMENTAL CONDITIONS

Light/Dark Cycle

Twelve hour light/dark cycle controlled via an automatic timer.

Temperature

Temperature was monitored and recorded twice daily.

Desired: 20 to 24°C

Actual: 20 to 23°C

Relative Humidity

Relative humidity was monitored and recorded once daily.

Desired: 40 to 70%

Actual: 32 to 76%

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2.12. TEST MATERIAL ADMINISTRATION

The test material was administered as a gas in the breathing air of the animals. The test atmospheres were generated by an appropriate procedure developed at the Testing Facility.

2.12.1. ROUTE OF ADMINISTRATION

The test material was administered via whole-body inhalation.

2.12.2. FREQUENCY OF TREATMENT

Females were treated 6 hrs/day over the Day 6-19 gestation interval.

2.12.3. JUSTIFICATION FOR ROUTE OF ADMINISTRATION

The inhalation route is one of the potential routes of human exposure to this test material.

2.12.4. DOSE LEVELS

Group I - 0 ppm
Group II - 10 ppm
Group III - 100 ppm
Group IV - 1100 ppm

2.12.5. INHALATION EXPOSURE GENERATION PROCEDURES

Complete exposure procedures are presented in Appendix N (pages 4 and 5).

2.12.6. CHAMBER MONITORING

Chamber operation and monitoring procedures are presented in Appendix N (pages 3-6).

2.12.7. JUSTIFICATION FOR EXPOSURE CONCENTRATIONS

The targeted exposure concentrations of vinyl chloride were 0, 10, 100 and 1100 ppm. These exposure levels correspond to oral equivalent doses of approximately 0, 9.2, 92 and 1012 mg/kg/day at ventilation rates of 1 L/min/kg, 100 percent absorption and a 6 hour/day exposure. The high concentration of vinyl chloride was selected based on the oral

equivalent of the limit dose of 1000 mg/kg body weight/day. The high exposure level of 1100 ppm was also expected to produce effects on the liver and other organ systems (ATSDR, 1993). The middle and low exposure levels were selected to provide a dose response for the observed effects and a no-observed effect level, respectively.

2.13. EXPERIMENTAL EVALUATIONS

2.13.1. VIABILITY CHECKS

Animals were observed, at least twice daily in their cages, for mortality, general appearance and signs of severe toxic or pharmacologic effects. Animals in extremely poor health or in a possible moribund condition were identified for further monitoring and possible euthanasia.

2.13.2. PHYSICAL EXAMINATIONS

Animals were removed from their cages and examined on Days 0 and 6-20 of gestation. Examinations included observations of general condition, skin and fur, eyes, nose, oral cavity, abdomen and external genitalia as well as evaluations of respiration. Unusual behavior and physical signs were recorded. During the test period, observations were performed postexposure when animals were being transferred to their home cages.

2.13.3. BODY WEIGHT

Animals were removed from their cages and weighed using a Mettler Balance, Model PE4000 (Mettler Instrument Corporation, Hightstown, New Jersey). Body weights were recorded on Days 0, 6, 9, 12, 15 and 20 of gestation.

2.13.4. FOOD CONSUMPTION

Food was available, without restriction, 7 days/week, except during exposure periods. Animals were presented with weighed feeders on Days 0, 6, 9, 12 and 15 of gestation. Feeders were removed on Days 6, 9, 12, 15 and 20 of gestation and a "feeder-out" weight recorded using a Mettler Balance, Model PE4000 (Mettler Instrument Corporation, Hightstown, New Jersey). The resulting weight was subtracted from the

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presentation weight of the feeder to obtain the grams consumed per animal per interval.

Calculations

grams of food consumed per interval + no. of days = grams/animal/day

grams of food consumed/kilogram of body weight/day (g/kg/day) =

$$\frac{\text{grams of feed consumed}}{\text{previous body weight (kg)}} + \text{no. of days}$$

Measurement intervals (i.e., the number of days over which food consumption was measured) and the body weight interval used to calculate grams of feed per kilogram of body weight per day (g/kg/day) are as follows:

- Day 0-6 = 6-day interval using Day 0 body weight.
- Day 6-9 = 3-day interval using Day 6 body weight.
- Day 9-12 = 3-day interval using Day 9 body weight.
- Day 12-15 = 3-day interval using Day 12 body weight.
- Day 15-20 = 5-day interval using Day 15 body weight.

2.14. POSTMORTEM

2.14.1. NECROPSY INFORMATION

Method of Euthanasia

Exsanguination following anesthesia with inhaled carbon dioxide.

2.14.2. MACROSCOPIC EXAMINATIONS

Complete macroscopic postmortem examinations were performed on all mated rats. Gross lesions were saved in 10% neutral buffered formalin. During these examinations, the liver and kidneys were also weighed and preserved in 10% neutral buffered formalin for possible future examination. Females were sacrificed on Day 20 of gestation and examined as follows:

Reproductive System

The intact uterus (ovaries attached) was removed from the abdominal cavity and weighed intact (with fetuses and placenta) using a Mettlers

AK-160 balance (Mettler Instrument Corporation, Hightstown, New Jersey). The uterus was then opened along the antimesometrial border and the number and location of the following were recorded for each uterine horn:

- live fetuses - movement in response to touch.
- dead fetuses - lack of movement in response to touch with no visible degeneration.
- late resorptions - recognizable dead fetus undergoing degeneration regardless of size.
- early resorptions - evidence of implantation but no recognizable fetus.
- implantation sites - total of resorptions and fetuses.

Uteri without grossly visible implantations were stained according to the procedure of Salewski (1964) to identify the presence of sites of early resorption. If no stained sites were present, the female was considered not pregnant.

Ovaries

The ovaries were dissected free from the uterus and evaluated for the presence and number of corpora lutea.

2.14.3. FETAL EVALUATIONS

External Evaluations

Each fetus was individually weighed using a Mettler Balance, Model PE4000, sexed externally (ano-genital distance) and examined for external malformations/variations to include observation for palatal defects.

Skeletal Evaluations

Approximately one-half of the fetuses in each litter (alternating fetuses within the litter) were processed for Alizarin Red S staining of the skeletal structures. Prior to processing, the intact fetuses were killed (overdose of inhaled carbon dioxide) and eviscerated (internal sex

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noted). Following staining, these fetuses were evaluated under a dissecting microscope for skeletal malformations and/or ossification variations.

Soft Tissue Evaluations

The remaining fetuses in each litter were processed for soft tissue examination using a microdissection technique similar to the procedure of Staples (1974). The evaluations were performed on the fresh fetal specimens soon after removal from the uterus. The fetuses designated for soft tissue evaluation were decapitated (head placed in Bouin's solution for later evaluation). The fetal specimens were dissected so as to permit evaluation of tissues in the thoracic, abdominal and pelvic cavities. At completion of the examination, these fetuses were eviscerated and processed for Alizarin Red S staining of the skeletal structures. The stained fetal specimens are being retained with the rest of the study specimens. Fetal heads were sectioned with a razor blade. The serial, transverse sections generated during this procedure were evaluated for malformations of the palate, eyes and brain. Fetal soft tissue evaluations (microdissection and head sections) were performed under a dissecting microscope.

Resorptions

Late resorptions were removed from the uterus, crown-rump distance recorded and examined for external malformations. Malformation data for late resorptions is reported but not included in the analyses of malformation data for live or dead fetuses recovered on Day 20 of gestation. Only late resorptions with external malformations were saved (10% neutral buffered formalin). Early resorptions were noted and discarded without any further evaluation.

2.15. STATISTICAL ANALYSIS

The following items were analyzed statistically in the final report:

2.15.1. CONTINUOUS DATA:

Body weights (all recorded intervals)*

Body weight change (between all recorded intervals to include Days 6-20 of gestation using the actual and corrected Day 20 gestation weights)*

Food consumption values (all recorded intervals)^a
Organ weight data^a
Number of corpora lutea^a
Uterine implantation data (fetuses^a, resorptions^b, implantations^a)
Pre-implantation loss^b
Post-implantation loss^b
Mean percent male and female fetuses per litter^a
Fetal weight distinguished by sex and as a composite for both sexes (litter as experimental unit)^a

2.15.2. CONTINUOUS DATA - MULTIPLE GROUP ANALYSIS:

Employed when data for more than one treated group is compared to control. All statistical tests were conducted at the 5% and 1%, two-sided risk levels.

^aStatistical evaluation of equality of means was made by the appropriate one way analysis of variance (ANOVA) technique, followed by a multiple comparison procedure, if needed. If ANOVA showed difference, no additional comparisons were made. If ANOVA was significant, Dunnett's test was used to determine which data, if any, differed from the control.

References for these techniques are as follows:

Dunlap, W.P. and J.A. Duffy (1975) "Fortran IV functions for calculating exact probabilities associated with Z, Chi-square, T and F values." Behav. Res. Methods and Instrumentations, 7:59-60.

Dunlap, W.P., M.S. Marx and G.J. Agamy (1981) "Fortran IV functions for calculating probabilities associated with Dunnett's Test", Behav. Res. Methods and Instrumentations, 13:363-366.

^bThe Kruskal-Wallis test (2 X n) was used to test equality of means. If no differences were seen, no additional analyses were performed. If differences were indicated, a 2 X 2 Kruskal-Wallis test was used to determine which treatment groups differed from control.

References for these techniques are as follows:

Dunlap, W.P. and J.A. Duffy (1975) "Fortran IV functions for calculating exact probabilities associated with Z, Chi-square, T and F values." *Behav. Res. Methods and Instrumentations*, 7:59-60.

Siegel, S. (1956) *Nonparametric Statistics for the Behavioral Sciences* McGraw-Hill, New York.

2.15.3. INCIDENCE DATA:

Mortality rate

Pregnancy rates

Incidence of litters containing fetuses with malformations (external, soft tissue and skeletal - total affected and by finding)

2.15.4. INCIDENCE DATA ANALYSIS:

A Fisher Exact Test with Bonferonni correction was performed to identify differences between the groups.

References for these techniques are as follows:

Hollander, M. and D. A. Wolf (1973) Nonparametric Statistical Methods, Wiley, New York, NY, pp. 120-123.

Siegel, S. (1956) Nonparametric Statistics for the Behavioral Sciences, McGraw-Hill, pp. 98-99 and 104-106.

2.16. DATA STORAGE

All data documenting experimental details and study procedures and observations will be recorded and maintained as raw data. At the completion of the study, all reports, raw data, preserved specimens, and retained samples pertaining to the portions of the study performed at Huntingdon Life Sciences, as well as the original study protocol and the original final report will be maintained in the Archives of Huntingdon Life Sciences for a period of ten years after submission of the signed final report. The Sponsor will be contacted in order to determine the final disposition of these materials.

2.17. PROTOCOL DEVIATION

The following protocol deviation occurred during the study but was not considered to have compromised the validity or integrity of the study:

Relative humidity in the animal quarters was out of the protocol specified range on several occasions.

3. RESULTS AND DISCUSSION

3.1. CHAMBER MONITORING RESULTS

(Appendix N)

The results of the Miran and gas chromatographic (GC) analyses of the exposure concentrations are summarized below. These data are presented in Appendix N, pages N-10 to N-18 and demonstrate for each of the treated groups good correlation between the Miran and GC values and that these exposure levels were similar to the calculated nominal levels.

Group	Target Conc. (ppm)	Mean Miran Analytical Conc. (ppm) ($\pm$ SD)	Mean GC Analytical Conc. ($\pm$ SD)	Mean Nominal Conc. (ppm) ($\pm$ SD)
I	0	0.0 ($\pm$ 0.1)	0.5 ($\pm$ 1.0)	0
II	10	10.8 ($\pm$ 1.1)	10.9 ($\pm$ 1.8)	9.2 (0.6)
III	100	102 ($\pm$ 11)	105 ($\pm$ 14)	102 ($\pm$ 9)
IV	1100	1110 ($\pm$ 45)	1212 ($\pm$ 120)	1110 ($\pm$ 43)

Key: Conc. = concentration; SD = Standard Deviation; GC = gas chromatograph

3.2. MATERNAL DATA

3.2.1. MORTALITY

(Table 1; Appendix A)

No mortality occurred in the control or vinyl chloride treated groups. All animals survived to scheduled sacrifice.

3.2.2. PREGNANCY RATES

(Table 1; Appendix F)

Pregnancy rates were comparable between the control and vinyl chloride-treated groups. Pregnancy rates for the control, 10, 100 and 1100 ppm treated groups were 92% , 96%, 88% and 96%, respectively.

3.2.3. PHYSICAL OBSERVATION DATA

(Table 2; Appendix A)

No adverse effect of treatment with vinyl chloride was indicated from clinical findings noted during the detailed physical examinations. There was a slight increase in the incidence of females with alopecia of the extremities and/or snout in the 100 ppm group but in the absence of a similar increase in the 1100 ppm group, this was not considered treatment-related. Other clinical findings seen in the treated groups occurred at low incidence or with similar frequency as control and were not considered treatment-related..

3.2.4. BODY WEIGHT DATA - GESTATION PERIOD

(Tables 3, 4 and 8; Appendices B, C and G)

Mean body weights for the treated groups were comparable to control data during the pretreatment period (Days 0-6) and early in the treatment period (Days 6-9, 9-12, 12-15). For Days 15-20 of gestation, mean body weights for all three treated groups were significantly lower than control. Because these differences were slight (less than 10% in comparison to control data in the 100 and 1100 ppm groups and 12% in the 10 ppm group) and not dose-responsive, their toxicological significance, if any, is unclear. The significant decrease in body weight gain seen for all three treated groups over the Day 6-20 gestation interval in comparison to control data was attributed to the reduction in body weight gain seen in these groups over the Day 15-20 gestation period. Mean body weight gains for all treated groups over the Day 6 to Day 20 gestation interval using the corrected Day 20 gestation weights (actual Day 20 gestation weight minus the weight of the gravid uterus) were comparable to control data.

3.2.5. FOOD CONSUMPTION DATA - GESTATION PERIOD

(Tables 5 and 6; Appendices D and E)

Mean food consumption data for the vinyl chloride-treated groups on both a grams/animal/day and grams/kg body weight/day basis were comparable to control during the pretreatment (Days 0-6) and treatment period (Days 6-9, 9-12, 12-15 and 15-20) were comparable to control and unaffected by treatment.

3.2.6. CORPORA LUTEA AND UTERINE IMPLANTATION DATA

(Table 7; Appendix F)

No effect of treatment with vinyl chloride at an exposure level up to and inclusive of 1100 ppm was evident from corpora lutea or uterine implantation data. The mean corpora lutea and uterine implantation data (implants, fetuses, resorptions) for the treated groups were comparable to control data. Likewise, the mean pre- and post-implantation loss indices were comparable between these same groups.

3.2.7. MACROSCOPIC POSTMORTEM EVALUATIONS

(Table 9; Appendix I)

The few findings seen among the vinyl chloride-treated females during the maternal macroscopic postmortem examinations occurred as single occurrences and were not considered treatment-related.

3.2.8. MATERNAL LIVER AND KIDNEY WEIGHT RATIOS

(Table 10; Appendix J)

Liver weights, absolute and relative to actual Day 20 gestation weights, were comparable to control data in the 10 and 100 ppm dose groups. In the 1100 ppm group, absolute liver weight was comparable to control data but the relative weight was significantly increased and this change was considered indicative of a treatment-related response.

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Kidney weights, absolute and relative to the Day 20 gestation weights, were comparable to control in the 10 ppm group. In the 100 and 1100 ppm groups, absolute kidney weights were comparable to control data but relative weights were slightly higher. These latter differences were statistically significant and considered indicative of a treatment-related response.

3.3. FETAL DATA

3.3.1. FETAL BODY WEIGHT DATA

(Table 7; Appendices F and H)

No adverse effect of treatment with vinyl chloride at a dose level up to and inclusive of 1100 ppm was seen from fetal body weight data. Mean fetal body weights distinguished by sex and for both sexes combined were comparable between the control and treated groups.

3.3.2. FETAL SEX DISTRIBUTION DATA

(Table 7; Appendix F)

No adverse effect of treatment with vinyl chloride at a dose level up to and inclusive of 1100 ppm was seen from fetal sex distribution data. The mean percentage of male and female fetuses per litter was comparable between the control and treated groups.

3.3.3. FETAL EXTERNAL EXAMINATION DATA

(Tables 11 and 12; Appendix K)

No malformations were seen in the external examination of the 318 control fetuses from 23 litters, 297 Group II (10 ppm) fetuses from 24 litters or 283 Group III (100 ppm) fetuses from 22 litters. In the 1100 ppm group, craniorachischisis, a severe malformation involving the cranium and spinal cord, was seen in one fetus from the litter of female No. 4622. No other external malformations were seen in the remaining 304 fetuses examined in the 1100 ppm group from 24 litters. Though not seen in recent historical control data for this laboratory (Appendix O, pages 0-7), a low incidence of craniorachischisis has been noted in the recently published MARTA/MTA compilation of historical control data for the Crl:CD® BR rat (average fetal and litter occurrences were

0.005% and 0.069, respectively.) The craniorachischisis seen in the high-dose group was considered to be an isolated occurrence and not treatment-related.

One late resorption from the 10 ppm group had multiple facial malformations involving absence of snout, fleshy growth in the region of the snout and absence of the upper and lower jaw. This was the only late resorption seen in this study from the control and treated females.

3.3.4. FETAL VISCERAL EXAMINATION DATA

(Tables 11 and 12; Appendix L)

No visceral malformations were seen in the 167 control fetuses from 23 litters, 155 Group II (10 ppm) fetuses from 24 litters or the 158 Group IV (1100 ppm) fetuses from 24 litters. A low incidence of dissimilar visceral malformations was seen in the 147 Group III (100 ppm) fetuses from 22 litters. In the absence of similar visceral malformations among the high-dose fetuses, the occurrence of these malformations in the mid-dose group were considered spontaneous and not treatment-related.

Other visceral findings such as distended ureter and/or distended renal pelvis are considered variations and these were seen with comparable frequency between the control and treated groups and no effect of treatment was evident from these data.

3.3.5. FETAL SKELETAL EXAMINATION DATA

(Tables 11 and 12; Appendix M)

No skeletal malformations were seen in the 151 control fetuses from 23 litters, 142 Group II (10 ppm) fetuses from 142 fetuses from 24 litters or 136 Group III (100 ppm) fetuses from 22 litters. In Group IV (1100 ppm), the only skeletal malformation involved the fetus noted during the external examination with craniorachischisis. No adverse effect of treatment was evident from fetal skeletal malformation data.

No adverse effect of treatment was evident from fetal ossification variation data. The litter incidences for the various ossification variations seen during the study were generally comparable between the control and treated groups. In the high-dose group, the incidence of litters containing at least one fetus with reduced ossification of the cervical arches was significantly lower than control. This was not considered to represent an adverse effect of treatment.

4. CONCLUSION

In this study, vinyl chloride was administered via whole body inhalation (6 hrs./day) to pregnant rats at dose levels of 0, 10, 100 and 1100 ppm during Days 6-19 of gestation. No maternal or developmental toxicity was seen at the 10 ppm exposure level. At the 100 ppm exposure level, the only maternal toxicity seen was an increase in the kidney weight relative to the Day 20 gestation weight. At the 1100 ppm exposure level, the only maternal toxicity was an increase in kidney and liver weights relative to the Day 20 gestation weights. No developmental toxicity was seen at either the 100 or 1100 ppm exposure levels. Thus, the no-observed-effect level (NOEL) for maternal toxicity with vinyl chloride in the pregnant rat was 10 ppm and the NOEL for developmental toxicity was 1100 ppm.

REFERENCES AND CALCULATIONS

REFERENCES

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REFERENCES AND CALCULATIONS

CALCULATIONS

Preimplantation Loss:

no. of corpora lutea - no. of implantation sites/no. of corpora lutea

Postimplantation Loss:

no. of implantation sites - no. of viable fetuses/no. of implantation sites

TABLE

1

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TABLE 1

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF SURVIVAL AND PREGNANCY

Group Dose Level		I 0	II 10	III 100
No. of females mated	N	25	25	25
Pregnant	N	23	24	22
- Died/sacrificed moribund	N	0	0	0
- Elective sacrifice	N	0	0	0
Nonpregnant	N	2	1	3
- Died/sacrificed moribund	N	0	0	0
- Elective sacrifice	N	0	0	0
Total no. of females died/ sacrificed moribund	N %	0 0.0	0 0.0	0 0.0
Examined at scheduled c-section	N	25	25	25
- Nonpregnant	N	2	1	3
- With total implant loss	N %	0 0.0	0 0.0	0 0.0
- With viable fetuses	N %	23 92.0	24 96.0	22 88.0

No statistically significant differences

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TABLE

2

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TABLE 2

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF CLINICAL OBSERVATIONS DURING GESTATION (frequency/animal)

Group Dose Level	I 0	II 10	III 100

TERMINAL SACRIFICE	25/25	25/25	25/25
Gen. Appearance			
RED EXUDATE FROM ANO-GENITAL AREA	0/ 0	1/ 1	0/ 0
Dermal-General			
ALOPECIA - EXTREMITIES/SNOUT	10/ 2	11/ 1	45/ 0
ALOPECIA - GENERAL	4/ 1	0/ 0	0/ 0
Ocular			
CHROMODACRYORRHEA - UNILATERAL	6/ 1	4/ 2	0/ 0
LACRIMATION - UNILATERAL	2/ 1	0/ 0	0/ 0
Oral/Buccal			
INCISORS BROKEN/MISSING	0/ 0	11/ 1	0/ 0
INCISORS MALOCCLUDED	9/ 1	8/ 2	0/ 0

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TABLE
3

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TABLE 3

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF GESTATION BODY WEIGHTS (GRAMS)

Group Dose Level		I 0	II 10	III 100
DAY 0	MEAN	214	214	210
	S.D.	13.7	12.3	12.9
	N	23	24	22
DAY 6	MEAN	243	240	240
	S.D.	14.8	13.3	13.7
	N	23	24	22
DAY 9	MEAN	254	250	251
	S.D.	16.0	13.8	13.2
	N	23	24	22
DAY 12	MEAN	270	266	266
	S.D.	15.8	16.7	13.2
	N	23	24	22
DAY 15	MEAN	287	282	282
	S.D.	19.0	15.8	14.5
	N	23	24	22
DAY 20	MEAN	353	340	341
	S.D.	25.3	19.2	23.6
	N	23	24	22

No statistically significant differences

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TABLE

4

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PAGE 1

TABLE 4

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF GESTATION BODY WEIGHT GAIN (GRAMS)

	Group		Dose Level		I		II		III		IV	
					0		10		100		1100	
DAYS 0 TO 6	MEAN	29	26						30		28	
	S.D.	5.6	5.8						8.9		10.3	
	N	23	24						22		24	
DAYS 6 TO 9	MEAN	10	10						10		8	
	S.D.	5.8	5.7						4.6		3.6	
	N	23	24						22		24	
DAYS 9 TO 12	MEAN	16	16						16		15	
	S.D.	3.5	5.7						3.9		4.8	
	N	23	24						22		24	
DAYS 12 TO 15	MEAN	17	16						15		16	
	S.D.	4.3	4.0						4.8		3.9	
	N	23	24						22		24	
DAYS 15 TO 20	MEAN	66	58*						60*		60*	
	S.D.	8.7	8.2						12.7		7.8	
	N	23	24						22		24	
DAYS 6 TO 20	MEAN	110	100*						101*		99*	
	S.D.	13.5	13.8						14.0		10.4	
	N	23	24						22		24	

Statistical key: * = p<0.05

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TABLE

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TABLE 5

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF GESTATION FOOD CONSUMPTION (GRAMS/ANIMAL/DAY)

Group Dose Level		I 0	II 10	III 100
DAYS 0 TO 6	MEAN	19	19	19
	S.D.	2.5	1.7	1.7
	N	23	24	22
DAYS 6 TO 9	MEAN	18	19	19
	S.D.	1.6	1.9	2.0
	N	23	24	22
DAYS 9 TO 12	MEAN	20	20	20
	S.D.	1.7	2.6	1.7
	N	23	24	22
DAYS 12 TO 15	MEAN	21	22	22
	S.D.	2.0	1.7	2.2
	N	22	24	22
DAYS 15 TO 20	MEAN	24	23	23
	S.D.	1.9	1.9	2.2
	N	23	24	22

No statistically significant differences

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TABLE

6

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TABLE 6

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF GESTATION FOOD CONSUMPTION (GRAMS/KG/DAY)

Group Dose Level		I 0	II 10	III 100
DAYS 0 TO 6	MEAN	90	89	93
	S.D.	10.2	8.5	10.7
	N	23	24	22
DAYS 6 TO 9	MEAN	76	77	77
	S.D.	5.3	6.7	8.0
	N	23	24	22
DAYS 9 TO 12	MEAN	79	81	81
	S.D.	6.3	8.0	5.6
	N	23	24	22
DAYS 12 TO 15	MEAN	79	81	81
	S.D.	4.8	5.3	7.3
	N	22	24	22
DAYS 15 TO 20	MEAN	84	83	82
	S.D.	4.2	5.9	4.7
	N	23	24	22

No statistically significant differences

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TABLE

7

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TABLE 7
Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF CESAREAN SECTION DATA

Group Dose Level			I 0	II 10	III 100
Pregnant	N		23	24	22
Dams with no Viable Fetuses	N		0	0	0
Dams with Viable Fetuses	N		23	24	22
Corpora Lutea	TOTAL		351	355	337
No. per animal	MEAN		15.3	14.8	15.3
	S.D.		1.45	3.41	4.31
Implantation Sites	TOTAL		327	309	289
No. per animal	MEAN		14.2	12.9	13.1
	S.D.		1.38	1.80	2.55
Preimplantation Loss	TOTAL		24	46	48
No. per animal	MEAN		1.0	1.9	2.2
	S.D.		1.19	2.75	3.02
% per animal	MEAN%		6.6	11.1	11.8
	S.D.		7.22	11.21	12.68
Live Fetuses	TOTAL		318	297	283
No. per animal	MEAN		13.8	12.4	12.9
	S.D.		1.64	1.84	2.57
Males	TOTAL		149	149	133
	MEAN%		46.7	50.7	46.5
	S.D.		14.39	16.50	12.41
Females	TOTAL		169	148	150
	MEAN%		53.3	49.3	53.5
	S.D.		14.39	16.50	12.41

No statistically significant differences

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TABLE 7

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF CESAREAN SECTION DATA

Group Dose Level		I 0	II 10	III 100
Postimplantation Loss No. per animal	TOTAL	9	12	6
	MEAN	0.4	0.5	0.3
	S.D.	0.58	0.78	0.77
% impl. per animal	MEAN%	2.9	3.8	2.0
	S.D.	4.26	5.66	5.40
Dead Fetuses No. per animal	TOTAL	0	0	0
	MEAN	0.0	0.0	0.0
	S.D.	0.00	0.00	0.00
% of impl. per animal	MEAN%	0.0	0.0	0.0
	S.D.	0.00	0.00	0.00
Resorptions: Early No. per animal	TOTAL	9	11	6
	MEAN	0.4	0.5	0.3
	S.D.	0.58	0.72	0.77
% of impl. per animal	MEAN%	2.9	3.5	2.0
	S.D.	4.26	5.17	5.40
Resorptions: Late No. per animal	TOTAL	0	1	0
	MEAN	0.0	0.0	0.0
	S.D.	0.00	0.20	0.00
% of impl. per animal	MEAN%	0.0	0.3	0.0
	S.D.	0.00	1.57	0.00

No statistically significant differences

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TABLE 7

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF CESAREAN SECTION DATA

	Group Dose Level	I		II		III		IV	
		0		10		100		1100	
Fetal Body Weight (g)	MEAN	3.4		3.4		3.4		3.3	
	S.D.	0.17		0.17		0.22		0.22	
	N	23		24		22		24	
Male Fetuses	MEAN	3.5		3.5		3.5		3.4	
	S.D.	0.22		0.19		0.24		0.21	
Female Fetuses	MEAN	3.3		3.3		3.3		3.2	
	S.D.	0.16		0.18		0.22		0.23	
No statistically significant differences									

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TABLE

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TABLE 8

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF GRAVID UTERINE WEIGHT AND NET BODY WEIGHT CHANGE (GRAMS)

	Group Dose Level	I 0	IX 10	III 100	IV 1100
NET BODY WT. CHANGE	MEAN S.D. N	110 13.5 23	100* 13.8 24	101* 14.0 22	99* 10.4 24
GRAVID UTERINE WT.	MEAN S.D. N	75 9.7 23	69 10.0 24	70 12.0 22	69 10.4 24
NET WEIGHT CHANGE MINUS UTERINE WT.	MEAN S.D. N	35 8.5 23	31 9.1 24	31 9.0 22	30 7.6 24

Statistical key: * = p<0.05

NET BODY WT. CHANGE - TERMINAL BODY WT. MINUS DAY 6 BODY WEIGHT
NET WEIGHT CHANGE - NET BODY WT. CHANGE MINUS UTERINE WEIGHT

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TABLE 9

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TABLE 9

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF MATERNAL NECROPSY OBSERVATIONS

Group Dose Level	I				II				III				IV			
	25				10				100				1100			
DAWS	N				25				25				25			
GROSS EXAM	N				1				0				0			1
ALOPECIA	N				1				0				0			1
	%				4.0				0.0				0.0			4.0
KIDNEY	N				0				1				0			0
KIDNEY DISTENDED	N				0				1				0			0
	%				0.0				4.0				0.0			0.0
BLADDER	N				0				0				0			1
BLADDER HYPERPLASIA	N				0				0				0			1
	%				0.0				0.0				0.0			4.0
UTERUS	N				0				0				0			1
UTERUS DISTENDED	N				0				0				0			1
	%				0.0				0.0				0.0			4.0

no significant differences

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TABLE

10

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TABLE 10
Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats
SUMMARY OF ABSOLUTE ORGAN WEIGHTS

Group		I	II	III
Dose Level		0	10	100
FINAL BODY WEIGHT g	MEAN	353	340	341
	S.D.	25.3	19.2	23.6
	N	23	24	22
LIVER g	MEAN	14.418	14.022	14.267
	S.D.	0.9598	1.0870	1.4462
	N	23	24	22
KIDNEYS g	MEAN	1.871	1.849	1.944
	S.D.	0.1256	0.1388	0.1322
	N	23	24	22

MEAN INCLUDES ONLY DAMS WITH VIABLE FETUSES AT TERMINATION

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TABLE 10
Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats
SUMMARY OF ORGAN TO BODY WEIGHT RATIO

Group Dose Level		I 0	II 10	III 100
FINAL BODY WEIGHT g	MEAN	353	340	341
	S.D.	25.3	19.2	23.6
	N	23	24	22
LIVER Ratio	MEAN	0.041	0.041	0.042
	S.D.	0.0023	0.0017	0.0026
	N	23	24	22
KIDNEYS Ratio	MEAN	0.005	0.005	0.006**
	S.D.	0.0004	0.0005	0.0005
	N	23	24	22

Statistical key: * = p<0.05 ** = p<0.01
MEAN INCLUDES ONLY DAMS WITH VIABLE FETUSES AT TERMINATION

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TABLE
11

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TABLE 11

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF FETAL OBSERVATIONS - MALFORMATIONS

Group Dose Level	I 0	II 10	III 100
Litters Examined Externally	23	24	22
Fetuses Examined	318	297	283
CRANIORACHISCHISIS			
Litter Incidence	0	0	0
Fetal Incidence	0	0	0
Litters Examined Viscerally	23	24	22
Fetuses Examined	167	155	147
LATERAL VENTRICLES - DISTENDED			
Litter Incidence	0	0	1
Fetal Incidence	0	0	1
FOLDED RETINA			
Litter Incidence	0	0	1
Fetal Incidence	0	0	1
Litters Examined Skeletally	23	24	22
Fetuses Examined	151	142	136
Number with findings	0	0	0
TOTAL MALFORMATIONS			
NUMBER WITH EXTERNAL MALFORMATIONS			
Fetal Incidence	0	0	0
Litter Incidence	0	0	0
NUMBER WITH VISCERAL MALFORMATIONS			
Fetal Incidence	0	0	2
Litter Incidence	0	0	2
NUMBER WITH SKELETAL MALFORMATIONS			
Fetal Incidence	0	0	0
Litter Incidence	0	0	0
TOTAL NUMBER WITH MALFORMATIONS			
Fetal Incidence	0	0	2
Litter Incidence	0	0	2

No statistically significant differences

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TABLE

12

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TABLE 12

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF FETAL OBSERVATIONS - VARIATIONS

Group Dose Level	I 0	II 10	III 100
Litters Examined Externally	23	24	22
Fetuses Examined	318	297	283
Number with findings	0	0	0
Litters Examined Viscerally	23	24	22
Fetuses Examined	167	155	147
URETER(S) DISTENDED			
Litter Incidence	3	1	1
Fetal Incidence	5	2	1
RENAL PELVIS DISTENDED			
Litter Incidence	6	5	4
Fetal Incidence	11	6	5
Litters Examined Skeletally	23	24	22
Fetuses Examined	151	142	136
INTERPARIETAL REDUCED OSSIFICATION			
Litter Incidence	12	17	15
Fetal Incidence	26	49	46
SUPRAOCCIPITAL REDUCED OSSIFICATION			
Litter Incidence	12	17	14
Fetal Incidence	24	43	36
HYOID BODY UNOSSIFIED			
Litter Incidence	18	19	13
Fetal Incidence	42	59	34

No statistically significant differences

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Huntingdon Life Sciences 96-4080D
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TABLE 12

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF FETAL OBSERVATIONS - VARIATIONS

Group Dose Level	I 0	II 10	III 100
SQUAMOSAL(S) REDUCED OSSIFICATION			
Litter Incidence	3	10	10
Fetal Incidence	6	18	15
MAXILLA(E) REDUCED OSSIFICATION			
Litter Incidence	2	6	2
Fetal Incidence	4	8	2
MALAR(S) REDUCED OSSIFICATION			
Litter Incidence	3	7	10
Fetal Incidence	4	13	15
PARIETAL(S) REDUCED OSSIFICATION			
Litter Incidence	4	6	6
Fetal Incidence	7	11	9
FRONTAL(S) REDUCED OSSIFICATION			
Litter Incidence	1	1	0
Fetal Incidence	3	1	0
PRESPHENOID REDUCED OSSIFICATION			
Litter Incidence	1	0	0
Fetal Incidence	1	0	0
MALAR UNOSSIFIED			
Litter Incidence	0	0	1
Fetal Incidence	0	0	1
SUPRAOCCIPITAL UNOSSIFIED			
Litter Incidence	0	0	1
Fetal Incidence	0	0	1

No statistically significant differences

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Huntingdon Life Sciences 96-4080D
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TABLE 12

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF FETAL OBSERVATIONS - VARIATIONS

Group Dose Level	I 0	II 10	III 100
CERVICAL ARCH(ES) REDUCED OSSIFICATION			
Litter Incidence	8	8	7
Fetal Incidence	13	16	12
CERVICAL RIB(S) PRESENT			
Litter Incidence	0	0	0
Fetal Incidence	0	0	0
THORACIC CENTRUM(A) REDUCED OSSIFICATION			
Litter Incidence	4	3	0
Fetal Incidence	6	4	0
THORACIC CENTRUM(A) BIPARTITE			
Litter Incidence	2	0	1
Fetal Incidence	2	0	1
THORACIC CENTRUM(A) UNOSSIFIED			
Litter Incidence	0	0	0
Fetal Incidence	0	0	0
LUMBAR ARCH(ES) REDUCED OSSIFICATION			
Litter Incidence	1	3	0
Fetal Incidence	2	3	0
SACRAL ARCH(ES) REDUCED OSSIFICATION			
Litter Incidence	12	16	14
Fetal Incidence	23	37	28
SACRAL ARCH(ES) UNOSSIFIED			
Litter Incidence	5	8	9
Fetal Incidence	8	21	17

Statistical key: * = $p < 0.05$

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TABLE 12

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF FETAL OBSERVATIONS - VARIATIONS

Group Dose Level	I 0	II 10	III 100
CAUDAL ARCH(BS) UNOSSIFIED			
Litter Incidence	12	14	14
Fetal Incidence	32	37	35
CAUDAL CENTRUM(A) UNOSSIFIED			
Litter Incidence	0	0	1
Fetal Incidence	0	0	3
STERNEBRA(E) 5 AND/OR 6 UNOSSIFIED			
Litter Incidence	23	23	21
Fetal Incidence	110	89	94
STERNEBRA(E) 1,2,3 AND/OR 4 UNOSSIFIED			
Litter Incidence	2	3	4
Fetal Incidence	2	3	6
STERNEBRA(E) 1,3 AND/OR 4 REDUCED OSSIFICATION			
Litter Incidence	0	2	3
Fetal Incidence	0	2	6
RIB(S) 13TH RUDIMENTARY			
Litter Incidence	2	1	2
Fetal Incidence	2	2	2
RIB(S) BENT			
Litter Incidence	0	1	0
Fetal Incidence	0	1	0
RIB(S) REDUCED OSSIFICATION			
Litter Incidence	1	1	0
Fetal Incidence	2	1	0

No statistically significant differences

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TABLE 12

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

SUMMARY OF FETAL OBSERVATIONS - VARIATIONS

Group Dose Level	I 0	II 10	III 100
METACARPAL(S) UNOSSIFIED			
Litter Incidence	0	0	2
Fetal Incidence	0	0	2
PUBIS(ES) UNOSSIFIED			
Litter Incidence	1	2	4
Fetal Incidence	1	2	5
ISCHIUM(A) UNOSSIFIED			
Litter Incidence	0	0	3
Fetal Incidence	0	0	3
PUBIS(ES) REDUCED OSSIFICATION			
Litter Incidence	2	5	4
Fetal Incidence	2	5	5
ISCHIUM(A) REDUCED OSSIFICATION			
Litter Incidence	1	3	0
Fetal Incidence	1	3	0

No statistically significant differences

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APPENDIX

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APPENDIX A

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL CLINICAL OBSERVATIONS DURING GESTATION

GROUP I 0 ppm

FEMALE#	OBSERVATIONS	DAY OF GESTATION														
			0	1	2	3	4	5	6	7	8	9	1	1	1	1
1601	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
1602	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
1603	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
1604	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
1605	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
1606	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
1607	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
1608	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
1609	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
1610	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
1611	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
1612	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P

CODES: 1-SLIGHT 2-MODERATE 3-MARKED P-PRESENT

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APPENDIX A

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL CLINICAL OBSERVATIONS DURING GESTATION

GROUP I 0 ppm

FEMALE#	OBSERVATIONS	DAY OF GESTATION													
			0	1	2	3	4	5	6	7	8	9	10	11	12
1623	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P
1624	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P
1625	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P

CODE: 1-SLIGHT 2-MODERATE 3-MARKED P-PRESENT

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Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL CLINICAL OBSERVATIONS DURING GESTATION

GROUP II		10ppm																
FEMALE#	OBSERVATIONS	DAY OF GESTATION																
			0	1	2	3	4	5	6	7	8	9	1	1	1	1		
2601	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P	P	
2602	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P								P	P	P	P	P	P	P	
2603	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P								P	P	P	P	P	P	P	
2604	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P								P	P	P	P	P	P	P	
2605	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P								P	P	P	P	P	P	P	
2606	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P								P	P	P	P	P	P	P	
2607	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P								P	P	P	P	P	P	P	
2608	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P								P	P	P	P	P	P	P	
2609	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P								P	P	P	P	P	P	P	
2610	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P								P	P	P	P	P	P	P	
2611	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P								P	P	P	P	P	P	P	
2612	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P								P	P	P	P	P	P	P	

CODE: 1-SLIGHT 2-MODERATE 3-MARKED P-PRESENT

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Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL CLINICAL OBSERVATIONS DURING GESTATION

GROUP II		10ppm																	
FEMALE#	OBSERVATIONS	DAY OF GESTATION	INDIVIDUAL CLINICAL OBSERVATIONS DURING GESTATION																
			0	1	2	3	4	5	6	7	8	9	0	1	1	1	1		
2613	TERMINAL SACRIFICE ALOPECIA - EXTREMITIES/SNOUT WITHIN NORMAL LIMITS	P								P	P	P	P		2	2	2	2	2
2614	TERMINAL SACRIFICE WITHIN NORMAL LIMITS	P								P	P	P	P	P	P	P	P	P	P
2615	TERMINAL SACRIFICE WITHIN NORMAL LIMITS	P								P	P	P	P	P	P	P	P	P	P
2616	TERMINAL SACRIFICE RED EXUDATE FROM ANO-GENITAL AREA CHROMODACRYORRHEA - UNILATERAL INCISORS MALOCCLUDED WITHIN NORMAL LIMITS	P								P	P	P	P	P	P			P	
2617	TERMINAL SACRIFICE WITHIN NORMAL LIMITS	P								P	P	P	P	P	P	P	P	P	P
2618	TERMINAL SACRIFICE CHROMODACRYORRHEA - UNILATERAL INCISORS BROKEN/MISSING INCISORS MALOCCLUDED WITHIN NORMAL LIMITS	P								P	P	P	P				P	P	P
2619	TERMINAL SACRIFICE WITHIN NORMAL LIMITS	P								P	P	P	P	P	P	P	P	P	P
2620	TERMINAL SACRIFICE WITHIN NORMAL LIMITS	P								P	P	P	P	P	P	P	P	P	P
2621	TERMINAL SACRIFICE WITHIN NORMAL LIMITS	P								P	P	P	P	P	P	P	P	P	P
2622	TERMINAL SACRIFICE WITHIN NORMAL LIMITS	P								P	P	P	P	P	P	P	P	P	P

CODE: 1-SLIGHT 2-MODERATE 3-MARKED P-PRESENT

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Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL CLINICAL OBSERVATIONS DURING GESTATION

GROUP II		10ppm																		
FEMALE#	OBSERVATIONS	DAY OF GESTATION																		
			0	1	2	3	4	5	6	7	8	9	0	1	1	1	1			
2623	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P	P	P		
2624	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P	P	P		
2625	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P	P	P		

CODE: 1-SLIGHT 2-MODERATE 3-MARKED P-PRESENT

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APPENDIX A

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL CLINICAL OBSERVATIONS DURING GESTATION

GROUP III 100 ppm

FEMALE#	OBSERVATIONS	DAY OF GESTATION														
			0	1	2	3	4	5	6	7	8	9	10	11	12	13
3601	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
3602	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
3603	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
3604	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
3605	TERMINAL SACRIFICE ALOPECIA - EXTREMITIES/SNOUT WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	2	2
3606	TERMINAL SACRIFICE ALOPECIA - EXTREMITIES/SNOUT WITHIN NORMAL LIMITS		P						P	P	P	2	2	2	2	2
3607	TERMINAL SACRIFICE ALOPECIA - EXTREMITIES/SNOUT WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
3608	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
3609	TERMINAL SACRIFICE ALOPECIA - EXTREMITIES/SNOUT WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
3610	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
3611	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P

CODE: 1-SLIGHT 2-MODERATE 3-MARKED P-PRESENT

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APPENDIX A

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL CLINICAL OBSERVATIONS DURING GESTATION

GROUP III 100 ppm

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FEMALE#	OBSERVATIONS	DAY OF GESTATION															1	1	1	1
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4			
3612	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P	P			
3613	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P	P			
3614	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P	P			
3615	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P	P			
3616	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P	P			
3617	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P	P			
3618	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P	P			
3619	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P	P			
3620	TERMINAL SACRIFICE ALOPECIA - EXTREMITIES/SNOUT WITHIN NORMAL LIMITS		P							P	P	P	P		2	2	2	2		
3621	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P	P			
3622	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P	P			
3623	TERMINAL SACRIFICE ALOPECIA - EXTREMITIES/SNOUT WITHIN NORMAL LIMITS		P							P	P	P	P	P		2	2	3	3	

CODE: 1-SLIGHT 2-MODERATE 3-MARKED P-PRESENT

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Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL CLINICAL OBSERVATIONS DURING GESTATION

GROUP III 100 ppm

FEMALE#	OBSERVATIONS	DAY OF GESTATION														
			0	1	2	3	4	5	6	7	8	9	0	1	2	3
3624	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P							P	P	P	P	P	P	P
3625	TERMINAL SACRIFICE WITHIN NORMAL LIMITS						P			P	P	P	P	P	P	P

CODE: 1-SLIGHT 2-MODERATE 3-MARKED P-PRESENT

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Vinyl Chloride Combined Inhalation Two-Generation Reproduction and Developmental Toxicity Study in CD Rats

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CODE: 1-SLIGHT 2-MODERATE 3-MARKED P-PRESENT

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APPENDIX A

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL CLINICAL OBSERVATIONS DURING GESTATION

GROUP IV 1100 ppm

FEMALE#	OBSERVATIONS	DAY OF GESTATION														
			0	1	2	3	4	5	6	7	8	9	0	1	2	3
4613	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
4614	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
4615	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
4616	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
4617	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
4618	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
4619	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
4620	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
4621	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
4622	TERMINAL SACRIFICE ALOPECIA - EXTREMITIES/SNOUT WITHIN NORMAL LIMITS		P						P	P		2	2	2	2	2
4623	TERMINAL SACRIFICE WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P
4624	TERMINAL SACRIFICE ALOPECIA - EXTREMITIES/SNOUT WITHIN NORMAL LIMITS		P						P	P	P	P	P	P	P	P

CODE: 1-SLIGHT 2-MODERATE 3-MARKED P-PRESENT

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INDIVIDUAL CLINICAL OBSERVATIONS DURING GESTATION

FEMALE#	OBSERVATIONS	DAY OF GESTATION																
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	
4625	TERMINAL SACRIFICE ALOPECIA - EXTREMITIES/SNOUT					2			2	2	2	2	2	3	3	3		

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APPENDIX B

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

GROUP I 0 ppm INDIVIDUAL GESTATION BODY WEIGHTS (GRAMS)

ANIMAL#	DAY OF GESTATION					
	0	6	9	12	15	20
1601	200	242	237	250	261	323
1602	252	285	294	309	333	415
1603	189	223	237	254	263	321
1604	207	230	246	259	273	333
1605	208	235	255	271	284	347
1606	217	249	261	277	297	368
1607	213	235	246	259	275	324
1608	223	252	264	276	296	364
1609	227	260	268	290	303	395
1610	211	244	252	267	283	344
1611	212	237	240	253	268	335
1612	201	225	233	252	268	332
1613	207	237	244	256	273	344
1614	215	247	260	274	287	352
1615x NP	217	250	261	267	240	276
1616	226	252	264	285	308	379
1617	227	250	264	280	298	376
1618x NP	205	240	254	263	256	244
1619	207	240	246	266	285	347
1620	221	258	277	293	314	381
1621	222	248	253	275	297	366
1622	191	223	226	244	257	316
1623	202	219	238	261	278	339
1624	218	244	255	272	290	355
1625	227	256	271	283	309	370
MEAN	214	243	254	270	287	353
S.D.	13.7	14.8	16.0	15.8	19.0	25.3
N	23	23	23	23	23	23

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

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APPENDIX B

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

GROUP 11 10ppm INDIVIDUAL GESTATION BODY WEIGHTS (GRAMS)

ANIMAL#	DAY OF GESTATION					
	0	6	9	12	15	20
2601	221	252	250	263	279	326
2602	226	265	274	293	312	364
2603	196	220	229	243	258	312
2604	206	232	245	252	272	338
2605	210	235	252	270	291	359
2606	217	241	257	272	287	341
2607	213	241	254	275	290	348
2608	225	246	265	269	281	335
2609	227	244	247	266	277	336
2610	208	238	250	259	279	325
2611x NP	217	239	248	252	243	251
2612	200	223	238	258	274	348
2613	209	236	248	264	280	334
2614	213	245	250	263	281	336
2615	218	236	246	267	276	345
2616	225	258	277	300	315	387
2617	244	274	279	302	314	373
2618	202	227	235	235	257	303
2619	208	230	233	247	269	333
2620	218	233	239	256	273	332
2621	223	243	249	265	273	331
2622	187	218	232	247	262	313
2623	206	238	243	261	281	349
2624	214	239	248	269	282	333
2625	231	251	268	288	300	357
MEAN	214	240	250	266	282	340
S.D.	12.3	13.3	13.8	16.7	15.8	19.2
N	24	24	24	24	24	24

NP=NOT PREGNANT x=EXCLUDED FROM MEAN

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APPENDIX B

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

GROUP III 100 ppm

INDIVIDUAL GESTATION BODY WEIGHTS (GRAMS)

ANIMAL#	DAY OF GESTATION					
	0	6	9	12	15	20
3601	224	258	265	281	306	376
3602	218	239	250	262	279	348
3603	199	227	239	253	267	333
3604	203	233	233	251	268	331
3605	213	241	251	269	288	357
3606	216	238	247	264	280	347
3607	218	245	260	270	283	336
3608x NP	220	240	248	245	249	258
3609	172	212	228	237	256	267
3610x NP	208	239	247	237	243	244
3611	220	252	265	278	291	349
3612	195	221	230	250	261	324
3613	210	236	249	268	274	329
3614	213	232	239	253	266	312
3615	218	242	258	279	294	359
3616	224	260	271	286	295	360
3617	195	220	236	251	266	327
3618	200	235	244	261	278	338
3619	210	237	247	271	277	345
3620	217	249	262	274	294	357
3621	223	257	254	275	298	361
3622	226	257	267	280	296	364
3623	209	237	248	265	275	323
3624x NP	213	227	226	230	232	234
3625	199	262	272	286	307	366
MEAN	210	240	251	266	282	341
S.D.	12.9	13.7	13.2	13.2	14.5	23.6
N	22	22	22	22	22	22

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

BFG42098

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX B

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

GROUP IV 1100 ppm INDIVIDUAL GESTATION BODY WEIGHTS (GRAMS)

ANIMAL#	DAY OF GESTATION					
	0	6	9	12	15	20
4601	204	224	232	247	265	307
4602	213	240	251	259	280	341
4603	201	224	235	253	264	317
4604	201	228	235	250	262	316
4605	215	244	251	265	278	328
4606	215	241	248	263	279	353
4607	217	251	265	280	298	361
4608	219	246	254	270	278	337
4609x NP	193	223	232	229	232	244
4610	199	235	241	248	264	319
4611	226	247	256	264	288	337
4612	233	260	261	270	293	352
4613	211	251	254	276	295	359
4614	212	238	245	266	281	351
4615	220	249	263	277	291	342
4616	222	246	256	277	289	359
4617	199	227	234	250	266	334
4618	199	238	247	267	283	354
4619	212	237	244	266	285	343
4620	215	250	260	272	290	352
4621	223	261	261	280	292	357
4622	224	253	265	281	292	351
4623	212	253	258	282	302	361
4624	212	246	252	263	281	336
4625	238	227	239	250	271	332
MEAN	214	242	250	266	282	342
S.D.	10.5	10.8	10.2	11.4	11.6	15.6
N	24	24	24	24	24	24

NP-NOT PREGNANT

x-EXCLUDED FROM MEAN

BFG42099

APPENDIX

C

11-NOV-15 09:34

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX C

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

GROUP 1 0 ppm INDIVIDUAL GESTATION BODY WEIGHT GAIN (GRAMS)

ANIMAL#	DAY OF GESTATION					
	0 - 6	6 - 9	9 - 12	12 - 15	15 - 20	6 - 20
1601	41	-5	13	11	62	82
1602	33	9	15	24	82	130
1603	34	14	17	10	58	98
1604	23	16	13	13	61	103
1605	28	20	17	13	63	112
1606	32	12	16	20	71	118
1607	22	11	13	16	49	89
1608	29	13	12	20	68	112
1609	33	8	22	14	91	135
1610	33	8	15	16	60	100
1611	25	3	13	15	67	98
1612	24	8	19	16	64	107
1613	30	8	11	18	71	107
1614	32	13	13	13	65	105
1615x NP	33	11	6	-27	36	26
1616	26	12	21	24	70	127
1617	23	14	17	18	79	127
1618x NP	36	14	9	-6	-13	4
1619	34	6	20	19	63	107
1620	37	19	16	21	68	123
1621	27	5	21	22	69	117
1622	31	3	18	14	59	94
1623	17	19	23	17	61	120
1624	26	11	17	17	66	111
1625	30	15	12	26	61	114
MEAN	29	10	16	17	66	110
S.D.	5.6	5.8	3.5	4.3	8.7	13.5
N	23	23	23	23	23	23

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

BFG42101

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX C

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

GROUP II 10ppm INDIVIDUAL GESTATION BODY WEIGHT GAIN (GRAMS)

ANIMAL#	DAY OF GESTATION					
	0 - 6	6 - 9	9 - 12	12 - 15	15 - 20	6 - 20
2601	31	-2	13	16	47	74
2602	39	9	19	19	52	99
2603	24	9	14	15	54	92
2604	25	13	8	20	66	107
2605	25	16	18	21	68	124
2606	24	16	15	15	54	100
2607	29	12	22	15	58	107
2608	20	19	4	12	54	89
2609	18	2	19	11	59	91
2610	30	11	10	20	45	87
2611x NP	22	9	4	-9	9	13
2612	23	15	19	16	74	125
2613	27	12	16	16	54	97
2614	32	5	14	18	54	91
2615	18	10	21	9	69	109
2616	33	19	23	15	72	130
2617	30	4	23	12	59	99
2618	25	7	0	22	46	75
2619	22	2	15	22	64	103
2620	15	6	17	18	59	99
2621	20	7	15	8	58	88
2622	31	14	15	15	52	96
2623	32	5	19	20	68	111
2624	25	9	21	14	51	94
2625	19	18	19	12	58	107
MEAN	26	10	16	16	58	100
S.D.	5.8	5.7	5.7	4.0	8.2	13.8
N	24	24	24	24	24	24

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

BFG42102

Huntingdon Life Sciences 96-4080P
Chemical Manufacturers Association

APPENDIX C

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

GROUP III 100 ppm

INDIVIDUAL GESTATION BODY WEIGHT GAIN (GRAMS)

ANIMAL#	DAY OF GESTATION					
	0 - 6	6 - 9	9 - 12	12 - 15	15 - 20	6 - 20
3601	34	7	16	24	70	118
3602	22	11	11	17	70	109
3603	28	13	14	14	66	106
3604	30	0	18	17	62	98
3605	27	10	19	19	69	117
3606	22	9	17	16	68	109
3607	27	15	10	13	54	91
3608x NP	20	8	-4	4	9	18
3609	40	16	9	19	11	55
3610x NP	31	8	-11	6	2	5
3611	32	13	13	14	58	98
3612	26	9	20	11	63	103
3613	26	13	19	6	55	93
3614	19	7	14	13	46	81
3615	24	16	21	15	65	117
3616	36	11	15	10	65	100
3617	25	16	15	15	61	107
3618	34	9	17	17	60	103
3619	27	10	25	6	67	108
3620	33	13	12	20	63	107
3621	35	-3	21	23	63	104
3622	31	11	13	16	68	108
3623	28	11	17	10	49	86
3624x NP	14	-1	3	2	2	6
3625	63	10	14	21	59	104
MEAN	30	10	16	15	60	101
S.D.	8.9	4.6	3.9	4.8	12.7	14.0
N	22	22	22	22	22	22

NP-NOT PREGNANT

x-EXCLUDED FROM MEAN

BFG42103

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX C

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

GROUP IV 1100 ppm INDIVIDUAL GESTATION BODY WEIGHT GAIN (GRAMS)

ANIMAL#	DAY OF GESTATION					
	0 - 6	6 - 9	9 - 12	12 - 15	15 - 20	6 - 20
4601	20	8	14	18	42	83
4602	27	12	8	21	61	102
4603	22	12	18	12	53	94
4604	28	7	15	12	54	88
4605	29	7	14	13	50	84
4606	27	7	15	17	73	111
4607	34	14	15	17	63	110
4608	27	9	15	9	59	92
4609x NP	30	10	-3	3	12	21
4610	35	7	7	16	54	84
4611	20	9	9	24	49	91
4612	27	1	9	23	59	93
4613	40	3	23	19	64	108
4614	26	8	21	15	70	113
4615	29	14	14	14	50	92
4616	23	10	21	12	70	113
4617	28	7	16	16	68	108
4618	39	10	20	16	71	116
4619	25	7	22	19	58	107
4620	34	10	12	18	62	102
4621	38	1	19	12	65	96
4622	29	12	15	12	59	98
4623	41	5	24	20	59	109
4624	34	5	11	18	55	90
4625	-11	13	10	22	61	106
MEAN	28	8	15	16	60	99
S.D.	10.3	3.6	4.8	3.9	7.8	10.4
N	24	24	24	24	24	24

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

BFG42104

APPENDIX

D

BFG42105

BFG 01619

30-SEP-19 16:45

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX D

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL GESTATION FOOD CONSUMPTION -- (GRAMS/ANIMAL/DAY)

GROUP I 0 ppm

ANIMAL#	DAY OF GESTATION				
	0 - 6	6 - 9	9 - 12	12 - 15	15 - 20
1601	21	16	19	19	22
1602	22	21	24	27	30
1603	19	19	18	19	24
1604	18	20	20	21	22
1605	18	19	22	21	24
1606	20	20	19	22	23
1607	19	17	19	20	21
1608	20	20	19	22	25
1609	20	19	21	21	25
1610	21	19	21	22	24
1611	19	16	20	21	24
1612	18	16	18	19	22
1613	18	19	18	20	25
1614	19	18	18	19	22
1615x NP	20	19	19	8	18
1616	21	20	23	26	27
1617	28	20	20	21	24
1618x NP	23	20	22	18	16
1619	18	17	20	SPILL	24
1620	20	21	21	24	25
1621	20	19	21	24	27
1622	17	15	20	19	22
1623	18	17	21	21	24
1624	17	18	20	21	24
1625	15	18	17	21	25
MEAN	19	18	20	21	24
S.D.	2.5	1.6	1.7	2.0	1.9
N	23	23	23	22	23

NP-NOT PREGNANT

x-EXCLUDED FROM MEAN

BFG42106

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX D

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL GESTATION FOOD CONSUMPTION -- (GRAMS/ANIMAL/DAY)

GROUP II 10ppm

ANIMAL#	DAY OF GESTATION				
	0 - 6	6 - 9	9 - 12	12 - 15	15 - 20
2601	20	16	21	23	24
2602	20	21	24	25	25
2603	18	17	18	20	22
2604	19	18	19	20	23
2605	21	19	22	23	27
2606	20	18	20	22	22
2607	20	18	21	23	26
2608	17	18	16	18	21
2609	20	16	19	20	23
2610	20	20	21	21	22
2611x NP	20	18	18	SPILL	17
2612	19	18	19	24	26
2613	19	19	20	22	22
2614	18	17	19	23	23
2615	18	19	18	20	24
2616	21	24	24	22	23
2617	23	22	24	24	25
2618	18	18	14	20	20
2619	17	15	17	20	22
2620	18	18	19	20	22
2621	17	17	21	21	24
2622	21	19	21	22	23
2623	17	18	20	22	25
2624	17	20	22	22	24
2625	18	20	25	23	26
MEAN	19	19	20	22	23
S.D.	1.7	1.9	2.6	1.7	1.9
N	24	24	24	24	24

NP-NOT PREGNANT

x-EXCLUDED FROM MEAN

BFG42107

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX D

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

GROUP III 100 ppm

INDIVIDUAL GESTATION FOOD CONSUMPTION -- (GRAMS/ANIMAL/DAY)

ANIMAL#	DAY OF GESTATION				
	0 - 6	6 - 9	9 - 12	12 - 15	15 - 20
3601	20	18	20	23	25
3602	19	19	19	22	24
3603	18	17	21	20	23
3604	18	15	18	19	20
3605	17	16	23	24	25
3606	19	18	18	22	23
3607	21	21	19	16	24
3608x NP	19	17	17	19	18
3609	21	21	18	22	18
3610x NP	20	20	16	14	16
3611	21	19	20	21	24
3612	17	16	18	19	21
3613	20	19	21	22	22
3614	17	17	19	20	21
3615	19	21	21	23	25
3616	22	21	24	24	24
3617	22	18	20	21	22
3618	19	17	21	21	21
3619	18	17	22	20	23
3620	22	22	19	26	27
3621	21	17	20	26	23
3622	19	18	21	22	24
3623	17	19	20	21	21
3624x NP	15	14	16	16	17
3625	21	22	24	23	27
MEAN	19	19	20	22	23
S.D.	1.7	2.0	1.7	2.2	2.2
N	22	22	22	22	22

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

BFG42108

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX D

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

GROUP IV 1100 ppm INDIVIDUAL GESTATION FOOD CONSUMPTION -- (GRAMS/ANIMAL/DAY)

ANIMAL#	DAY OF GESTATION				
	0 - 6	6 - 9	9 - 12	12 - 15	15 - 20
4601	15	16	19	23	21
4602	17	19	20	22	25
4603	18	17	19	19	22
4604	17	18	20	21	22
4605	19	16	18	20	21
4606	19	15	19	21	24
4607	19	20	22	24	27
4608	18	18	20	20	22
4609x NP	20	19	15	18	17
4610	20	18	19	20	25
4611	19	19	21	22	22
4612	21	19	19	23	24
4613	21	18	21	23	23
4614	18	16	20	21	23
4615	22	21	22	24	23
4617	19	18	19	21	21
4619	18	16	19	20	22
4620	22	18	21	21	24
4621	20	18	21	22	24
4622	19	19	21	24	26
4623	22	18	21	24	26
4624	19	19	19	22	23
4625	18	18	18	20	31
MEAN	19	18	20	22	24
S.D.	1.7	1.4	1.3	1.6	2.3
N	22	22	22	22	22

NP-NOT PREGNANT

x-EXCLUDED FROM MEAN

BFG42109

APPENDIX

E

BFG 01624

BFG42110

30-SEP-19 16:46

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX E

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL GESTATION FOOD CONSUMPTION -- (GRAMS/KG/DAY)

GROUP I 0 ppm

ANIMAL#	DAY OF GESTATION				
	0 - 6	6 - 9	9 - 12	12 - 15	15 - 20
1601	104	68	79	76	84
1602	88	75	81	87	89
1603	99	84	77	76	90
1604	88	85	80	80	81
1605	85	80	85	77	85
1606	91	80	71	78	79
1607	91	71	77	79	78
1608	90	80	73	80	85
1609	88	71	78	73	83
1610	101	79	83	82	86
1611	90	68	85	82	90
1612	88	73	78	76	82
1613	85	80	76	80	91
1614	86	72	68	70	78
1615x NP	92	77	73	28	76
1616	95	79	87	90	86
1617	123	78	76	73	79
1618x NP	113	81	87	69	61
1619	88	72	81	SPILL	84
1620	89	82	77	81	79
1621	89	75	84	86	91
1622	88	67	88	79	86
1623	88	77	90	80	87
1624	76	74	77	76	82
1625	68	69	64	73	80
MEAN	90	76	79	79	84
S.D.	10.2	5.3	6.3	4.8	4.2
N	23	23	23	22	23

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

BFG42111

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX E

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL GESTATION FOOD CONSUMPTION -- (GRAMS/KG/DAY)

GROUP II 10ppm

ANIMAL#	DAY OF GESTATION				
	0 - 6	6 - 9	9 - 12	12 - 15	15 - 20
2601	90	65	86	87	87
2602	90	79	86	84	80
2603	92	76	79	81	84
2604	90	77	77	78	84
2605	99	81	87	85	92
2606	93	73	79	81	77
2607	94	75	84	85	90
2608	75	75	62	66	73
2609	87	66	78	76	83
2610	96	83	86	82	78
2611x NP	91	77	71	SPILL	71
2612	93	81	80	91	97
2613	90	79	81	83	80
2614	87	69	74	86	83
2615	82	79	75	76	86
2616	95	94	87	74	72
2617	95	79	86	79	80
2618	89	80	60	84	76
2619	79	66	73	79	82
2620	84	79	80	78	81
2621	75	72	85	80	89
2622	113	87	92	89	89
2623	82	76	84	83	89
2624	80	82	89	82	84
2625	79	80	92	81	87
MEAN	89	77	81	81	83
S.D.	8.5	6.7	8.0	5.3	5.9
N	24	24	24	24	24

NP-NOT PREGNANT

x-EXCLUDED FROM MEAN

BFG42112

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX E

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL GESTATION FOOD CONSUMPTION -- (GRAMS/KG/DAY)

GROUP III 100 ppm

ANIMAL#	DAY OF GESTATION				
	0 - 6	6 - 9	9 - 12	12 - 15	15 - 20
3601	89	70	76	81	82
3602	87	78	74	83	84
3603	90	76	86	80	85
3604	90	65	77	74	76
3605	82	67	91	89	88
3606	87	74	75	83	81
3607	96	86	74	61	84
3608x NP	84	70	68	77	72
3609	124	97	81	91	71
3610x NP	97	86	66	60	66
3611	94	77	76	77	81
3612	87	74	80	74	82
3613	96	79	85	82	82
3614	82	74	78	79	78
3615	87	87	82	82	86
3616	98	80	87	82	80
3617	114	83	87	82	84
3618	93	72	87	82	76
3619	85	72	90	74	84
3620	100	90	72	94	92
3621	95	66	78	93	78
3622	84	72	80	77	81
3623	83	79	82	78	77
3624x NP	71	61	69	72	71
3625	107	84	87	82	89
MEAN	93	77	81	81	82
S.D.	10.7	8.0	5.6	7.3	4.7
N	22	22	22	22	22

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

BFG42113

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX E

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL GESTATION FOOD CONSUMPTION -- (GRAMS/KG/DAY)

GROUP IV 1100 ppm

ANIMAL#	DAY OF GESTATION				
	0 - 6	6 - 9	9 - 12	12 - 15	15 - 20
4601	72	69	82	94	80
4602	80	80	78	85	88
4603	88	74	79	75	84
4604	87	78	86	82	85
4605	87	64	70	75	74
4606	86	64	77	78	84
4607	90	78	85	85	90
4608	82	73	80	72	80
4609x NP	104	86	65	77	72
4610	103	77	78	80	94
4611	82	78	82	84	77
4612	88	72	74	84	80
4613	101	72	84	84	79
4614	83	69	80	79	83
4615	98	84	84	87	78
4617	96	78	83	84	81
4619	84	68	78	77	77
4620	101	71	80	78	84
4621	89	67	79	77	83
4622	85	75	79	86	90
4623	102	72	83	85	85
4624	92	76	75	85	83
4625	76	78	75	79	114
MEAN	89	73	79	82	84
S.D.	8.4	5.3	3.9	4.9	8.2
N	22	22	22	22	22

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

BFG42114

APPENDIX

F

BFG42115

BFG 01629

30-SEP-19 16:46

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX F

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FEMALE REPRODUCTION DATA AND MEAN FETAL WEIGHT DATA

GROUP I 0 ppm

ANIMAL#	CORPORA LUTEA	%PREIMPL. LOSS	IMPLANT SITES	FETUSES			RESORPTIONS			SEX	
				LIVE	DEAD		EARLY	LATE	TOTAL	MALE	FEMALE
				(n)	(n)				(n)		
1601	15	6.7	14	13	0	0.0	1	0	1	9	4
1602	15	0.0	15	15	0	0.0	0	0	0	4	11
1603	15	13.3	13	12	0	0.0	1	0	1	6	6
1604	14	7.1	13	13	0	0.0	0	0	0	8	5
1605	17	29.4	12	11	0	0.0	1	0	1	6	5
1606	17	5.9	16	16	0	0.0	0	0	0	8	8
1607	16	18.8	13	12	0	0.0	1	0	1	7	5
1608	13	0.0	13	13	0	0.0	0	0	0	4	9
1609	18	5.6	17	17	0	0.0	0	0	0	10	7
1610	14	0.0	14	13	0	0.0	1	0	1	4	9
1611	15	13.3	13	13	0	0.0	0	0	0	7	6
1612	14	0.0	14	14	0	0.0	0	0	0	4	10
1613	16	6.3	15	14	0	0.0	1	0	1	4	10
1614	15	6.7	14	12	0	0.0	2	0	2	6	6
1615	NP										
1616	16	12.5	14	13	0	0.0	1	0	1	6	7
1617	18	5.6	17	17	0	0.0	0	0	0	9	8
1618	NP										
1619	14	7.1	13	13	0	0.0	0	0	0	7	6
1620	15	0.0	15	15	0	0.0	0	0	0	8	7
1621	15	0.0	15	15	0	0.0	0	0	0	10	5
1622	12	0.0	12	12	0	0.0	0	0	0	2	10
1623	16	6.3	15	15	0	0.0	0	0	0	9	6
1624	16	6.3	15	15	0	0.0	0	0	0	5	10
1625	15	0.0	15	15	0	0.0	0	0	0	6	9
MEAN	15.3	6.6	14.2	13.8	0.0	0.0	0.4	0.0	0.4	6.5	7.3
S.D.	1.45	7.22	1.38	1.64	0.00	0.00	0.58	0.00	0.58	2.19	2.06
N	23	23	23	23	23	23	23	23	23	23	23

NP-NOT PREGNANT

BFG42116

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX F

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FEMALE REPRODUCTION DATA AND MEAN FETAL WEIGHT DATA

GROUP II 10ppm

ANIMAL#	CORPORA LUTEA	%PREIMPL. LOSS	IMPLANT SITES	FETUSES			RESORPTIONS				SEX	
				LIVE	DEAD	%	EARLY	LATE	TOTAL	%	MALE	FEMALE
				(n)		%			(n)	%		
2601	8	12.5	7	7	0	0.0	0	0	0	0.0	3	4
2602	26	50.0	13	11	0	0.0	1	1	2	15.4	9	2
2603	14	7.1	13	12	0	0.0	1	0	1	7.7	6	6
2604	17	23.5	13	13	0	0.0	0	0	0	0.0	5	8
2605	15	6.7	14	14	0	0.0	0	0	0	0.0	7	7
2606	15	13.3	13	13	0	0.0	0	0	0	0.0	6	7
2607	15	0.0	15	12	0	0.0	3	0	3	20.0	8	4
2608	13	15.4	11	11	0	0.0	0	0	0	0.0	4	7
2609	14	14.3	12	12	0	0.0	0	0	0	0.0	8	4
2610	13	7.7	12	11	0	0.0	1	0	1	8.3	3	8
2611	NP											
2612	15	13.3	13	13	0	0.0	0	0	0	0.0	8	5
2613	13	7.7	12	12	0	0.0	0	0	0	0.0	9	3
2614	12	8.3	11	10	0	0.0	1	0	1	9.1	6	4
2615	15	0.0	15	14	0	0.0	1	0	1	6.7	4	10
2616	22	27.3	16	16	0	0.0	0	0	0	0.0	5	11
2617	15	13.3	13	12	0	0.0	1	0	1	7.7	5	7
2618	14	7.1	13	13	0	0.0	0	0	0	0.0	4	9
2619	15	0.0	15	15	0	0.0	0	0	0	0.0	7	8
2620	13	0.0	13	13	0	0.0	0	0	0	0.0	9	4
2621	13	0.0	13	13	0	0.0	0	0	0	0.0	7	6
2622	12	0.0	12	11	0	0.0	1	0	1	8.3	9	2
2623	17	11.8	15	15	0	0.0	0	0	0	0.0	7	8
2624	14	7.1	13	12	0	0.0	1	0	1	7.7	6	6
2625	15	20.0	12	12	0	0.0	0	0	0	0.0	4	8
MEAN	14.8	11.1	12.9	12.4	0.0	0.0	0.5	0.0	0.5	3.8	6.2	6.2
S.D.	3.41	11.21	1.80	1.84	0.00	0.00	0.72	0.20	0.78	5.66	1.96	2.43
N	24	24	24	24	24	24	24	24	24	24	24	24

NP=NOT PREGNANT

BFG42117

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX F

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FEMALE REPRODUCTION DATA AND MEAN FETAL WEIGHT DATA

GROUP III 100 ppm

ANIMAL#	CORPORA LUTEA	%PREIMPL. LOSS	IMPLANT SITES	FETUSES			RESORPTIONS				SEX		
				LIVE	DEAD (n)	‡	EARLY	LATE	TOTAL (n)	‡	MALE	FEMALE	
3601		19	26.3	14	14	0	0.0	0	0	0	0.0	7	7
3602		18	5.6	17	17	0	0.0	0	0	0	0.0	7	10
3603		13	0.0	13	13	0	0.0	0	0	0	0.0	7	6
3604		17	11.8	15	15	0	0.0	0	0	0	0.0	8	7
3605		28	42.9	16	13	0	0.0	3	0	3	18.8	6	7
3606		17	5.9	16	16	0	0.0	0	0	0	0.0	8	8
3607		13	7.7	12	10	0	0.0	2	0	2	16.7	5	5
3608	NP												
3609		6	0.0	6	6	0	0.0	0	0	0	0.0	1	5
3610	NP												
3611		14	14.3	12	11	0	0.0	1	0	1	8.3	6	5
3612		20	30.0	14	14	0	0.0	0	0	0	0.0	7	7
3613		13	23.1	10	10	0	0.0	0	0	0	0.0	6	4
3614		9	11.1	8	8	0	0.0	0	0	0	0.0	3	5
3615		14	0.0	14	14	0	0.0	0	0	0	0.0	8	6
3616		14	7.1	13	13	0	0.0	0	0	0	0.0	3	10
3617		14	7.1	13	13	0	0.0	0	0	0	0.0	5	8
3618		14	0.0	14	14	0	0.0	0	0	0	0.0	5	9
3619		14	7.1	13	13	0	0.0	0	0	0	0.0	6	7
3620		20	40.0	12	12	0	0.0	0	0	0	0.0	8	4
3621		16	6.3	15	15	0	0.0	0	0	0	0.0	5	10
3622		15	6.7	14	14	0	0.0	0	0	0	0.0	9	5
3623		16	6.3	15	15	0	0.0	0	0	0	0.0	6	9
3624	NP												
3625		13	0.0	13	13	0	0.0	0	0	0	0.0	7	6
MEAN		15.3	11.8	13.1	12.9	0.0	0.0	0.3	0.0	0.3	2.0	6.0	6.8
S.D.		4.31	12.68	2.55	2.57	0.00	0.00	0.77	0.00	0.77	5.40	1.91	1.92
N		22	22	22	22	22	22	22	22	22	22	22	22

NP=NOT PREGNANT

BFG42118

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX F

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FEMALE REPRODUCTION DATA AND MEAN FETAL WEIGHT DATA

GROUP IV 1100 ppm

ANIMAL#	CORPORA LUTEA	%PREIMPL. LOSS	IMPLANT SITES	FETUSES			RESORPTIONS				SEX	
				LIVE	DEAD (n)	%	EARLY	LATE	TOTAL (n)	%	MALE	FEMALE
4601	10	10.0	9	9	0	0.0	0	0	0	0.0	5	4
4602	17	17.6	14	12	0	0.0	2	0	2	14.3	8	4
4603	15	20.0	12	11	0	0.0	1	0	1	8.3	6	5
4604	12	0.0	12	12	0	0.0	0	0	0	0.0	8	4
4605	13	7.7	12	11	0	0.0	1	0	1	8.3	6	5
4606	16	0.0	16	16	0	0.0	0	0	0	0.0	8	8
4607	15	6.7	14	13	0	0.0	1	0	1	7.1	4	9
4608	15	26.7	11	11	0	0.0	0	0	0	0.0	8	3
4609	NP											
4610	10	40.0	6	6	0	0.0	0	0	0	0.0	3	3
4611	15	6.7	14	12	0	0.0	2	0	2	14.3	5	7
4612	14	0.0	14	14	0	0.0	0	0	0	0.0	8	6
4613	15	6.7	14	14	0	0.0	0	0	0	0.0	6	8
4614	22	27.3	16	16	0	0.0	0	0	0	0.0	6	10
4615	14	7.1	13	13	0	0.0	0	0	0	0.0	4	9
4616	16	6.3	15	15	0	0.0	0	0	0	0.0	8	7
4617	15	6.7	14	14	0	0.0	0	0	0	0.0	6	8
4618	21	23.8	16	14	0	0.0	2	0	2	12.5	7	7
4619	15	6.7	14	14	0	0.0	0	0	0	0.0	7	7
4620	17	11.8	15	15	0	0.0	0	0	0	0.0	7	8
4621	15	6.7	14	13	0	0.0	1	0	1	7.1	6	7
4622	17	11.8	15	11	0	0.0	4	0	4	26.7	6	5
4623	15	13.3	13	12	0	0.0	1	0	1	7.7	7	5
4624	14	14.3	12	12	0	0.0	0	0	0	0.0	5	7
4625	15	0.0	15	15	0	0.0	0	0	0	0.0	7	8
MEAN	15.1	11.6	13.3	12.7	0.0	0.0	0.6	0.0	0.6	4.4	6.3	6.4
S.D.	2.68	9.99	2.30	2.27	0.00	0.00	1.01	0.00	1.01	6.93	1.43	1.98
N	24	24	24	24	24	24	24	24	24	24	24	24

NP=NOT PREGNANT

BFG42119

APPENDIX

G

BFG42120

BFG 01634

20-NOV-11 09:30

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX G

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL GRAVID UTERINE WEIGHT AND NET BODY WEIGHT CHANGE (GRAMS)

0 ppm

ANIMAL#	UTERUS WEIGHT	ADJUSTED WEIGHT	NET WEIGHT CHANGE FROM DAY 6	WEIGHT CHANGE FROM DAY 6
1601	67	256	15	82
1602	91	324	39	130
1603	64	257	34	98
1604	68	265	35	103
1605	63	284	49	112
1606	83	285	36	118
1607	63	261	26	89
1608	73	291	39	112
1609	96	298	39	135
1610	69	275	31	100
1611	72	263	26	98
1612	83	248	23	107
1613	73	271	34	107
1614	63	289	42	105
1615x NP	1	275	25	26
1616	76	303	51	127
1617	90	286	37	127
1618x NP	3	241	1	4
1619	73	275	34	107
1620	80	301	43	123
1621	87	279	30	117
1622	67	249	27	94
1623	79	260	41	120
1624	81	274	30	111
1625	70	301	45	114
MEAN	75.	278.	35.	110.
S.D.	9.7	19.5	8.5	13.5
N	23	23	23	23

ADJUSTED WEIGHT = TERMINAL BODY WEIGHT MINUS GRAVID UTERINE WEIGHT

NET WEIGHT CHANGE FROM DAY 6 = TERMINAL CORRECTED BODY WEIGHT MINUS DAY 6 BODY WEIGHT

NP-NOT PREGNANT

x-EXCLUDED FROM MEAN

BFG42121

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX G

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL GRAVID UTERINE WEIGHT AND NET BODY WEIGHT CHANGE (GRAMS)

10 ppm

ANIMAL#	UTERUS WEIGHT	ADJUSTED WEIGHT	NET WEIGHT CHANGE FROM DAY 6	WEIGHT CHANGE FROM DAY 6
2601	39	287	35	74
2602	62	302	37	99
2603	69	243	23	92
2604	75	263	32	107
2605	80	279	44	124
2606	70	271	30	100
2607	66	282	41	107
2608	61	274	28	89
2609	66	270	26	91
2610	59	266	27	87
2611x NP	3	249	10	13
2612	71	277	54	125
2613	69	265	29	97
2614	60	276	31	91
2615	74	271	35	109
2616	91	296	39	130
2617	64	309	35	99
2618	65	238	10	75
2619	81	253	22	103
2620	74	258	25	99
2621	75	256	14	88
2622	62	251	34	96
2623	81	268	30	111
2624	69	264	25	94
2625	71	287	36	107
MEAN	69.	271.	31.	100.
S.D.	10.0	17.4	9.1	13.8
N	24	24	24	24

ADJUSTED WEIGHT - TERMINAL BODY WEIGHT MINUS GRAVID UTERINE WEIGHT

NET WEIGHT CHANGE FROM DAY 6 - TERMINAL CORRECTED BODY WEIGHT MINUS DAY 6 BODY WEIGHT

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

BFG42122

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX G

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL GRAVID UTERINE WEIGHT AND NET BODY WEIGHT CHANGE (GRAMS)

100 ppm

ANIMAL#	UTERUS WEIGHT	ADJUSTED WEIGHT	NET WEIGHT CHANGE FROM DAY 6	WEIGHT CHANGE FROM DAY 6
3601	78	298	40	118
3602	92	256	17	109
3603	70	263	37	106
3604	79	252	19	98
3605	67	290	50	117
3606	84	263	25	109
3607	57	279	34	91
3608x NP	1	257	17	18
3609	38	229	17	55
3610x NP	1	243	4	5
3611	60	289	37	98
3612	74	250	29	103
3613	60	269	33	93
3614	48	265	33	81
3615	74	285	43	117
3616	77	284	24	100
3617	75	251	32	107
3618	74	264	29	103
3619	72	273	36	108
3620	69	288	38	107
3621	80	281	23	104
3622	78	286	30	108
3623	72	251	14	86
3624x NP	1	233	5	6
3625	72	294	32	104
MEAN	70.	271.	31.	101.
S.D.	12.0	17.8	9.0	14.0
N	22	22	22	22

ADJUSTED WEIGHT = TERMINAL BODY WEIGHT MINUS GRAVID UTERINE WEIGHT

NET WEIGHT CHANGE FROM DAY 6 = TERMINAL CORRECTED BODY WEIGHT MINUS DAY 6 BODY WEIGHT

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

BFG42123

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX G

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL GRAVID UTERINE WEIGHT AND NET BODY WEIGHT CHANGE (GRAMS)

GROUP IV 1100 ppm

ANIMAL#	UTERUS WEIGHT	ADJUSTED WEIGHT	NET WEIGHT CHANGE FROM DAY 6	WEIGHT CHANGE FROM DAY 6
4601	51	257	33	83
4602	70	271	31	102
4603	58	259	35	94
4604	61	255	27	88
4605	62	266	22	84
4606	83	270	29	111
4607	77	284	33	110
4608	69	269	23	92
4609x NP	12	232	9	21
4610	39	280	45	84
4611	65	273	26	91
4612	81	271	12	93
4613	71	287	36	108
4614	80	271	33	113
4615	67	275	25	92
4616	78	282	36	113
4617	83	252	25	108
4618	72	282	44	116
4619	70	273	37	107
4620	74	278	28	102
4621	75	282	22	96
4622	66	285	32	98
4623	69	292	40	109
4624	64	272	26	90
4625	79	253	27	106
MEAN	69.	272.	30.	99.
S.D.	10.4	11.2	7.6	10.4
N	24	24	24	24

ADJUSTED WEIGHT = TERMINAL BODY WEIGHT MINUS GRAVID UTERINE WEIGHT

NET WEIGHT CHANGE FROM DAY 6 = TERMINAL CORRECTED BODY WEIGHT MINUS DAY 6 BODY WEIGHT

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

BFG42124

APPENDIX

H

BFG42125

BFG 01639

30-SEP-15 16:47

Huntingdon Life Sciences 96-1080D
Chemical Manufacturers Association

APPENDIX H

Vinyl Chloride Combined Inhalation Two-Generation Reproduction and Developmental Toxicity Study in CD Rats

GROUP I		INDIVIDUAL FETAL BODY WEIGHTS (GRAMS)													
0 ppm															
ANIMAL#	MEAN	FETUS#													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
1601	3.2	E	3.1	3.2	3.3	3.3	3.2	3.2/	3.0	3.3	3.1	3.3	3.0	3.4	3.1
1602	3.9	4.0	3.7	3.9	4.0	3.6	4.1	4.2/	4.2	3.6	3.8	4.1	3.9	3.6	3.9
1603	3.3	3.3	3.0	3.4	3.3	3.3	3.2/	3.2	3.3	3.3	3.6	E	3.7	3.5	3.3
1604	3.2	3.1	3.3	3.0	2.7	3.4	3.3	3.2/	3.2	3.0	3.1	3.4	3.5	3.3	3.3
1605	3.7	3.7	3.7	3.6	E	3.4	2.3	3.9	3.8	3.9/	3.7	4.3	3.9	3.1	3.3
1606	3.2	3.3	3.5	3.3	3.0	3.3	3.5/	3.5	3.2	3.3	3.3	3.5	3.1	3.1	3.3
1607	3.3	2.9	E	3.3	3.5	3.2/	3.6	3.2	3.6	3.3	3.3	3.4	3.2	3.0	3.3
1608	3.6	3.8	3.6	3.8	3.7	3.8	3.2	3.8	3.6	3.3	3.3	4.0/	3.4	3.8	3.3
1609	3.4	3.4	3.3	3.6	3.3	3.7	3.3	3.0	3.5	3.4	3.4/	3.3	3.2	3.6	3.3
1610	3.3	2.3	E	3.6	3.4	3.5	3.7	3.4	3.5	3.5/	3.5	3.1	3.3	3.4	3.3
1611	3.4	3.4	3.4	3.3	3.6	3.5	3.4	3.1	3.4	3.5/	3.7	3.4	3.1	3.2	3.3
1612	3.5	3.6	3.8	3.6	3.7	3.4/	3.3	3.5	3.6	3.6	3.4	3.5	3.5	3.4	3.3
1613	3.4	2.6	3.3	3.7	E	3.9	3.4	3.6	4.0	3.3	3.3	3.0/	3.2	3.3	3.3
1614	3.0	3.4	3.2	2.6	2.4	2.8	3.4	E	2.5	3.4/	E	3.3	2.8	3.3	3.3
1615	NP														
1616	3.3	3.4	3.3	3.0	3.6	3.2	3.1	3.4/	3.6	3.2	E	3.0	3.2	3.2	3.3
1617	3.3	3.3	3.6	3.3	3.3	2.5	3.4	3.4	3.6/	3.4	3.8	3.3	3.4	3.3	3.3
1618	NP														
1619	3.3	3.0	3.1	3.4	3.6	3.4	3.2/	3.2	3.4	3.3	3.3	3.4	3.3	3.4	3.3
1620	3.3	3.3	3.3	3.1	3.1	3.3	3.7	3.3	3.2	3.2/	3.0	3.4	3.2	3.6	3.3
1621	3.4	3.6	3.4	3.6	3.5	3.3	3.2/	3.3	3.5	3.2	3.3	3.5	3.7	3.6	3.3
1622	3.3	2.6	3.3	3.5	3.5/	3.3	3.7	2.7	3.4	3.3	3.3	3.2	3.3	3.3	3.3
1623	3.4	2.8	3.4	3.4	3.5	3.8	3.7/	3.7	3.4	3.3	3.3	3.5	3.6	3.4	3.3
1624	3.4	3.2	3.4	3.6	3.5	3.4	3.3	3.4/	3.4	3.2	3.6	3.4	3.5	3.9	3.3
1625	3.5	3.0	3.3	3.4	3.9	3.5	3.7	3.4	3.5/	3.6	3.7	3.3	3.3	4.3	3.3
MEAN	3.4														
S.D.	0.2														
N	23														

E-Early resorption L-Late resorption B-Abortion site I-Implantation site D-Dead fetus P-Deliv
/-Denotes position of cervix

NP-NOT PREGNANT

BFG42126

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX H

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

GROUP II		INDIVIDUAL FETAL BODY WEIGHTS (GRAMS)													
10ppm															
ANIMAL#	MEAN	FETUS#		3	4	5	6	7	8	9	10	11	12	13	14
		1	2												
2601	3.5	3.6	3.1	3.9	3.7/	3.0	3.9	3.6							
2602	3.3	3.1	3.3	3.0	3.4	3.6/	3.1	3.2	L	E	3.6	3.6	3.5	3.3	
2603	3.0	3.0	3.3	3.1	3.3	E	3.2/	2.7	2.8	2.8	2.6	2.9	3.2	3.3	
2604	3.5	3.5	3.7	3.9	3.4	3.2	3.7	3.7/	3.5	3.0	3.7	3.5	3.3	3.8	
2605	3.3	3.2	3.3	3.5	3.5	3.4	3.5	3.0	3.3/	3.4	3.4	3.2	3.6	3.3	3.
2606	3.3	3.2	3.3	3.3	3.2	3.5	3.4	3.1	3.5/	3.9	3.5	3.3	3.1	3.1	
2607	3.6	3.7	E	3.4	3.7	3.7	3.6	3.5	3.4/	3.6	3.7	3.6	E	3.7	3.
2608	3.6	4.0	3.7	3.7	3.2	3.5	3.8	3.8/	3.5	3.6	3.9	3.2			
2609	3.5	3.4	3.5	3.6	3.1	3.5	3.8	3.3/	3.5	3.9	3.4	3.7	3.6		
2610	3.4	3.4	3.2	3.4	3.3	3.4/	3.6	3.0	3.6	E	3.6	3.6	3.5		
2611	NP														
2612	3.3	2.8	3.1	3.2	3.3	3.3	3.5	3.3	3.4	3.5	3.5/	3.2	3.4	3.5	
2613	3.2	3.0	3.2	3.2	3.0	3.1	3.0	3.4/	3.3	3.3	3.5	3.4	3.2		
2614	3.6	3.3	3.4	3.3	3.6	3.3	3.8/	3.6	E	3.8	4.0	3.6			
2615	3.3	2.6	3.1	3.1	3.2	3.4	3.7	3.6	3.2	3.3	3.4/	E	3.3	3.1	3.
2616	3.5	3.5	3.7	3.2	3.6	3.4	3.3	3.6/	3.5	3.7	3.6	3.1	3.7	3.0	3.
2617	3.2	2.9	3.2	3.2	3.7	3.1	3.3	2.9/	2.8	3.4	3.4	E	3.3	3.0	
2618	3.2	3.3	3.2	3.0	3.2	3.0	3.1/	3.3	3.3	3.4	3.3	3.4	3.2	3.1	
2619	3.3	3.3	3.3	3.0	3.1	3.2	3.3	3.4	3.4/	3.6	3.3	3.5	3.8	3.6	3.
2620	3.3	3.3	3.2	3.6	3.4	3.6	3.2	3.0	3.4	3.6/	3.3	3.2	3.1	3.4	
2621	3.5	3.3	3.7	3.3	3.5	3.6/	3.3	3.4	3.7	3.5	3.7	4.0	3.5	3.3	
2622	3.6	3.5	3.5	4.0	3.7	E	3.6	3.3/	3.9	3.4	3.7	3.6	3.7		
2623	3.3	3.2	3.5	3.6	3.4	3.3	3.3	3.0	3.2	3.4/	3.2	3.1	3.3	3.5	3.
2624	3.5	3.8	3.9	3.8	3.4	3.5	3.6	3.1	3.1	3.6/	E	3.7	3.3	3.5	
2625	3.7	3.7	3.6	3.6	3.8	3.6	3.7	3.6	3.9	3.7/	4.0	3.7	3.9		
MEAN	3.4														
S.D.	0.2														
N	24														

E-Early resorption L-Late resorption B-Abortion site I-Implantation site D-Dead fetus P-Deliv
/-Denotes position of cervix

NP-NOT PREGNANT

BFG42127

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX H

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

GROUP III 100 ppm

INDIVIDUAL FETAL BODY WEIGHTS (GRAMS)

ANIMAL#	MEAN	FETUS#													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
3601	3.5	3.6	3.2	3.6	3.3	3.8	3.8	3.8	3.2	3.0	3.5/	3.2	3.8	3.6	3.1
3602	3.1	3.0	3.2	3.1	3.4	3.3	3.6	3.0	3.0	3.2/	2.9	3.4	3.1	3.3	2.8
3603	3.4	3.6	3.5	3.4	3.5	3.4/	3.6	3.0	2.8	3.5	3.4	3.5	3.4	3.5	3.1
3604	3.4	3.0	3.2	3.6	3.4	3.5	3.1	3.0	3.3/	3.4	3.8	3.7	3.3	3.3	3.1
3605	3.1	E	2.7	E	3.2	3.2	2.9	3.3/	3.1	3.0	3.3	3.3	3.2	3.2	3.1
3606	3.2	3.0	3.1	3.0	3.3	3.2	3.0	3.1	3.4	3.1/	3.4	3.1	3.2	3.2	3.1
3607	3.7	3.6	3.5	3.4	3.7	E	E/	3.6	3.7	3.9	3.8	4.0	3.4		
3608	NP														
3609	3.5	3.6	3.8	3.2/	3.3	3.6	3.6								
3610	NP														
3611	3.4	2.8	3.5	E	3.7	3.3	3.1	3.4/	3.6	3.5	3.3	3.8	3.7		
3612	3.2	2.8	3.2	3.0	3.7	3.4	3.0	3.2/	3.3	3.1	3.4	3.3	3.5	3.2	3.1
3613	3.7	3.6	3.7	3.5	3.5	3.5	3.5/	3.9	3.9	4.0	3.8				
3614	3.4	3.4	3.6	3.4	3.2	3.6	3.4	3.0/	3.2						
3615	3.1	3.3	3.1	2.9	3.3	2.9	2.9	3.1	2.8/	3.0	3.3	3.0	3.2	3.0	3.1
3616	3.6	3.6	3.6	3.8	3.9	3.7	3.4	3.5	3.6/	3.6	3.8	3.6	3.4	3.2	3.1
3617	3.8	3.9	4.0	3.6	3.9	3.7	3.9	3.9/	3.6	3.9	4.0	4.1	3.6	3.5	3.1
3618	3.4	3.5	3.6	3.6	3.5	3.5/	3.5	3.3	3.4	3.3	3.1	3.5	3.6	3.4	3.1
3619	3.3	3.6	3.5	3.1	3.3	3.3	3.2	3.0/	3.4	3.3	3.5	3.2	3.1	3.3	3.1
3620	3.5	3.7	3.6	3.6	3.4	3.8	3.5	3.5/	3.5	3.6	3.8	3.4	2.8		
3621	3.5	3.3	3.4	3.6	3.6	3.8	3.5	3.8	3.5/	3.5	3.7	3.5	3.5	3.4	3.1
3622	3.7	3.4	3.7	3.8	3.3	3.8	3.7/	4.0	3.8	3.6	3.6	3.9	3.7	3.8	3.1
3623	3.0	2.7	2.8	2.7	3.0	3.0	3.2	3.0	3.2	2.7	3.0/	2.9	3.2	3.0	3.1
3624	NP														
3625	3.5	3.6	3.5	3.2	3.1	3.7	3.9	3.3	3.6	3.3/	3.9	3.5	3.7	3.4	
MEAN	3.4														
S.D.	0.2														
N	22														

R-Early resorption L-Late resorption B-Abortion site I-Implantation site D-Dead fetus P-Delivered
/-Denotes position of cervix

NP=NOT PREGNANT

BFG42128

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX H

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FETAL BODY WEIGHTS (GRAMS)

GROUP IV 1100 ppm

ANIMAL#	MEAN	FETUS#													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
4601	3.4	3.3	3.5	3.2	3.6	3.6	3.0/	4.0	3.6	2.9					
4602	3.7	E	E	3.7	3.6	3.4	3.7	3.7	3.6	4.0/	3.9	4.2	4.0	3.7	3.8
4603	3.3	3.1	3.3	E	3.3	3.2	3.1	3.5/	3.5	3.5	2.9	3.0	3.4		
4604	3.2	3.1	3.1	3.5	3.4	2.9	3.2	3.3	3.5/	3.3	3.1	3.0	3.2		
4605	3.2	3.3	3.0	3.6	E	3.2/	3.5	3.4	3.3	3.5	3.0	2.4	3.1		
4606	3.2	3.5	3.3	3.3	2.9	3.1	3.2	3.3/	3.7	2.7	3.2	3.6	2.8	3.3	3.4
4607	3.2	3.2	3.1	3.4	E	3.3	3.0	3.6	3.4	3.1/	3.0	3.2	2.3	3.3	3.4
4608	3.7	3.6	3.7	3.3	4.0	3.9	3.5	3.4	3.7/	3.9	3.5	4.3			
4609	NP														
4610	3.7	3.6/	3.6	3.8	3.8	3.6	3.8								
4611	3.2	2.7	3.3	3.0	E	3.1	3.5	E/	3.3	3.0	3.2	2.7	3.4	3.2	3.3
4612	3.7	3.5	4.1	3.8	3.9	3.8	3.2	3.1	3.7	3.6	3.4/	3.9	3.9	3.4	3.5
4613	3.3	3.0	3.4	3.6	3.1	3.3	3.7	3.1	3.3/	3.1	3.4	3.2	3.0	3.3	3.4
4614	3.2	3.2	3.1	3.5	3.1	3.1	3.3	3.3/	3.3	3.1	3.0	3.3	3.1	3.2	3.3
4615	3.1	2.7	3.5	3.3	2.9	3.6	2.6	3.0	3.0	2.9/	3.1	3.2	3.2	3.3	3.4
4616	3.3	3.4	3.1	3.3	3.5	3.4	3.3	3.3/	3.3	3.3	3.7	3.4	3.2	3.4	3.5
4617	3.4	3.4	3.6	3.6	3.2	3.4	3.6/	3.0	3.2	3.6	3.6	3.4	3.8	3.2	3.3
4618	3.3	E	2.9	3.4	3.3	3.3	3.7	3.0	3.3	3.3/	3.0	3.0	3.3	3.2	3.3
4619	3.1	3.0	3.1	3.0	3.1	3.1	3.0/	3.0	3.2	2.7	3.0	3.3	3.3	3.0	3.1
4620	3.1	3.1	2.8	3.3	2.9	3.1	3.4	2.9/	3.0	3.4	3.0	3.0	3.1	3.2	3.3
4621	3.4	E	3.2	3.5	3.3	3.0	3.5	3.5/	3.4	3.2	3.6	3.8	3.2	3.6	3.7
4622	3.3	3.2	3.2	3.6	E	2.7	E	E/	E	3.8	3.4	3.8	3.2	3.5	2.8
4623	3.7	E	3.8	3.9	3.6	3.7	3.7	3.7/	3.5	3.6	3.2	3.7	4.0	3.9	
4624	3.1	2.9	3.3	3.2	3.3/	3.2	3.1	3.4	3.0	2.9	3.2	3.0	2.8		
4625	3.3	2.1	3.7	3.4	3.5	3.2	3.3	3.3	3.3/	3.8	3.3	3.1	3.3	3.0	3.1
MEAN	3.3														
S.D.	0.2														
N	24														

E-Early resorption L-Late resorption B-Abortion site I-Implantation site D-Dead fetus P-Deliv
/-Denotes position of cervix

NP=NOT PREGNANT

BFG42129

APPENDIX

I

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Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX I

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL MATERNAL NECROPSY OBSERVATIONS

GROUP I	0 ppm		
ANIMAL#		ORGAN	OBSERVATION
1601			NO REMARKABLE OBSERVATIONS
1602			NO REMARKABLE OBSERVATIONS
1603			NO REMARKABLE OBSERVATIONS
1604			NO REMARKABLE OBSERVATIONS
1605			NO REMARKABLE OBSERVATIONS
1606			NO REMARKABLE OBSERVATIONS
1607			NO REMARKABLE OBSERVATIONS
1608			NO REMARKABLE OBSERVATIONS
1609			NO REMARKABLE OBSERVATIONS
1610			NO REMARKABLE OBSERVATIONS
1611			NO REMARKABLE OBSERVATIONS
1612			NO REMARKABLE OBSERVATIONS
1613		GROSS EXAM	ALOPECIA, MODERATE BOTH HINDPANS AND BOTH INGUINAL AREA
1614			NO REMARKABLE OBSERVATIONS
1615			NO REMARKABLE OBSERVATIONS
1616			NO REMARKABLE OBSERVATIONS
1617			NO REMARKABLE OBSERVATIONS

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Chemical Manufacturers Association

APPENDIX I

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL MATERNAL NECROPSY OBSERVATIONS

GROUP I 0 ppm

ANIMAL#	ORGAN	OBSERVATION
1618		NO REMARKABLE OBSERVATIONS
1619		NO REMARKABLE OBSERVATIONS
1620		NO REMARKABLE OBSERVATIONS
1621		NO REMARKABLE OBSERVATIONS
1622		NO REMARKABLE OBSERVATIONS
1623		NO REMARKABLE OBSERVATIONS
1624		NO REMARKABLE OBSERVATIONS
1625		NO REMARKABLE OBSERVATIONS

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Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX I

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL MATERNAL NECROPSY OBSERVATIONS

GROUP II	10ppm		
ANIMAL#		ORGAN	OBSERVATION
2601			NO REMARKABLE OBSERVATIONS
2602			NO REMARKABLE OBSERVATIONS
2603			NO REMARKABLE OBSERVATIONS
2604			NO REMARKABLE OBSERVATIONS
2605			NO REMARKABLE OBSERVATIONS
2606			NO REMARKABLE OBSERVATIONS
2607			NO REMARKABLE OBSERVATIONS
2608			NO REMARKABLE OBSERVATIONS
2609			NO REMARKABLE OBSERVATIONS
2610			NO REMARKABLE OBSERVATIONS
2611			NO REMARKABLE OBSERVATIONS
2612			NO REMARKABLE OBSERVATIONS
2613			NO REMARKABLE OBSERVATIONS
2614			NO REMARKABLE OBSERVATIONS
2615			NO REMARKABLE OBSERVATIONS
2616			NO REMARKABLE OBSERVATIONS
2617			NO REMARKABLE OBSERVATIONS

BFG42133

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX I

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL MATERNAL NECROPSY OBSERVATIONS

GROUP II	10ppm		
ANIMAL#		ORGAN	OBSERVATION
2618		KIDNEY	KIDNEY DISTENDED; EXTREME; LEFT
2619			NO REMARKABLE OBSERVATIONS
2620			NO REMARKABLE OBSERVATIONS
2621			NO REMARKABLE OBSERVATIONS
2622			NO REMARKABLE OBSERVATIONS
2623			NO REMARKABLE OBSERVATIONS
2624			NO REMARKABLE OBSERVATIONS
2625			NO REMARKABLE OBSERVATIONS

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Chemical Manufacturers Association

APPENDIX I

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL MATERNAL NECROPSY OBSERVATIONS

GROUP III 100 ppm

ANIMAL#	ORGAN	OBSERVATION
3601		NO REMARKABLE OBSERVATIONS
3602		NO REMARKABLE OBSERVATIONS
3603		NO REMARKABLE OBSERVATIONS
3604		NO REMARKABLE OBSERVATIONS
3605		NO REMARKABLE OBSERVATIONS
3606		NO REMARKABLE OBSERVATIONS
3607		NO REMARKABLE OBSERVATIONS
3608		NO REMARKABLE OBSERVATIONS
3609		NO REMARKABLE OBSERVATIONS
3610		NO REMARKABLE OBSERVATIONS
3611		NO REMARKABLE OBSERVATIONS
3612		NO REMARKABLE OBSERVATIONS
3613		NO REMARKABLE OBSERVATIONS
3614		NO REMARKABLE OBSERVATIONS
3615		NO REMARKABLE OBSERVATIONS
3616		NO REMARKABLE OBSERVATIONS
3617		NO REMARKABLE OBSERVATIONS

NP=NOT PREGNANT

BFG42135

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX I

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL MATERNAL NECROPSY OBSERVATIONS

GROUP III 100 ppm

ANIMAL#	ORGAN	OBSERVATION
3618		NO REMARKABLE OBSERVATIONS
3619		NO REMARKABLE OBSERVATIONS
3620		NO REMARKABLE OBSERVATIONS
3621		NO REMARKABLE OBSERVATIONS
3622		NO REMARKABLE OBSERVATIONS
3623		NO REMARKABLE OBSERVATIONS
3624		NO REMARKABLE OBSERVATIONS
3625		NO REMARKABLE OBSERVATIONS

NP=NOT PREGNANT

BFG42136

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX I

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL MATERNAL NECROPSY OBSERVATIONS

GROUP IV	1100 ppm		
ANIMAL#		ORGAN	OBSERVATION
4601			NO REMARKABLE OBSERVATIONS
4602			NO REMARKABLE OBSERVATIONS
4603			NO REMARKABLE OBSERVATIONS
4604			NO REMARKABLE OBSERVATIONS
4605			NO REMARKABLE OBSERVATIONS
4606			NO REMARKABLE OBSERVATIONS
4607			NO REMARKABLE OBSERVATIONS
4608			NO REMARKABLE OBSERVATIONS
4609		BLADDER	BLADDER HYPERDISTENSION; MODERATE FLUID FILLED (THICK WHITE)
		UTERUS	UTERUS DISTENDED; MODERATE FLUID FILLED (CLEAR)
4610			NO REMARKABLE OBSERVATIONS
4611			NO REMARKABLE OBSERVATIONS
4612			NO REMARKABLE OBSERVATIONS
4613			NO REMARKABLE OBSERVATIONS
4614			NO REMARKABLE OBSERVATIONS
4615			NO REMARKABLE OBSERVATIONS
4616			NO REMARKABLE OBSERVATIONS

BFG42137

Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX I

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL MATERNAL NECROPSY OBSERVATIONS

GROUP IV 1100 ppm

ANIMAL#	ORGAN	OBSERVATION
4617		NO REMARKABLE OBSERVATIONS
4618		NO REMARKABLE OBSERVATIONS
4619		NO REMARKABLE OBSERVATIONS
4620		NO REMARKABLE OBSERVATIONS
4621		NO REMARKABLE OBSERVATIONS
4622		NO REMARKABLE OBSERVATIONS
4623		NO REMARKABLE OBSERVATIONS
4624		NO REMARKABLE OBSERVATIONS
4625	GROSS EXAM	ALOPECIA; EXTREME SNOUT/EXTREMITIES (FOREPAWS BILATERAL)

BFG42138

APPENDIX J

BFG42139

BFG 01653

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96-4080D

APPENDIX J
Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats
ORGAN AND FINAL BODY WEIGHTS

FEMALES 0 ppm

Animal Number		FINAL BODY WEIGHT g	LIVER		KIDNEYS	
			Weight g	Ratio	Weight g	Ratio
1601		323	12.928	0.0400	2.073	0.0064
1602		415	16.275	0.0392	1.918	0.0046
1603		321	15.012	0.0468	1.762	0.0055
1604		333	12.692	0.0381	1.655	0.0050
1605		347	15.847	0.0456	1.914	0.0055
1606		368	14.706	0.0400	1.856	0.0050
1607		324	13.266	0.0410	1.729	0.0053
1608		364	14.640	0.0402	2.028	0.0056
1609		395	15.694	0.0398	1.942	0.0049
1610		344	13.205	0.0384	1.848	0.0054
1611		335	14.201	0.0424	1.884	0.0056
1612		332	13.658	0.0412	1.973	0.0059
1613		344	14.334	0.0417	1.805	0.0053
1614		352	13.916	0.0396	1.978	0.0056
1615x	NP	276	11.295	0.0409	1.823	0.0066
1616		379	14.214	0.0376	1.951	0.0052
1617		376	15.165	0.0403	1.899	0.0050
1618x	NP	244	10.529	0.0432	2.192	0.0090
1619		347	15.095	0.0435	1.973	0.0057
1620		381	15.429	0.0405	1.983	0.0052
1621		366	14.494	0.0397	1.826	0.0050
1622		316	14.019	0.0443	1.555	0.0049
1623		339	13.266	0.0391	1.699	0.0050
1624		355	14.822	0.0417	1.940	0.0055
1625		370	14.691	0.0397	1.852	0.0050

RATIO = ORGAN WEIGHT/BODY WEIGHT

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

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96-4080D

APPENDIX J
Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats
ORGAN AND FINAL BODY WEIGHTS

FEMALES 10 ppm

Animal Number	FINAL BODY WEIGHT g	LIVER		KIDNEYS	
		Weight g	Ratio	Weight g	Ratio
2601	326	14.235	0.0437	2.127	0.0065
2602	364	15.410	0.0424	2.025	0.0056
2603	312	13.064	0.0419	1.826	0.0059
2604	338	13.317	0.0394	1.835	0.0054
2605	359	14.056	0.0391	1.944	0.0054
2606	341	13.602	0.0399	1.829	0.0054
2607	348	14.670	0.0421	1.995	0.0057
2608	335	14.685	0.0439	1.592	0.0048
2609	336	12.664	0.0377	1.740	0.0052
2610	325	12.878	0.0397	1.745	0.0054
2611x NP	251	8.954	0.0357	2.149	0.0086
2612	348	15.006	0.0431	1.849	0.0053
2613	334	13.201	0.0395	1.705	0.0051
2614	336	14.223	0.0424	1.617	0.0048
2615	345	14.366	0.0417	1.964	0.0057
2616	387	16.425	0.0424	1.849	0.0048
2617	373	16.199	0.0435	1.938	0.0052
2618	303	12.208	0.0403	1.885	0.0062
2619	333	13.599	0.0408	1.827	0.0055
2620	332	14.081	0.0424	1.876	0.0056
2621	331	12.852	0.0389	1.835	0.0055
2622	313	12.952	0.0414	1.635	0.0052
2623	349	14.555	0.0417	1.825	0.0052
2624	333	13.441	0.0404	2.111	0.0063
2625	357	14.844	0.0416	1.813	0.0051

RATIO = ORGAN WEIGHT/BODY WEIGHT

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

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96-4080D

APPENDIX J
Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats
ORGAN AND FINAL BODY WEIGHTS

FEMALES 100 ppm

Animal Number	FINAL BODY WEIGHT g	LIVER		KIDNEYS	
		Weight g	Ratio	Weight g	Ratio
3601	376	15.594	0.0415	2.022	0.0054
3602	348	13.351	0.0383	1.883	0.0054
3603	333	14.102	0.0424	2.079	0.0062
3604	331	12.689	0.0384	1.749	0.0053
3605	357	16.735	0.0468	2.053	0.0057
3606	347	13.854	0.0399	1.898	0.0055
3607	336	14.017	0.0417	2.041	0.0061
3608x	NP 258	9.709	0.0376	2.112	0.0082
3609	267	9.854	0.0369	1.940	0.0073
3610x	NP 244	9.135	0.0374	2.043	0.0084
3611	349	14.837	0.0425	2.052	0.0059
3612	324	14.419	0.0445	2.014	0.0062
3613	329	15.103	0.0460	2.084	0.0063
3614	312	13.272	0.0425	1.814	0.0058
3615	359	14.559	0.0405	1.771	0.0049
3616	360	14.510	0.0403	1.873	0.0052
3617	327	14.059	0.0430	1.678	0.0051
3618	338	13.335	0.0395	1.938	0.0057
3619	345	14.633	0.0424	2.085	0.0060
3620	357	16.464	0.0461	1.994	0.0056
3621	361	14.733	0.0408	1.936	0.0054
3622	364	15.151	0.0416	2.032	0.0056
3623	323	12.900	0.0399	1.710	0.0053
3624x	NP 234	9.663	0.0413	1.830	0.0078
3625	366	15.710	0.0429	2.128	0.0058

RATIO = ORGAN WEIGHT/BODY WEIGHT

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

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96-4080D

APPENDIX J
Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats
ORGAN AND FINAL BODY WEIGHTS

FEMALES GROUP IV 1100 ppm

Animal Number	FINAL BODY WEIGHT g	LIVER		KIDNEYS	
		Weight g	Ratio	Weight g	Ratio
4601	307	12.622	0.0411	1.649	0.0054
4602	341	13.707	0.0402	1.815	0.0053
4603	317	13.672	0.0431	1.614	0.0051
4604	316	13.249	0.0419	1.862	0.0059
4605	328	13.430	0.0410	1.737	0.0053
4606	353	14.969	0.0425	1.877	0.0053
4607	361	14.557	0.0404	1.798	0.0050
4608	337	13.588	0.0403	2.069	0.0061
4609x NP	244	8.717	0.0358	1.597	0.0066
4610	319	15.693	0.0493	1.958	0.0061
4611	337	13.171	0.0390	2.195	0.0065
4612	352	14.228	0.0404	1.918	0.0054
4613	359	15.670	0.0437	1.976	0.0055
4614	351	15.246	0.0434	1.881	0.0054
4615	342	14.641	0.0429	2.009	0.0059
4616	359	15.218	0.0424	1.923	0.0054
4617	334	15.468	0.0463	2.070	0.0062
4618	354	15.375	0.0435	2.149	0.0061
4619	343	14.835	0.0432	1.938	0.0056
4620	352	16.225	0.0461	1.975	0.0056
4621	357	15.275	0.0428	2.029	0.0057
4622	351	16.486	0.0470	2.013	0.0057
4623	361	15.762	0.0436	1.866	0.0052
4624	336	14.117	0.0421	2.115	0.0063
4625	332	13.425	0.0404	1.742	0.0052

RATIO = ORGAN WEIGHT/BODY WEIGHT

NP=NOT PREGNANT

x=EXCLUDED FROM MEAN

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APPENDIX

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APPENDIX K

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FETAL EXTERNAL OBSERVATIONS

0 ppm

FEMALE#	FETUS#	ORGAN	CLASS	OBSERVATION
1601	2 F		WITHIN	NORMAL LIMITS
	3 F		WITHIN	NORMAL LIMITS
	4 M		WITHIN	NORMAL LIMITS
	5 M		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS
	7 F		WITHIN	NORMAL LIMITS
	8 F		WITHIN	NORMAL LIMITS
	9 M		WITHIN	NORMAL LIMITS
	10 M		WITHIN	NORMAL LIMITS
	11 M		WITHIN	NORMAL LIMITS
	12 M		WITHIN	NORMAL LIMITS
	13 M		WITHIN	NORMAL LIMITS
	14 M		WITHIN	NORMAL LIMITS
1602	1 M		WITHIN	NORMAL LIMITS
	2 F		WITHIN	NORMAL LIMITS
	3 F		WITHIN	NORMAL LIMITS
	4 M		WITHIN	NORMAL LIMITS
	5 F		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS
	7 F		WITHIN	NORMAL LIMITS
	8 F		WITHIN	NORMAL LIMITS
	9 F		WITHIN	NORMAL LIMITS
	10 F		WITHIN	NORMAL LIMITS
	11 M		WITHIN	NORMAL LIMITS
	12 F		WITHIN	NORMAL LIMITS
	13 F		WITHIN	NORMAL LIMITS
	14 F		WITHIN	NORMAL LIMITS
	15 F		WITHIN	NORMAL LIMITS
1603	1 M		WITHIN	NORMAL LIMITS
	2 F		WITHIN	NORMAL LIMITS
	3 F		WITHIN	NORMAL LIMITS
	4 F		WITHIN	NORMAL LIMITS
	5 M		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS

CLASS CODES: M=Malformation V=Variation

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APPENDIX K

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FETAL, EXTERNAL OBSERVATIONS

0 ppm

FEMALE#	FETUS#	ORGAN	CLASS OBSERVATION
1603	(CONTINUED)		
	7 F		WITHIN NORMAL LIMITS
	8 F		WITHIN NORMAL LIMITS
	9 M		WITHIN NORMAL LIMITS
	10 M		WITHIN NORMAL LIMITS
	12 F		WITHIN NORMAL LIMITS
	13 M		WITHIN NORMAL LIMITS
1604	1 F		WITHIN NORMAL LIMITS
	2 M		WITHIN NORMAL LIMITS
	3 F		WITHIN NORMAL LIMITS
	4 F		WITHIN NORMAL LIMITS
	5 M		WITHIN NORMAL LIMITS
	6 M		WITHIN NORMAL LIMITS
	7 M		WITHIN NORMAL LIMITS
	8 F		WITHIN NORMAL LIMITS
	9 M		WITHIN NORMAL LIMITS
	10 M		WITHIN NORMAL LIMITS
	11 M		WITHIN NORMAL LIMITS
	12 F		WITHIN NORMAL LIMITS
	13 M		WITHIN NORMAL LIMITS
1605	1 F		WITHIN NORMAL LIMITS
	2 M		WITHIN NORMAL LIMITS
	3 M		WITHIN NORMAL LIMITS
	5 F		WITHIN NORMAL LIMITS
	6 M		WITHIN NORMAL LIMITS
	7 M		WITHIN NORMAL LIMITS
	8 F		WITHIN NORMAL LIMITS
	9 F		WITHIN NORMAL LIMITS
	10 F		WITHIN NORMAL LIMITS
	11 M		WITHIN NORMAL LIMITS
	12 M		WITHIN NORMAL LIMITS
1606	1 F		WITHIN NORMAL LIMITS
	2 M		WITHIN NORMAL LIMITS
	3 M		WITHIN NORMAL LIMITS
	4 F		WITHIN NORMAL LIMITS

CLASS CODES: M-Malformation V-Variation

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APPENDIX K

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FETAL EXTERNAL OBSERVATIONS

0 ppm

FEMALE#	FETUS#	ORGAN	CLASS	OBSERVATION
1606	(CONTINUED)			
	5 F		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS
	7 F		WITHIN	NORMAL LIMITS
	8 F		WITHIN	NORMAL LIMITS
	9 F		WITHIN	NORMAL LIMITS
	10 M		WITHIN	NORMAL LIMITS
	11 M		WITHIN	NORMAL LIMITS
	12 M		WITHIN	NORMAL LIMITS
	13 F		WITHIN	NORMAL LIMITS
	14 M		WITHIN	NORMAL LIMITS
	15 M		WITHIN	NORMAL LIMITS
	16 F		WITHIN	NORMAL LIMITS
1607	1 F		WITHIN	NORMAL LIMITS
	3 F		WITHIN	NORMAL LIMITS
	4 M		WITHIN	NORMAL LIMITS
	5 F		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS
	7 M		WITHIN	NORMAL LIMITS
	8 M		WITHIN	NORMAL LIMITS
	9 M		WITHIN	NORMAL LIMITS
	10 F		WITHIN	NORMAL LIMITS
	11 M		WITHIN	NORMAL LIMITS
	12 F		WITHIN	NORMAL LIMITS
	13 M		WITHIN	NORMAL LIMITS
1608	1 M		WITHIN	NORMAL LIMITS
	2 F		WITHIN	NORMAL LIMITS
	3 F		WITHIN	NORMAL LIMITS
	4 F		WITHIN	NORMAL LIMITS
	5 F		WITHIN	NORMAL LIMITS
	6 F		WITHIN	NORMAL LIMITS
	7 M		WITHIN	NORMAL LIMITS
	8 F		WITHIN	NORMAL LIMITS
	9 F		WITHIN	NORMAL LIMITS
	10 F		WITHIN	NORMAL LIMITS
	11 M		WITHIN	NORMAL LIMITS

CLASS CODES: M=Malformation V=Variation

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APPENDIX K

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rate

INDIVIDUAL FETAL EXTERNAL OBSERVATIONS

0 ppm

FEMALE#	FETUS#	ORGAN	CLASS	OBSERVATION
1608 (CONTINUED)				
	12 F			WITHIN NORMAL LIMITS
	13 M			WITHIN NORMAL LIMITS
1609				
	1 M			WITHIN NORMAL LIMITS
	2 M			WITHIN NORMAL LIMITS
	3 M			WITHIN NORMAL LIMITS
	4 M			WITHIN NORMAL LIMITS
	5 M			WITHIN NORMAL LIMITS
	6 M			WITHIN NORMAL LIMITS
	7 F			WITHIN NORMAL LIMITS
	8 F			WITHIN NORMAL LIMITS
	9 F			WITHIN NORMAL LIMITS
	10 F			WITHIN NORMAL LIMITS
	11 M			WITHIN NORMAL LIMITS
	12 M			WITHIN NORMAL LIMITS
	13 M			WITHIN NORMAL LIMITS
	14 F			WITHIN NORMAL LIMITS
	15 F			WITHIN NORMAL LIMITS
	16 M			WITHIN NORMAL LIMITS
	17 F			WITHIN NORMAL LIMITS
1610				
	1 F			WITHIN NORMAL LIMITS
	3 M			WITHIN NORMAL LIMITS
	4 F			WITHIN NORMAL LIMITS
	5 M			WITHIN NORMAL LIMITS
	6 F			WITHIN NORMAL LIMITS
	7 F			WITHIN NORMAL LIMITS
	8 M			WITHIN NORMAL LIMITS
	9 F			WITHIN NORMAL LIMITS
	10 M			WITHIN NORMAL LIMITS
	11 F			WITHIN NORMAL LIMITS
	12 F			WITHIN NORMAL LIMITS
	13 F			WITHIN NORMAL LIMITS
	14 F			WITHIN NORMAL LIMITS

CLASS CODES: N-Malformation V-Variation

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APPENDIX K

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FETAL EXTERNAL OBSERVATIONS

0 ppm

FEMALE#	FETUS#	ORGAN	CLASS	OBSERVATION
1611	1 M		WITHIN	NORMAL LIMITS
	2 M		WITHIN	NORMAL LIMITS
	3 M		WITHIN	NORMAL LIMITS
	4 F		WITHIN	NORMAL LIMITS
	5 M		WITHIN	NORMAL LIMITS
	6 F		WITHIN	NORMAL LIMITS
	7 F		WITHIN	NORMAL LIMITS
	8 M		WITHIN	NORMAL LIMITS
	9 F		WITHIN	NORMAL LIMITS
	10 M		WITHIN	NORMAL LIMITS
	11 M		WITHIN	NORMAL LIMITS
	12 F		WITHIN	NORMAL LIMITS
	13 F		WITHIN	NORMAL LIMITS
1612	1 F		WITHIN	NORMAL LIMITS
	2 M		WITHIN	NORMAL LIMITS
	3 F		WITHIN	NORMAL LIMITS
	4 M		WITHIN	NORMAL LIMITS
	5 M		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS
	7 F		WITHIN	NORMAL LIMITS
	8 F		WITHIN	NORMAL LIMITS
	9 F		WITHIN	NORMAL LIMITS
	10 F		WITHIN	NORMAL LIMITS
	11 F		WITHIN	NORMAL LIMITS
	12 F		WITHIN	NORMAL LIMITS
	13 F		WITHIN	NORMAL LIMITS
	14 F		WITHIN	NORMAL LIMITS
1613	1 F		WITHIN	NORMAL LIMITS
	2 F		WITHIN	NORMAL LIMITS
	3 F		WITHIN	NORMAL LIMITS
	5 M		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS
	7 M		WITHIN	NORMAL LIMITS
	8 M		WITHIN	NORMAL LIMITS

CLASS CODES: M=Malformation V=Variation

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Chemical Manufacturers Association

APPENDIX K

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FETAL EXTERNAL OBSERVATIONS

0 ppm

FEMALE#	FETUS#	ORGAN	CLASS	OBSERVATION
1613	(CONTINUED)			
	9 F		WITHIN	NORMAL LIMITS
	10 F		WITHIN	NORMAL LIMITS
	11 F		WITHIN	NORMAL LIMITS
	12 F		WITHIN	NORMAL LIMITS
	13 F		WITHIN	NORMAL LIMITS
	14 F		WITHIN	NORMAL LIMITS
	15 F		WITHIN	NORMAL LIMITS
1614	1 F		WITHIN	NORMAL LIMITS
	2 F		WITHIN	NORMAL LIMITS
	3 M		WITHIN	NORMAL LIMITS
	4 M		WITHIN	NORMAL LIMITS
	5 F		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS
	8 M		WITHIN	NORMAL LIMITS
	9 M		WITHIN	NORMAL LIMITS
	11 F		WITHIN	NORMAL LIMITS
	12 F		WITHIN	NORMAL LIMITS
	13 F		WITHIN	NORMAL LIMITS
	14 M		WITHIN	NORMAL LIMITS
1616	1 F		WITHIN	NORMAL LIMITS
	2 F		WITHIN	NORMAL LIMITS
	3 M		WITHIN	NORMAL LIMITS
	4 M		WITHIN	NORMAL LIMITS
	5 F		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS
	7 F		WITHIN	NORMAL LIMITS
	8 F		WITHIN	NORMAL LIMITS
	9 M		WITHIN	NORMAL LIMITS
	11 F		WITHIN	NORMAL LIMITS
	12 F		WITHIN	NORMAL LIMITS
	13 M		WITHIN	NORMAL LIMITS
	14 M		WITHIN	NORMAL LIMITS

CLASS CODES: M=Malformation V=Variation

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APPENDIX K

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FETAL EXTERNAL OBSERVATIONS

0 ppm

FEMALE#	FETUS#	ORGAN	CLASS OBSERVATION
1617	1 M		WITHIN NORMAL LIMITS
	2 M		WITHIN NORMAL LIMITS
	3 F		WITHIN NORMAL LIMITS
	4 M		WITHIN NORMAL LIMITS
	5 F		WITHIN NORMAL LIMITS
	6 F		WITHIN NORMAL LIMITS
	7 F		WITHIN NORMAL LIMITS
	8 F		WITHIN NORMAL LIMITS
	9 M		WITHIN NORMAL LIMITS
	10 M		WITHIN NORMAL LIMITS
	11 M		WITHIN NORMAL LIMITS
	12 M		WITHIN NORMAL LIMITS
	13 F		WITHIN NORMAL LIMITS
	14 F		WITHIN NORMAL LIMITS
	15 M		WITHIN NORMAL LIMITS
	16 F		WITHIN NORMAL LIMITS
	17 M		WITHIN NORMAL LIMITS
1619	1 F		WITHIN NORMAL LIMITS
	2 M		WITHIN NORMAL LIMITS
	3 M		WITHIN NORMAL LIMITS
	4 M		WITHIN NORMAL LIMITS
	5 M		WITHIN NORMAL LIMITS
	6 F		WITHIN NORMAL LIMITS
	7 M		WITHIN NORMAL LIMITS
	8 F		WITHIN NORMAL LIMITS
	9 F		WITHIN NORMAL LIMITS
	10 F		WITHIN NORMAL LIMITS
	11 M		WITHIN NORMAL LIMITS
	12 F		WITHIN NORMAL LIMITS
	13 M		WITHIN NORMAL LIMITS
1620	1 M		WITHIN NORMAL LIMITS
	2 M		WITHIN NORMAL LIMITS
	3 F		WITHIN NORMAL LIMITS
	4 F		WITHIN NORMAL LIMITS

CLASS CODES: M=Malformation V=Variation

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Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX K

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FETAL EXTERNAL OBSERVATIONS

0 ppm

FEMALE#	FETUS#	ORGAN	CLASS	OBSERVATION
1620	(CONTINUED)			
	5 F		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS
	7 F		WITHIN	NORMAL LIMITS
	8 F		WITHIN	NORMAL LIMITS
	9 F		WITHIN	NORMAL LIMITS
	10 M		WITHIN	NORMAL LIMITS
	11 M		WITHIN	NORMAL LIMITS
	12 F		WITHIN	NORMAL LIMITS
	13 M		WITHIN	NORMAL LIMITS
	14 M		WITHIN	NORMAL LIMITS
	15 M		WITHIN	NORMAL LIMITS
1621	1 F		WITHIN	NORMAL LIMITS
	2 F		WITHIN	NORMAL LIMITS
	3 M		WITHIN	NORMAL LIMITS
	4 M		WITHIN	NORMAL LIMITS
	5 M		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS
	7 M		WITHIN	NORMAL LIMITS
	8 M		WITHIN	NORMAL LIMITS
	9 F		WITHIN	NORMAL LIMITS
	10 F		WITHIN	NORMAL LIMITS
	11 M		WITHIN	NORMAL LIMITS
	12 M		WITHIN	NORMAL LIMITS
	13 M		WITHIN	NORMAL LIMITS
	14 F		WITHIN	NORMAL LIMITS
	15 M		WITHIN	NORMAL LIMITS
1622	1 F		WITHIN	NORMAL LIMITS
	2 F		WITHIN	NORMAL LIMITS
	3 F		WITHIN	NORMAL LIMITS
	4 M		WITHIN	NORMAL LIMITS
	5 F		WITHIN	NORMAL LIMITS
	6 F		WITHIN	NORMAL LIMITS
	7 F		WITHIN	NORMAL LIMITS
	8 M		WITHIN	NORMAL LIMITS
	9 F		WITHIN	NORMAL LIMITS

CLASS CODES: M=Malformation V=Variation

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Chemical Manufacturers Association

APPENDIX K

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FETAL EXTERNAL OBSERVATIONS

0 ppm			CLASS OBSERVATION	
FEMALE#	FETUS#	ORGAN	CLASS OBSERVATION	
1622 (CONTINUED)	10 F		WITHIN NORMAL LIMITS	
	11 F		WITHIN NORMAL LIMITS	
	12 F		WITHIN NORMAL LIMITS	
1623	1 F		WITHIN NORMAL LIMITS	
	2 F		WITHIN NORMAL LIMITS	
	3 M		WITHIN NORMAL LIMITS	
	4 M		WITHIN NORMAL LIMITS	
	5 M		WITHIN NORMAL LIMITS	
	6 M		WITHIN NORMAL LIMITS	
	7 M		WITHIN NORMAL LIMITS	
	8 M		WITHIN NORMAL LIMITS	
	9 F		WITHIN NORMAL LIMITS	
	10 F		WITHIN NORMAL LIMITS	
	11 M		WITHIN NORMAL LIMITS	
	12 M		WITHIN NORMAL LIMITS	
	13 M		WITHIN NORMAL LIMITS	
	14 F		WITHIN NORMAL LIMITS	
	15 F		WITHIN NORMAL LIMITS	
1624	1 F		WITHIN NORMAL LIMITS	
	2 F		WITHIN NORMAL LIMITS	
	3 F		WITHIN NORMAL LIMITS	
	4 M		WITHIN NORMAL LIMITS	
	5 M		WITHIN NORMAL LIMITS	
	6 F		WITHIN NORMAL LIMITS	
	7 F		WITHIN NORMAL LIMITS	
	8 F		WITHIN NORMAL LIMITS	
	9 F		WITHIN NORMAL LIMITS	
	10 F		WITHIN NORMAL LIMITS	
	11 M		WITHIN NORMAL LIMITS	
	12 M		WITHIN NORMAL LIMITS	
	13 F		WITHIN NORMAL LIMITS	
	14 M		WITHIN NORMAL LIMITS	
	15 F		WITHIN NORMAL LIMITS	

CLASS CODES: M-Malformation V-Variation

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Huntingdon Life Sciences 96-4080D
Chemical Manufacturers Association

APPENDIX K

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FETAL EXTERNAL OBSERVATIONS

0 ppm

FEMALE#	FETUS#	ORGAN	CLASS	OBSERVATION
1625	1 M		WITHIN	NORMAL LIMITS
	2 F		WITHIN	NORMAL LIMITS
	3 F		WITHIN	NORMAL LIMITS
	4 M		WITHIN	NORMAL LIMITS
	5 M		WITHIN	NORMAL LIMITS
	6 F		WITHIN	NORMAL LIMITS
	7 F		WITHIN	NORMAL LIMITS
	8 M		WITHIN	NORMAL LIMITS
	9 F		WITHIN	NORMAL LIMITS
	10 M		WITHIN	NORMAL LIMITS
	11 F		WITHIN	NORMAL LIMITS
	12 F		WITHIN	NORMAL LIMITS
	13 F		WITHIN	NORMAL LIMITS
	14 M		WITHIN	NORMAL LIMITS
	15 F		WITHIN	NORMAL LIMITS

CLASS CODES: M-Malformation V-Variation

BFG42154

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Chemical Manufacturers Association

APPENDIX K

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rate

INDIVIDUAL FETAL EXTERNAL OBSERVATIONS

10 ppm

FEMALE#	FETUS#	ORGAN	CLASS OBSERVATION
2601	1 M		WITHIN NORMAL LIMITS
	2 P		WITHIN NORMAL LIMITS
	3 P		WITHIN NORMAL LIMITS
	4 P		WITHIN NORMAL LIMITS
	5 P		WITHIN NORMAL LIMITS
	6 M		WITHIN NORMAL LIMITS
	7 M		WITHIN NORMAL LIMITS
2602	1 M		WITHIN NORMAL LIMITS
	2 M		WITHIN NORMAL LIMITS
	3 P		WITHIN NORMAL LIMITS
	4 M		WITHIN NORMAL LIMITS
	5 M		WITHIN NORMAL LIMITS
	6 M		WITHIN NORMAL LIMITS
	7 M		WITHIN NORMAL LIMITS
	8 L	GROSS EXAM	* MISSHAPEN HEAD
2603			ABSENCE OF SNOUT; FLESHY GROWTH ON THE REGION OF SNOUT;
			ABSENCE OF UPPER AND LOWER JAW
		CROWN-RUMP	CROWN-RUMP DISTANCE
			2.9 CM
	10 M		WITHIN NORMAL LIMITS
	11 M		WITHIN NORMAL LIMITS
	12 M		WITHIN NORMAL LIMITS
	13 P		WITHIN NORMAL LIMITS
	1 P		WITHIN NORMAL LIMITS
	2 M		WITHIN NORMAL LIMITS
	3 P		WITHIN NORMAL LIMITS
	4 M		WITHIN NORMAL LIMITS
	5 P		WITHIN NORMAL LIMITS
	6 M		WITHIN NORMAL LIMITS
	7 P		WITHIN NORMAL LIMITS
	8 M		WITHIN NORMAL LIMITS
	9 P		WITHIN NORMAL LIMITS
	10 M		WITHIN NORMAL LIMITS
	11 P		WITHIN NORMAL LIMITS
	12 M		WITHIN NORMAL LIMITS

CLASS CODES: M-Malformation V-Variation
FETAL STATUS CODES: L-late resorption

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APPENDIX K

Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FETAL EXTERNAL OBSERVATIONS

10 ppm

FEMALE#	FETUS#	ORGAN	CLASS OBSERVATION
2603	(CONTINUED)		
	13 M		WITHIN NORMAL LIMITS
2604	1 F		WITHIN NORMAL LIMITS
	2 F		WITHIN NORMAL LIMITS
	3 M		WITHIN NORMAL LIMITS
	4 F		WITHIN NORMAL LIMITS
	5 F		WITHIN NORMAL LIMITS
	6 M		WITHIN NORMAL LIMITS
	7 F		WITHIN NORMAL LIMITS
	8 F		WITHIN NORMAL LIMITS
	9 F		WITHIN NORMAL LIMITS
	10 M		WITHIN NORMAL LIMITS
	11 F		WITHIN NORMAL LIMITS
	12 M		WITHIN NORMAL LIMITS
	13 M		WITHIN NORMAL LIMITS
2605	1 F		WITHIN NORMAL LIMITS
	2 F		WITHIN NORMAL LIMITS
	3 M		WITHIN NORMAL LIMITS
	4 M		WITHIN NORMAL LIMITS
	5 F		WITHIN NORMAL LIMITS
	6 M		WITHIN NORMAL LIMITS
	7 F		WITHIN NORMAL LIMITS
	8 F		WITHIN NORMAL LIMITS
	9 F		WITHIN NORMAL LIMITS
	10 M		WITHIN NORMAL LIMITS
	11 M		WITHIN NORMAL LIMITS
	12 M		WITHIN NORMAL LIMITS
	13 M		WITHIN NORMAL LIMITS
	14 F		WITHIN NORMAL LIMITS
2606	1 M		WITHIN NORMAL LIMITS
	2 M		WITHIN NORMAL LIMITS
	3 F		WITHIN NORMAL LIMITS
	4 F		WITHIN NORMAL LIMITS
	5 F		WITHIN NORMAL LIMITS
	6 M		WITHIN NORMAL LIMITS

CLASS CODES: M=Malformation V=Variation

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Vinyl Chloride Combined Inhalation Two-Generation
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INDIVIDUAL FETAL EXTERNAL OBSERVATIONS

10 ppm

FEMALE#	FETUS#	ORGAN	CLASS	OBSERVATION
2606	(CONTINUED)			
	7 F		WITHIN	NORMAL LIMITS
	8 M		WITHIN	NORMAL LIMITS
	9 F		WITHIN	NORMAL LIMITS
	10 M		WITHIN	NORMAL LIMITS
	11 F		WITHIN	NORMAL LIMITS
	12 M		WITHIN	NORMAL LIMITS
	13 F		WITHIN	NORMAL LIMITS
2607	1 M		WITHIN	NORMAL LIMITS
	3 F		WITHIN	NORMAL LIMITS
	4 M		WITHIN	NORMAL LIMITS
	5 F		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS
	7 M		WITHIN	NORMAL LIMITS
	8 F		WITHIN	NORMAL LIMITS
	9 M		WITHIN	NORMAL LIMITS
	10 M		WITHIN	NORMAL LIMITS
	11 F		WITHIN	NORMAL LIMITS
	13 M		WITHIN	NORMAL LIMITS
	14 M		WITHIN	NORMAL LIMITS
2608	1 M		WITHIN	NORMAL LIMITS
	2 F		WITHIN	NORMAL LIMITS
	3 M		WITHIN	NORMAL LIMITS
	4 F		WITHIN	NORMAL LIMITS
	5 F		WITHIN	NORMAL LIMITS
	6 F		WITHIN	NORMAL LIMITS
	7 M		WITHIN	NORMAL LIMITS
	8 F		WITHIN	NORMAL LIMITS
	9 M		WITHIN	NORMAL LIMITS
	10 F		WITHIN	NORMAL LIMITS
	11 F		WITHIN	NORMAL LIMITS
2609	1 F		WITHIN	NORMAL LIMITS
	2 M		WITHIN	NORMAL LIMITS
	3 M		WITHIN	NORMAL LIMITS
	4 F		WITHIN	NORMAL LIMITS

CLASS CODES: M=Malformation V=Variation

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Vinyl Chloride Combined Inhalation Two-Generation
Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FETAL EXTERNAL OBSERVATIONS

10 ppm

FEMALE#	FETUS#	ORGAN	CLASS	OBSERVATION
2609	(CONTINUED)			
	5 M		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS
	7 F		WITHIN	NORMAL LIMITS
	8 M		WITHIN	NORMAL LIMITS
	9 M		WITHIN	NORMAL LIMITS
	10 F		WITHIN	NORMAL LIMITS
	11 M		WITHIN	NORMAL LIMITS
	12 M		WITHIN	NORMAL LIMITS
2610	1 F		WITHIN	NORMAL LIMITS
	2 F		WITHIN	NORMAL LIMITS
	3 M		WITHIN	NORMAL LIMITS
	4 F		WITHIN	NORMAL LIMITS
	5 F		WITHIN	NORMAL LIMITS
	6 F		WITHIN	NORMAL LIMITS
	7 F		WITHIN	NORMAL LIMITS
	8 F		WITHIN	NORMAL LIMITS
	10 M		WITHIN	NORMAL LIMITS
	11 F		WITHIN	NORMAL LIMITS
	12 M		WITHIN	NORMAL LIMITS
2612	1 F		WITHIN	NORMAL LIMITS
	2 F		WITHIN	NORMAL LIMITS
	3 F		WITHIN	NORMAL LIMITS
	4 F		WITHIN	NORMAL LIMITS
	5 M		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS
	7 M		WITHIN	NORMAL LIMITS
	8 M		WITHIN	NORMAL LIMITS
	9 M		WITHIN	NORMAL LIMITS
	10 M		WITHIN	NORMAL LIMITS
	11 F		WITHIN	NORMAL LIMITS
	12 M		WITHIN	NORMAL LIMITS
	13 M		WITHIN	NORMAL LIMITS

CLASS CODES: M=Malformation V=Variation

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Reproduction and Developmental Toxicity Study in CD Rats

INDIVIDUAL FETAL EXTERNAL OBSERVATIONS

10 ppm

FEMALE#	FETUS#	ORGAN	CLASS	OBSERVATION
2613	1 M		WITHIN	NORMAL LIMITS
	2 M		WITHIN	NORMAL LIMITS
	3 M		WITHIN	NORMAL LIMITS
	4 F		WITHIN	NORMAL LIMITS
	5 M		WITHIN	NORMAL LIMITS
	6 F		WITHIN	NORMAL LIMITS
	7 M		WITHIN	NORMAL LIMITS
	8 M		WITHIN	NORMAL LIMITS
	9 M		WITHIN	NORMAL LIMITS
	10 M		WITHIN	NORMAL LIMITS
	11 M		WITHIN	NORMAL LIMITS
	12 F		WITHIN	NORMAL LIMITS
2614	1 F		WITHIN	NORMAL LIMITS
	2 F		WITHIN	NORMAL LIMITS
	3 F		WITHIN	NORMAL LIMITS
	4 M		WITHIN	NORMAL LIMITS
	5 F		WITHIN	NORMAL LIMITS
	6 M		WITHIN	NORMAL LIMITS
	7 M		WITHIN	NORMAL LIMITS
	9 M		WITHIN	NORMAL LIMITS
	10 M		WITHIN	NORMAL LIMITS
	11 M		WITHIN	NORMAL LIMITS
2615	1 F		WITHIN	NORMAL LIMITS
	2 F		WITHIN	NORMAL LIMITS
	3 F		WITHIN	NORMAL LIMITS
	4 F		WITHIN	NORMAL LIMITS
	5 M		WITHIN	NORMAL LIMITS
	6 F		WITHIN	NORMAL LIMITS
	7 M		WITHIN	NORMAL LIMITS
	8 F		WITHIN	NORMAL LIMITS
	9 F		WITHIN	NORMAL LIMITS
	10 M		WITHIN	NORMAL LIMITS
	12 M		WITHIN	NORMAL LIMITS
	13 F		WITHIN	NORMAL LIMITS

CLASS CODES: M-Malformation V-Variation