



FINAL REPORT

Oral (Gavage) Combined Developmental and Perinatal/Postnatal Reproduction Toxicity Study of PFH Ammonium Salt (Ammonium salt of Perfluorinated Hexanoic Acid) in Mice

Author

, Ph.D., DABT, Fellow ATS
(Study Director)

Study Completed On

Final Report 25 August 2011

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Charles River Laboratories Preclinical Services Protocol Number: UZS00010

1. STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA Section 10(d) (1)(A), (B), or (C).

This statement supersedes any other claims of confidentiality found in this report.

Company:

Company Agent:

Title:

Date: _____

Signature: _____

2. GLP COMPLIANCE STATEMENT

This final report accurately reflects the raw data obtained during the performance of the study. No deviations from the Good Laboratory Practice (GLP) regulations of the U.S. Environmental Protection Agency^a, the Japanese Ministry of Agriculture, Forestry and Fisheries^b, and the Organisation for Economic Co-operation and Development^c occurred that affected the quality or integrity of the study, with the following exceptions.

- All reports generated by Charles River Laboratories Preclinical Services Montreal were conducted in accordance with the appropriate FDA and/or OECD Principles of GLP. The OECD regulations were appropriate for these analyses.

Submitter:

Date

Sponsor:

Date

Aug 20 '1

Date

Executive Director, Site Operations and Toxicology
Study Director

-
- U.S. Environmental Protection Agency. Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); Good Laboratory Practice Standards; Final Rule. 40 CFR Part 160.
 - Japanese Ministry of Agriculture, Forestry and Fisheries (1999). Notification on the Good Laboratory Practice (GLP) Standards for Agricultural Chemicals. 11 Nousan No. 6283.
 - Organisation for Economic Co-operation and Development (1998). The Revised OECD Principles of Good Laboratory Practice [C(97)186/Final].

3. FLAGGING STATEMENT

I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study. This study neither meets nor exceeds any of the applicable criteria.

Company:

Company Agent:

Title:

Date: _____

Signature: _____

4. QUALITY ASSURANCE STATEMENT

Protocol: UZS00010

This study has been inspected by the Quality Assurance Unit to assure conformance with the Good Laboratory Practice (GLP) regulations promulgated by the U.S. Environmental Protection Agency which are compatible with current Organisation for Economic Co-operation and Development; and the Japanese Ministry of Agriculture, Forestry and Fisheries Good Laboratory Practices. Reports were submitted in accordance with Standard Operating Procedures as follows

QAU INSPECTION DATES

Dates of Inspection	Phase(s) Inspected	<u>Dates Findings Submitted to:</u>	
		Study Director	Study Director Management
10 DEC 2009	Protocol	10 DEC 2009	10 DEC 2009
28 DEC 2009	Protocol Amendment 1	28 DEC 2009	28 DEC 2009
09 FEB 2010	Protocol Amendment 2	09 FEB 2010	09 FEB 2010
28 DEC 2009	Test Substance Preparation	28 DEC 2009	28 DEC 2009
31 DEC 2009	Test Substance Administration	31 DEC 2009	31 DEC 2009
12 JAN 2010	Natural Delivery/Litter Observations	12 JAN 2010	12 JAN 2010
26 JAN 2010	Eye Opening	26 JAN 2010	26 JAN 2010
04 FEB 2010	Dam/Litter Sacrifice	05 FEB 2010	05 FEB 2010
23 FEB 2010	F1 Generation Necropsy	23 FEB 2010	23 FEB 2010
23 FEB 2010	Blood Collection	23 FEB 2010	23 FEB 2010
16, 26 MAR & 06-08, 12 APR 2010	In-Life Data	12 APR 2010	12 APR 2010
24 MAR 2010	Formulations Data	29 MAR 2010	29 MAR 2010

Dates Findings Submitted to:

Dates of Inspection	Phase(s) Inspected	Study Director	Study Director Management
06, 08-09 APR 2010	Necropsy Data	09 APR 2010	09 APR 2010
13, 14, 17, 18 MAY 2010	Report Tables	18 MAY 2010	18 MAY 2010
06, 07, 10-11 MAY 2010	Methods	11 MAY 2010	11 MAY 2010
20 MAY 2010	Results	20 MAY 2010	20 MAY 2010
21 MAY 2010	Summary	21 MAY 2010	21 MAY 2010
05, 08 AUG 2011	Final Report	08 AUG 2011	08 AUG 2011

QA statements were provided by the following Test Sites and were reviewed:

Test Site(s)	Phase	QA Statement Location
Charles River Preclinical Services Montreal	Formulation Analysis	Appendix 4
Charles River Preclinical Services Montreal	Bioanalytical	Appendix 5
Charles River Preclinical Services Montreal	Pharmacokinetic Analysis	Appendix 5

The Final Report has been reviewed to assure that it accurately describes the materials and methods, and that the reported results accurately reflect the raw data.

26 AUG 2011

Date

Quality Assurance Auditor II
Charles River Laboratories
Preclinical Services, Pennsylvania

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5. SUMMARY AND CONCLUSION

5.1. Purpose

The purpose of this study was to test for toxic effects/disturbances resulting from PFH Ammonium Salt (Ammonium salt of Perfluorinated Hexanoic Acid) treatment of Crl:CD1(ICR) pregnant female mice and development of the embryo and fetus consequent to exposure of the dam from implantation to closure of the hard palate and during lactation. This study was designed to evaluate the ICH Harmonised Tripartite Guideline stages C through F of the reproductive process and detect effects on gestation, parturition, lactation and maternal behavior in female mice, and on the development of the offspring of the treated female mice. Because manifestations of effects induced during this period may be delayed in the offspring, observations were continued through sexual maturity of the F1 generation mice.

5.2. Methods^a

Eighty presumed pregnant Crl:CD1(ICR) mice were randomly assigned to four dosage groups (Groups I through IV), 20 mice per group. Solutions of the test substance, PFH Ammonium Salt (Ammonium salt of Perfluorinated Hexanoic Acid), and/or the vehicle, reverse osmosis membrane processed deionized water (R.O. deionized water), were administered orally once daily to these naturally bred mice on day 6 of presumed gestation (DG 6) through DG 18 at dosages of 0 (Vehicle), 7, 35 and 175 mg/kg/day. The dosage volume was 5 mL/kg. After completion of the 20 day postpartum period (PPD 20), F0 generation female mice were sacrificed and liver samples were collected from 5 mice per group for pharmacokinetic analysis; mice that did not deliver a litter were sacrificed on DG 23. Additionally, on PPD 20, all pups not selected for continued evaluation were sacrificed. F1 generation mice selected for continued evaluation were sacrificed on PPD 41. Blood and liver samples were collected from five mice per sex per group for pharmacokinetic analysis.

The following parameters were evaluated for F0 generation female mice: viability, clinical observations, body weights, body weight changes, maternal behavior, litter observations, natural delivery, pup body weights, dam and pup necropsy observations.

The following parameters were evaluated for F1 generation male and female mice: viability, clinical observations, body weights, body weight changes, eye opening, age of sexual maturity and necropsy observations.

a. Detailed descriptions of all procedures used in the conduct of this study are provided in the appropriate sections of this report and in APPENDIX 1 (PROTOCOL).

5.3. Results

5.3.1. F0 Generation Mice

No mortality related to PFH ammonium salt occurred. All mice survived until scheduled sacrifice, with the exception of one mouse in the 7 mg/kg/day dosage group that was sacrificed on DG 17 when it delivered its litter; and one mouse in the 35 mg/kg/day dosage group was sacrificed on day 2 of lactation (DL 2) due to no surviving pups. All other clinical observations during the gestation and lactation period were considered unrelated to the test substance.

There were no test substance related necropsy observations.

Body weight gains during the gestation and lactation period were unaffected by dosages of the test substance as high as 175 mg/kg/day.

Pregnancy occurred in 20, 17, 20 and 20 of the 20 mated female mice in the 0 (Vehicle), 7, 35 and 175 mg/kg/day dosage groups, respectively. All pregnant dams delivered a litter.

The number of stillborn pups and pups dying on PPD 1 were significantly increased and the average pup weight per litter was significantly reduced on PPD 1 in the 175 mg/kg/day dosage group compared to the 0 (Vehicle) mg/kg/day dosage group values. All other natural delivery and litter observations were unaffected by dosages of the test substance as high as 175 mg/kg/day.

Terminal body weights were comparable among the four dosage groups. The absolute weights of the liver and the ratio of the liver weight to the terminal body weight did not differ significantly among the groups.

Two litters in the 175 mg/kg/day dosage group had a pup each with corneal opacity and one pup each with microphthalmia. One litter in this dosage group also had a pup with a lenticular opacity. No other clinical observations in the F1 generation pups were attributed to dosages of the test substance as high as 175 mg/kg/day.

The day of eye opening did not differ among the groups.

No necropsy observations in the F1 generation pups were attributed to dosages of the test substance as high as 175 mg/kg/day.

5.3.2. F1 Generation Mice

All F1 generation male and female mice survived to scheduled sacrifice. All clinical observations in the F1 generation male and female mice were considered unrelated to maternal administration of the test substance.

Necropsy observations in the F1 generation female and male mice occurred in one mouse each in the 35 and 175 mg/kg/day dosage groups, respectively. One male mouse had a clear fluid filled cyst in the liver and one female mouse had a dark flat red mass in the mesentery.

Body weights and body weight gains of the F1 generation male and female mice were unaffected by maternal dosages of the test substance as high as 175 mg/kg/day.

Sexual maturation was unaffected by maternal dosages of the test substance as high as 175 mg/kg/day.

Terminal body weights were comparable among the four groups. Maternal dosages of the test substance as high as 175 mg/kg/day did not affect the liver weights or the ratio of liver weights to the terminal body weight. There were no significant differences among the groups.

5.4. Conclusion

On the basis of these data, the maternal no-observable-adverse-effect-level (NOEL) for PFH Ammonium Salt is 175 mg/kg/day (the highest dosage tested.). The NOAEL in the F1 generation is 35 mg/kg/day (the 175 mg/kg/day dosage had an increase in the number of stillborn pups and pups dying day 1 along with a reduction in pup weights on postnatal day 1, two litters in this dosage group also had a corneal opacity). None of the effects observed in the pups preweaning persisted into the postweaning period.

6/21/2011

Date

Executive Director, Site Operations and Toxicology
Study Director

6. DESCRIPTION OF TEST PROCEDURES

6.1. Conduct of Study

6.1.1. Sponsor

Daikin Industries, LTD, Chemical Division, Umeda Center Building, 4-12 Nakazaki-Nishi, 2-chrome, Kita-ku, Osaka 530-8323, JAPAN

6.1.2. Testing Facility

Charles River Laboratories Preclinical Services, 905 Sheehy Drive, Building A, Horsham, PA 19044, USA

6.1.3. Study Number

UZS00010

6.1.4. Purpose of the Study

The purpose of this study was to test for toxic effects/disturbances resulting from PFH Ammonium Salt (Ammonium salt of Perfluorinated Hexanoic Acid) treatment of Crl:CD1(ICR) pregnant female mice and development of the embryo and fetus consequent to exposure of the dam from implantation to closure of the hard palate and during lactation. This study was designed to evaluate the ICH Harmonised Tripartite Guideline stages C through F of the reproductive process and detect effects on gestation, parturition, lactation and maternal behavior in female mice, and on the development of the offspring of the treated female mice. Because manifestations of effects induced during this period may be delayed in the offspring, observations were continued through sexual maturity of the F1 generation mice.

6.1.5. Study Design

This study was conducted in compliance with the Good Laboratory Practice (GLP) regulations of the U.S. Environmental Protection Agency (EPA)⁽¹⁾, the Japanese Ministry of Agriculture, Forestry and Fisheries⁽²⁾ and the Organisation for Economic Co-operation and Development (OECD)⁽³⁾. The pharmacokinetic analysis and analytical portion of the study were conducted in accordance with the appropriate FDA and OECD Principles of GLP (ENV/MC/CHEM(98)17).

6.1.6. Ownership of the Study

The Sponsor owns the study. All raw data, analyses, reports and preserved tissues are the property of the Sponsor.

6.1.7. Study Monitor

. (Daikin Industries, Ltd., 1-1 Nishi Hitotsuya, Settsu City,
Osaka, 566-8585, JAPAN)

6.1.8. Study Director

, Ph.D., DABT, Fellow ATS (Executive Director, Site Operations
and Toxicology)
Address as cited previously for Testing Facility.

6.1.9. Technical Performance

6.1.9.1. Charles River Laboratories Preclinical Services, Pennsylvania, USA

6.1.9.2. Charles River Laboratories Preclinical Services, Montreal, CANADA

. (Principal Investigator) - Dose formulation analysis
Principal Investigator) - Pharmacokinetic analysis

6.1.10. Report Preparation

6.1.11. Report Review

. (Principal Scientist)

6.1.12. Date Protocol Signed

21 December 2009

6.1.13. Dates of Technical Performance

Experimental Start Date (OECD)	23 DEC 2009
Experimental Start Date (EPA)	30 DEC 2009
Experimental Termination/Completion Date	20 JUN 2011

6.1.13.1. F0 Generation Mice

Mouse Arrival	15 DEC 2009
Cohabitation Period	23 DEC 2009 PM – 28 DEC 2009 AM
DG ^a 0	24 DEC 2009 – 28 DEC 2009
Dosage Period (DG 6 through 18)	30 DEC 2009 – 15 JAN 2010
Delivery Period (DL ^b 0)	11 JAN 2010 – 16 JAN 2010
DG 23 Sacrifice (Mice that did not deliver a litter)	16 JAN 2010
DL 20 Sacrifice (Dams and pups not selected for continued observation)	31 JAN 2010 – 05 FEB 2010

6.1.13.2. F1 Generation Mice

Sexual Maturation	
Female Mice	31 JAN 2010 – 15 FEB 2010
Male Mice	06 FEB 2010 – 14 FEB 2010
Terminal Blood Collection (PPD ^c 41)	22 FEB 2010 – 23 FEB 2010
Scheduled Sacrifice	21 FEB 2010 – 26 FEB 2010

6.1.14. Records Maintained

The original report, raw data and reserve samples of the bulk test substance and bulk vehicle are retained in the archives of the Testing Facility. Preserved tissues are retained in the archives of the Testing Facility for ten years after the mailing of the draft final report, after which time the Sponsor will decide their final disposition. All unused test substance formulations were discarded at the Testing Facility. The bulk test substance was transferred to Charles River Laboratories Study No. 20005045 and documented in the raw data. Remaining unused blood, serum and liver samples will be retained at Charles River Laboratories – Montreal, Canada for approximately 1 year after dispatch of the final report or until authorized to discard by the Study Director.

-
- a. DG is an abbreviation used for day of (presumed) gestation.
 - b. DL is an abbreviation used for day of lactation.
 - c. PPD is an abbreviation used for day postpartum.

6.2. Test Substance and Vehicle Information

Test Substance Information			
Name	PFH Ammonium Salt (C-1500N) ^a	Description	Colorless liquid
Storage	Room temperature	Supplier	Sponsor
Lot Number		Date Received	Expiration Date
7005		22 APR 2009	31 JUL 2012
Vehicle Information			
R.O. Deionized Water ^b		c	

a. Synonymous with C-1500N and Ammonium salt of Perfluorinated Hexanoic Acid. The test substance was supplied as a 50% aqueous solution.

b. R.O. deionized water is an abbreviation used for reverse osmosis membrane processed deionized water.

c. R.O. deionized water is available from a continuous source at the Testing Facility and is maintained at room temperature.

Temperature:				
Sampling				
Bulk Test Substance				
Sample Size: 10 mL				
Date Sampled	Date Shipped	Recipient	Holding/Shipping Conditions	
15 JAN 2010	19 JAN 2010	Montreal, CANADA ^a	RT/AT	
Bulk Test Substance Reserve				
Sample Size: 5 mL				
Date Sampled	Storage Condition		Date Archived	
17 JAN 2010	RT		17 FEB 2010	
Bulk Vehicle Reserve				
Sample Size: 5 mL				
Date Sampled	Storage Conditions		Date Archived	
17 JAN 2010	RT		17 FEB 2010	
Concentration and Homogeneity ^b				
Sample Size: 2 mL				
Date Sampled	Date Shipped	Recipient	Holding/Shipping Conditions	Purpose
29 DEC 2009	29 DEC 2009	Montreal, CANADA ^a	RT/AT	C, H
29 DEC 2009	05 JAN 2010		RT/AT	C, H (backup samples)
05 JAN 2010	05 JAN 2010		RT/AT	C
05 JAN 2010	12 JAN 2010		RT/AT	C (backup samples)
12 JAN 2010	12 JAN 2010		RT/AT	C
12 JAN 2010	19 JAN 2010		RT/AT	C (backup samples)

a. Charles River Laboratories - Montreal, CANADA

b. Quadruplicate samples for analysis of concentration and homogeneity, were taken from the top, middle and bottom of each concentration 24 hours or more after preparation, and no more than 24 hours before dosing on the first day all concentrations were prepared. Quadruplicate samples, for analysis of concentration, were taken from the middle of each concentration at the mid-point of the study period and on the last day all concentrations are prepared 24 hours or more after preparation, and no more than 24 hours before dosing. Two samples from each quadruplicate set were shipped (ambient conditions) for analysis; the remaining samples were retained at the Testing Facility as backup samples and shipped (ambient condition) one week after successful delivery of the initial shipment. Samples were stored at room temperature until analysis.

RT – Room temperature

AT – Ambient temperature

C – Concentration

H – Homogeneity

6.2.1. Special Handling Instructions

Double nitrile gloves, dust-mist/HEPA-filtered mask, appropriate eye protection and protective clothing were worn during formulation preparation and dosage.

6.2.2. Analysis of Activity/Purity

The test substance was considered 95% active/pure by weight of PFH acid for the purpose of dosage calculations.

The test substance is a marketed product and characterized by its labeling. Information to document or certify the identity, composition, strength and activity/purity of the test substance was provided by the Sponsor to the Testing Facility. A Certificate of Analysis is available in APPENDIX 3. The Certificate of Analysis was not in compliance with the GLPs listed in this report. This deviation did not adversely affect the outcome or interpretation of the study because this is a chemical product.

Neither the Sponsor nor the Study Director was aware of any potential contaminants likely to have been present in the vehicle that would have interfered with the results of this study.

6.2.2.1. Test Substance Preparation and Storage Conditions

Solutions of the test substance were prepared once weekly at the Testing Facility and stirred continuously for at least 24 hours prior to dosage administration and stored at room temperature. The vehicle (R.O. water) was available from a continuous source at the Testing Facility and maintained at room temperature.

6.2.3. Analytical Results

The study samples analyzed were within the acceptance criteria of $\pm 10\%$ of their mean nominal concentrations. For homogeneity, the relative standard deviation (RSD) for the formulation for the grand mean of the average value for the top, middle and bottom formulations for each group was $\leq 5\%$. Homogeneity results showed that the formulation technique used produces homogenous preparations. Detailed results of the prepared test substance concentration, homogeneity and bulk stability analysis are available in APPENDIX 4.

Stability of the prepared test substance formulations were assessed under Charles River Laboratories Preclinical Services Montreal Study Number 211052. Stability was demonstrated for 10 days at room temperature from 7 mg/mL to 70 mg/mL.

6.3. Test System**6.3.1. Species/Strain**

Mouse/Crl:CD1(ICR)

6.3.2. Supplier (Source)

Charles River Laboratories, Inc., St Constant, CANADA

6.3.3. Sex

Female (Note: Male mice were used only for the purpose of breeding and are not considered part of the Test System.)

6.3.4. Rationale for Test System

The Crl:CD1(ICR) mouse was selected as the Test System because: 1) it is one mammalian species accepted and widely used throughout the industry for nonclinical studies of developmental toxicity (embryo-fetal toxicity/teratogenicity); 2) this strain has been demonstrated to be sensitive to developmental toxicants; and 3) historical data and experience exist at the Testing Facility.

6.3.5. Test System Data

Number of Mice Acclimated	100
Number of Mice Assigned to Study	80
Approximate Date of Birth	14 OCT 2009
Approximate Age at Arrival	63 days
Weight (g) the Day after Arrival	25.6 – 33.3
Weight (g) at Study Assignment (DG 0)	25.8 – 31.7

6.3.6. Method of Randomization**6.3.6.1. F0 Generation Mice**

Upon arrival, mice were assigned to individual housing on the basis of computer-generated random units. Healthy, mated female mice were assigned to four dosage groups (Groups I through IV), 20 mice per group, using a computer-generated (weight ordered) randomization procedure based on body weights recorded on DG 0.

6.3.6.2. F1 Generation Pups/Mice

Litters were not culled during the lactation period because random selection of pups for culling could have resulted in potential biases in pup viabilities and body weight gains during this period.

All F1 generation mice were weaned at the same age, based on observed growth and viability of the pups, on day 20 postpartum.

At weaning, a table of random units were used to select 20 male and 20 female pups per group, resulting in a total of 160 F1 generation mice (80 per sex) chosen for continued evaluation. At least one male pup and one female pup per litter, when possible, were selected.

6.3.7. System of Identification

6.3.7.1. F0 Generation Mice

Male mice were given permanent identification numbers upon assignment to the Testing Facility's breeder male mouse population. Breeder mice were permanently identified using a tail tattoo (AIMS Black Pigment #242). Female mice were given temporary numbers at receipt and given permanent identification numbers when assigned to the study on the basis of DG 0 body weights. Female mice were permanently identified using a tail tattoo. Cage tags were marked with the study number, permanent mouse number, sex, generation, test substance identification, group number and dosage level.

6.3.7.2. F1 Generation Pups/Mice

Pups were not individually identified during the lactation period; all parameters were evaluated in terms of the litter. At weaning, F1 generation mice were identified by tail tattoo. Cage tags were marked with the study number, permanent mouse number, sex, generation, test substance identification, group number and dosage level.

6.4. Husbandry

6.4.1. Research Facility Registration

USDA Registration No. 14-R-0144 under the Animal Welfare Act, 7 U.S.C. 2131 *et seq.*

6.4.2. Study Rooms

The study rooms were maintained under conditions of positive airflow relative to a hallway and independently supplied with a minimum of ten changes per hour of 100% fresh air that had been passed through 99.97% HEPA filters. Room temperature and humidity were monitored constantly throughout the study. Room temperature was targeted at 64°F to 79°F (18°C to 26°C); relative humidity was targeted at 30% to 70%^a.

a. See APPENDIX 6 (ENVIRONMENTAL AND HUSBANDRY REPORTS).

6.4.3. Housing

All cage sizes and housing conditions were in compliance with the *Guide for the Care and Use of Laboratory Animals*⁽⁴⁾.

6.4.3.1. F0 Generation Mice

F0 generation mice were individually housed in stainless steel, wire-bottomed cages, except during the cohabitation and postpartum periods. During cohabitation, each pair of male and female mice was housed in the male mouse's cage. Each dam and delivered litter was housed in a common nesting box during the postpartum period.

6.4.3.2. F1 Generation Mice

After weaning (PPD 20), F1 generation mice were housed in nesting boxes. Mice were pair housed until at least PND 27, after which point they were individually housed.

6.4.4. Light

An automatically controlled 12-hours light:12-hours dark fluorescent light cycle was maintained. Each dark period began at 1900 hours ($\pm$ 30 minutes).

6.4.5. Sanitization

Cages were changed approximately every other week. Bedding was changed as often as necessary to keep the mice dry and clean.

6.4.6. Feed

Mice were given *ad libitum* access to Certified Rodent Diet[®] #5002 (PMI[®] Nutrition International, Inc., St. Louis, MO, USA) in individual feeders.

6.4.7. Feed Analysis

Analyses were routinely performed by the feed supplier. No contaminants at levels exceeding the maximum concentration for certified feed or deviations from expected nutritional requirements were detected by these analyses. Copies of the results of the feed analyses are available APPENDIX 6 and in the raw data.

Neither the Sponsor nor the Study Director was aware of any potential contaminants likely to have been present in the feed that would have interfered with the results of this study.

6.4.8. Water

Local water that had been processed by passage through a reverse osmosis membrane (R.O. water) was available to the mice *ad libitum* from individual water bottles attached to the cages. Chlorine was added to the processed water as a bacteriostat.

6.4.9. Water Analysis

The processed water is analyzed twice annually for possible chemical contamination (Lancaster Laboratories, Lancaster, PA, USA) and monthly for possible bacterial contamination (QC Laboratories, Southampton, PA, USA). Copies of the results of the water analyses are available in APPENDIX 6 and in the raw data.

Neither the Sponsor nor the Study Director was aware of any potential contaminants likely to have been present in the water that would have interfered with the results of this study.

6.4.10. Bedding Material

Bed-o'cobs[®] bedding (The Andersons Industrial Products Group, Maumee, OH, USA) was used as the nesting material.

6.4.11. Bedding Analysis

Each lot of bedding is analyzed for possible contamination (Lancaster Laboratories, Lancaster, PA, USA). Copies of the results of the bedding analyses are available in APPENDIX 6 and in the raw data.

Neither the Sponsor nor the Study Director was aware of any potential contaminants likely to have been present in the bedding that would have interfered with the results of this study.

6.4.12. Day Numbering System

Gestation day 0 is defined as the day spermatozoa are observed in a smear of the vaginal contents and/or a copulatory plug observed *in situ*.

The day of birth is designated postnatal day 0 (day 0 of lactation) in Addendum 10 to the Pesticide Assessment Guidelines of the U.S. Environmental Protection Agency (EPA). This same day is designated day 1 postpartum (day 1 of lactation) in the Standard Operating Procedures of the Testing Facility. In the report text, as well as summary and individual tables, the day of birth was adjusted so that the day of birth and all subsequent lactation/postpartum days match the EPA guideline.

6.5. Methods

6.5.1. F0 Generation Mice

Dosage Group	Number of Mice Assigned to Study	Dosage (mg/kg/day)	Concentration (mg/mL)	Dosage Volume (mL/kg)	Assigned Mice Number
I	20	0 (Vehicle)	0	5	401 – 420
II	20	7	1.4	5	421 – 440
III	20	35	7	5	441 – 460
IV	20	175	35	5	461 – 480

The test substance was considered 95% by weight of PFH acid for dosage calculations.

6.5.2. F1 Generation Mice

Dosage Group	Maternal Dosage (mg/kg/day)	Number of Mice Per Sex	Assigned F1 Generation Mouse Numbers	
			Male Mice	Female Mice
I	0 (Vehicle)	20	501 – 520	601 – 620
II	7	20	521 – 540	621 – 640
III	35	20	541 – 560	641 – 660
IV	175	20	561 – 580	661 – 680

6.5.3. Rationale for Dosage Selection

Perfluorobutyrate (PFBA) is a perfluoroalkyl acid (PFAA) found in the environment. Previous studies have indicated developmental toxicity of PFAAs (perfluorooctane sulfonate [PFOS] and perfluorooctanoate [PFOA]). PFBA/NH₄⁺ was given to timed-pregnant CD-1 mice by oral gavage daily from gestation day (DG) 1 to 17 at 35, 175 and 350 mg/kg; controls received water. At DG 18, serum levels of PFBA were 3.8, 4.4 and 2.5 µg/mL, respectively, in the three treated groups. PFBA did not significantly affect maternal weight gain, number of implantations, fetal viability, fetus weight, or incidence of fetal malformations. Incidence of full-litter loss was significantly greater in the 350 mg/kg group, and maternal liver weights were significantly increased in the 175 and 350 mg/kg groups. In contrast to PFOA, and PFOS, PFBA exposure during pregnancy did not adversely affect neonatal survival or postnatal growth. Liver enlargement was detected in the PFBA-exposed pups on postnatal (PD) 1, but not by PD 10. Expression of selected hepatic genes in PFBA-exposed pups at PD 1 did not reveal any significant changes from controls. A significant delay in eye-opening in offspring was detected in all three PFBA groups, and slight delays in the onset of puberty were noted in the 175 and 350 mg/kg groups. These data suggest that exposure to PFBA during pregnancy in the mouse did not produce developmental toxicity comparable to that observed with PFOA, in part, due to rapid elimination of the chemical⁽⁵⁾. In the acute pharmacokinetic study (UZS00009), mice were administered a single dose at 35, 175 or 350 mg/kg. All mice survived to scheduled sacrifice, and no adverse clinical signs occurred during this study. Based on these results, dosages of 7, 35 and 175 mg/kg/day were selected for the developmental and perinatal/postnatal reproduction toxicity study.

6.5.4. Route and Rationale for Route of Administration

The oral (gavage) route was selected for use because: 1) in comparison with the dietary route, the exact dosage can be accurately administered; and 2) it is one possible route of human exposure.

6.5.5. Method and Frequency of Administration

6.5.5.1. F0 Generation Mice

Female mice were administered the test substance and/or vehicle once daily from DG 6 through DG 18. Dosages were adjusted daily for body weight changes and given at approximately the same time each day. Dams in the process of delivering pups were not administered the test substance or vehicle in order to preclude possible disruption to maternal behavior and/or cannibalization of the pups.

6.5.5.2. F1 Generation Pups

F1 generation pups were not directly administered the test substance and/or vehicle, but may have been possibly exposed to the test substance and/or vehicle during maternal gestation (*in utero* exposure) or via maternal milk during the lactation period.

6.5.6. Method of Study Performance

6.5.6.1. F0 Generation Mice

After acclimation, 99 virgin female mice were cohabitated with 99 breeder male mice, one male mouse per female mouse. The cohabitation period consisted of a maximum of 5 days. Female mice with a copulatory plug observed *in situ* were considered to be at DG 0 and assigned to individual housing.

Mice were observed for viability at least twice each day of the study and for clinical observations and general appearance at least weekly during acclimation and on DG 0. The mice were also examined for clinical observations, abortions, premature deliveries and deaths prior to dosage administration and between one and two hours after dosage administration and once each day during the postdosage period.

Body weights were recorded at least weekly during the acclimation period, on DG 0, and daily during the dosage and postdosage periods.

Mice were evaluated for adverse clinical signs observed during parturition, duration of gestation (DG 0 to the day the first pup was observed), litter sizes (all pups delivered) and pup viability at birth, fertility index (percentage of matings that result in pregnancies), gestation index (percentage of pregnancies that result in birth of live litters), number of offspring per litter (live and dead pups), number of implantation sites, general condition

of dam and litter during the postpartum period, viability indices (percentage of pups born that survive 4 and 7 days) and lactation index (percentage of pups born that survive 20 days). Maternal behavior was evaluated on DLs 0, 4, 7, 14 and 20^a.

6.5.6.2. F1 Generation Pups

Day 0 of lactation (postpartum) was defined as the day of birth and was also the first day on which all pups in a litter were individually weighed (pup body weights were recorded after all pups in a litter were delivered and groomed by the dam).

Each litter was evaluated for viability at least twice daily. The pups in each litter were counted once daily. Clinical observations were recorded once daily during the preweaning period^a. Pup body weights were recorded on DLs 0 (birth), 4, 7, 14 and 20.

During the preweaning period, pups were evaluated for eye opening beginning PPD 10.

6.5.6.3. F1 Generation Mice

Mice were observed for viability daily during the postweaning period. These mice were also examined for clinical observations and general appearance once daily during the postweaning period. Body weights were recorded weekly during the postweaning period.

Female mice were evaluated for the age of vaginal patency, beginning on PPD 20. Male mice were evaluated for the age of preputial separation, beginning on PPD 26.

6.5.7. Gross Necropsy^b

Gross lesions were retained in neutral buffered 10% formalin for possible future evaluation^c. Unless specifically cited below, all other tissues were discarded. Representative photographs of gross lesions are available in the raw data.

Mice and pups were sacrificed by carbon dioxide asphyxiation.

-
- a. See APPENDIX 2 (DEVIATIONS).
 - b. A table of random units was used to select one F0 generation vehicle group mouse and one F1 generation vehicle group mouse of each sex from which all tissues examined at necropsy were retained, in order to provide control tissues for potential comparative histopathological evaluations.
 - c. See APPENDIX 2.

6.5.7.1. F0 Generation Mice

After completion of the 20-day postpartum period, female mice were sacrificed by carbon dioxide asphyxiation and a gross necropsy of the thoracic, abdominal and pelvic viscera was performed. Five livers per group were excised, weighed and frozen on dry ice. The number and distribution of implantation sites were recorded after staining with 10% ammonium sulfide⁽⁶⁾. Livers were maintained frozen ($\leq -70^{\circ}\text{C}$) until shipment for analysis to Charles River Laboratories – Montreal, Canada (PCS-MTL).

Mice that did not deliver a litter were sacrificed on DG 23 and examined for gross lesions. The number and distribution of implantation sites were recorded after staining with 10% ammonium sulfide⁽⁶⁾. Livers were excised, weighed and frozen on dry ice. Livers were maintained frozen ($\leq -70^{\circ}\text{C}$) until shipment for analysis to PCS-MTL.

The dam with no surviving pups was sacrificed after the last pup was found dead. A gross necropsy of the thoracic, abdominal and pelvic viscera was performed and implantation sites were recorded after staining with 10% ammonium sulfide⁽⁶⁾. The liver was excised, weighed and frozen on dry ice. The liver was maintained frozen ($\leq -70^{\circ}\text{C}$) until shipment for analysis to CRL-MTL.

One mouse was sacrificed prior to scheduled termination after it was found delivering. The mouse was examined for gross lesions. The lungs, trachea and esophagus were perfused and saved in neutral buffered 10% formalin for possible future evaluation. The heart, kidneys, stomach and spleen were retained in neutral buffered 10% formalin for possible histological evaluation. A gross necropsy of the thoracic, abdominal and pelvic viscera was performed. The number and distribution of implantation sites were recorded after staining with 10% ammonium sulfide⁽⁶⁾. The pup was examined to the extent possible, using the same method described for term pups. The liver was excised, weighed and frozen on dry ice. The liver was maintained frozen ($\leq -70^{\circ}\text{C}$) until shipment for analysis to CRL-MTL.

The liver samples were analyzed at PCS-MTL (test site reference no. 141663) using a validated LC-MS/MS method (PCS-MTL Study no. 141659). The bioanalytical method was validated to meet the minimum requirements of the appropriate PCS-MTL Standard Operating Procedures. The pharmacokinetic report generated for this phase of the study is available in APPENDIX 5.

6.5.7.2. F1 Generation Pups

Pups that died before initial examination of the litter for pup viability were evaluated for vital status at birth. The lungs were removed and immersed in water. Pups with lungs that sank were considered stillborn; pups with lungs that floated were considered liveborn and to have died shortly after birth.

Pups found dead were examined for gross lesions and for the cause of death. All pups found dead on PPD 1 to 3 were preserved in Bouin's solution for possible future evaluation; all pups found dead on PPD 4 to 20 were preserved in neutral buffered 10% formalin.

On DL 20, all pups not selected for continued evaluation were sacrificed by carbon dioxide asphyxiation and examined for gross lesions. Necropsy of the pups included a single cut at the suture of the frontal and parietal bones of the skull, and the cross-sectioned brain was examined for hydrocephaly.

6.5.7.3. F1 Generation Mice

Five mice per sex per group (total 40 mice) were sacrificed on PPD 41 for sample collection for pharmacokinetic analysis. Blood samples (0.5 mL to 1.0 mL) and livers were collected from these mice. Blood samples were collected via the vena cava after sacrifice. The blood samples were transferred into uncoated (red top) tubes and spun in a refrigerated (4°C) centrifuge for 10 minutes at 3500 RPM. The resulting serum was transferred into appropriately labeled polypropylene tubes. All samples were frozen on dry ice as soon as possible and maintained frozen ($\leq -70^{\circ}\text{C}$) until shipment for analysis to PCS-MTL.

A gross necropsy of the thoracic, abdominal and pelvic viscera was performed. The livers (5 per group per sex) were excised, weighed and frozen on dry ice. Livers were maintained frozen ($\leq -70^{\circ}\text{C}$) until shipment for analysis to PCS-MTL.

The test substance was used as reference material for pharmacokinetic analysis.

The serum samples were analyzed at PCS-MTL (test site reference no. 141662) using a validated LC-MS/MS method (PCS-MTL Study no. 141837). The bioanalytical method was validated and met the minimum requirements of the appropriate PCS-MTL Standard Operating Procedures. The pharmacokinetic report generated for this phase of the study is available in APPENDIX 5.

The remaining mice were sacrificed by carbon dioxide asphyxiation on PPD 41. A gross necropsy of the thoracic, abdominal and pelvic viscera was performed.

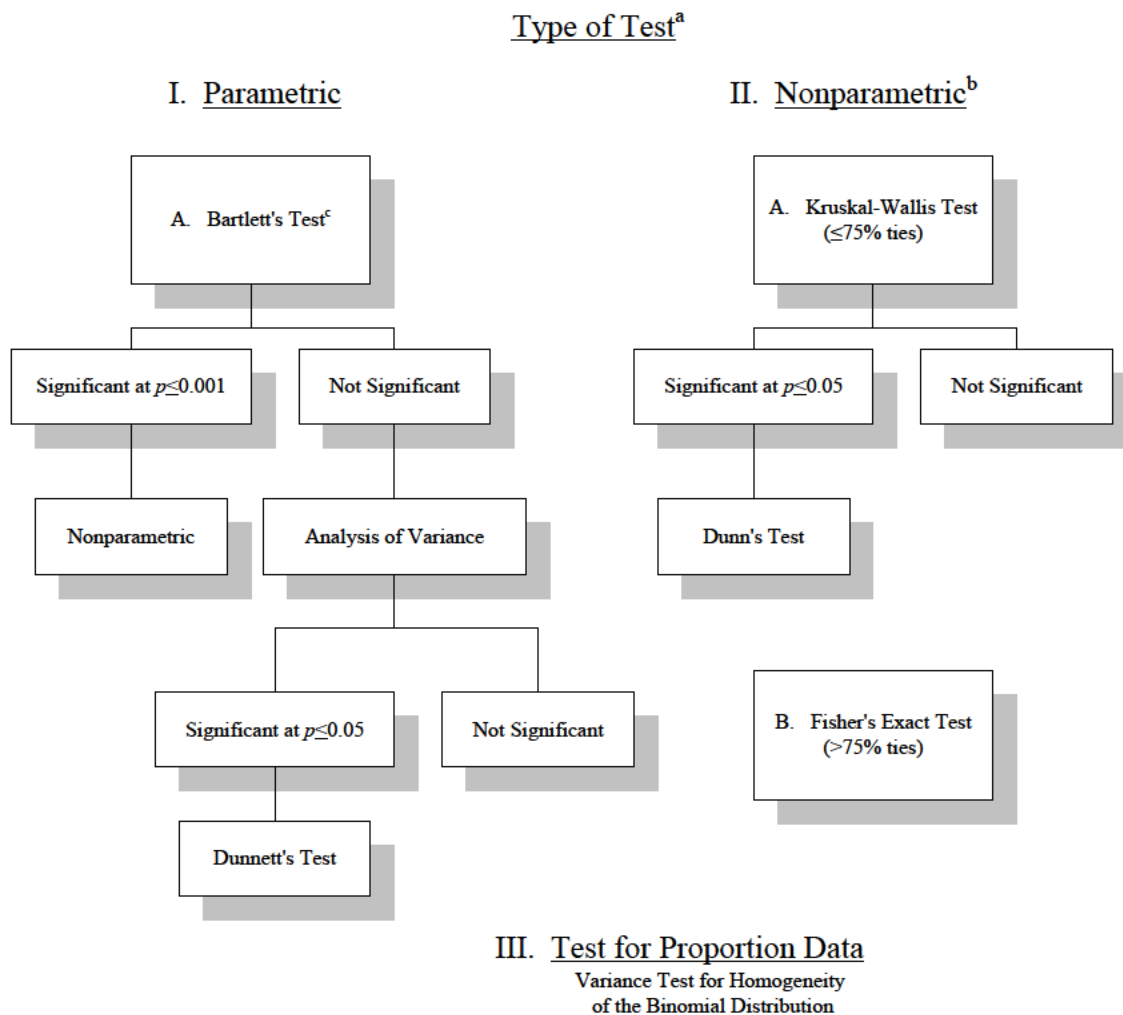
6.5.8. Data Collection and Statistical Analyses

Data generated during the course of this study were recorded either by hand or using the *Argus Automated Data Collection and Management System*, and the *Vivarium Temperature and Relative Humidity Monitoring System*. All data were tabulated, summarized and/or statistically analyzed using the *Argus Automated Data Collection and Management System*, the *Vivarium Temperature and Relative Humidity Monitoring System*, Microsoft® Excel (part of Microsoft® Office 97/2000/2003/XP/2007) Quattro Pro 8 and SAS.

Empower (Waters Corporation) was used for formulation sample analysis.

Data collection for serum and liver concentration analysis using LC-MS/MS were performed using Analyst from MDS Sciex. Statistical analysis, including regression analysis, and descriptive statistics such as arithmetic means and standard deviations, accuracy and precision were performed using Watson laboratory Information Management system (LIMS) and Microsoft Excel. Tables were prepared from retrospective manual entry on computer (Microsoft Word). All raw data and documents generated at PCS-MTL during this study and the final report will be transferred to the scientific archives of PCS-MTL for a period of approximately 1 year from finalization. Storage details following the 1 year archive period will be documented in the raw data.

Averages and percentages were calculated. Litter values were used where appropriate. The following schematic represents the statistical analyses of the data:



-
- a. Statistically significant probabilities are reported as either $p \leq 0.05$ or $p \leq 0.01$.
 b. Proportion data are not included in this category.
 c. Test for homogeneity of variance.

Clinical observations and other proportional data were analyzed using the Variance Test for Homogeneity of the Binomial Distribution⁽⁷⁾.

Continuous data, such as body weights, organ weights, percentage of litter reaching a developmental landmark and percent mortality per litter were analyzed as described under the parametric heading of the schematic. Bartlett's Test of Homogeneity of Variances⁽⁸⁾ was used to estimate the probability that the dosage groups had different variances. A non-significant result ($p > 0.001$) indicated that an assumption of homogeneity of variance was not inappropriate, and the data were compared using the Analysis of Variance⁽⁹⁾. If that test was significant ($p \leq 0.05$), the groups given the test substance were compared with the control group using Dunnett's Test⁽¹⁰⁾. If Bartlett's Test was significant ($p > 0.001$), the Analysis of Variance Test was inappropriate, and the data were analyzed as described under the Nonparametric heading of the schematic. When 75% or fewer of the scores were tied, the Kruskal-Wallis Test⁽¹¹⁾ was used to analyze the data, and in the event of a significant result ($p \leq 0.05$), Dunn's Method of Multiple Comparisons⁽¹²⁾ was used to compare the groups given the test substance with the control group. When more than 75% of the scores were tied, Fisher's Exact Test⁽¹³⁾ was used to compare the proportion of ties in the dosage group.

Variables with graded count scores, such as litter size were analyzed using the procedures described under the Nonparametric heading of the schematic.

7. RESULTS - F0 GENERATION FEMALE MICE

7.1. Mortality, Clinical and Necropsy Observations (Summaries - Tables 1 and 8; Individual Data - Tables 24 and 31)

No mortality related to PFH ammonium salt occurred.

All mice survived until scheduled sacrifice, with the exception of one mouse in the 7 mg/kg/day dosage group that was sacrificed on day 17 of gestation (DG 17) when it delivered its litter; and one mouse in the 35 mg/kg/day dosage group that was sacrificed on day 2 of lactation (DL 2) due to no surviving pups.

All clinical observations during the gestation and lactation periods were considered unrelated to the test substance because: 1) the incidences were not dosage dependent; and 2) the observations occurred in only one mouse in a group. These clinical observations included a red perivaginal substance and urine-stained abdominal fur.

There were no test substance related necropsy observations. All necropsy observations were considered unrelated to the test substance because: 1) the incidences were not dosage dependent; or 2) the observations occurred in only one mouse. These necropsy observations included numerous clear cysts in the liver (one 7 mg/kg/day dosage group mouse), clear fluid filled cyst in the capsule of the kidney (one 35 mg/kg/day dosage group mouse), thick walls of the uterus (one 7 mg/kg/day dosage group mouse) and clear fluid filled cysts in the uterus (one 35 mg/kg/day dosage group mouse)

7.2. Body Weight and Body Weight Changes (Figure 1; Summaries - Tables 2 through 5; Individual Data - Tables 25 and 26)

Body weights and body weight gains during the gestation and lactation periods were unaffected by dosages of the test substance as high as 175 mg/kg/day. All values were comparable among the four dosage groups and did not differ significantly.

7.3. Natural Delivery Observations (Summaries - Tables 6 and 7; Individual Data - Tables 27 through 30)

Pregnancy occurred in 20, 17, 20 and 20 of the 20 mated female mice in the 0 (Vehicle), 7, 35 and 175 mg/kg/day dosage groups, respectively. All pregnant dams delivered litters. All mated mice were pregnant and delivered a litter.

The number of stillborn pups and pups dying on day 1 postpartum were significantly increased ($p \leq 0.05$) and the average pup weight per litter was significantly reduced on day 1 postpartum in the 175 mg/kg/day dosage group compared to the 0 (Vehicle) mg/kg/day dosage group values.

All other natural delivery and litter observations were unaffected by dosages of the test substance as high as 175 mg/kg/day. Values for the numbers of dams delivering litters, the duration of gestation, averages for implantation sites per delivered litter, the gestation index (number of dams with one or more liveborn pups/number of pregnant mice), the numbers of dams with stillborn pups and of dams with all pups dying, litter sizes, viability index, surviving pups per litter, percent male pups per number of pups sexed per litter, live litter size at weighing and pup weight per litter were comparable among the four dosage groups and did not significantly differ.

A significant reduction ($p \leq 0.01$) in the lactation index in the 7 mg/kg/day dosage group was not considered related to the test substance because it was not dosage-dependent.

**7.4. Terminal Body Weights, Liver Weights and Ratios (%) of Liver Weight to Terminal Body Weight
(Summary – Table 9; Individual Data - Table 32)**

Terminal body weights were comparable among the four dosage groups. The absolute weights of the liver and the ratio of the liver weight to the terminal body weight did not differ significantly among the groups.

**7.5. Clinical (including Eye Opening) and Necropsy Observations -
F1 Generation Pups
(Summaries - Tables 10, 11 and 12; Individual Data - Tables 33
through 35)**

Two litters in the 175 mg/kg/day dosage group had a pup each with corneal opacity and one pup each with microphthalmia. One litter in this dosage group also had a pup with a lenticular opacity. No other clinical observations in the F1 generation pups were attributed to dosages of the test substance as high as 175 mg/kg/day.

No other clinical observations in the F1 generation pups were attributed to dosages of the test substance as high as 175 mg/kg/day because: 1) the incidences were not dosage-dependent; 2) the observation occurred in only one to three litters; and/or 3) the observation occurred only in the vehicle control group.

These clinical observations included dehydration cold to touch, tip of tail red, pale body, not nesting, a head laceration, scab on the lower midline or head and a mass on the back.

The day of eye opening did not differ among the groups.

No necropsy observations in the F1 generation pups were attributed to dosages of the test substance as high as 175 mg/kg/day. There was only a single finding (gas filled intestine) in a 7 mg/kg/day dosage group mouse for mice found dead and all other mice appeared normal for those mice sacrificed on day 20 postpartum.

8. RESULTS - F1 GENERATION MICE - POSTWEANING

8.1. Mortality, Clinical and Necropsy Observations (Summaries - Tables 13, 14, 20 and 21; Individual Data - Tables 36, 37, 42 and 43)

All F1 generation male and female mice survived to scheduled sacrifice.

All clinical observations in the F1 generation male and female mice were considered unrelated to maternal administration of the test substance because: 1) the incidences were not dosage dependent; 2) the observation occurred in only one mouse; and/or 3) the observation is common in this species and strain. These clinical observations included lacrimation, ptosis, scab on the tail and a lenticular opacity.

Necropsy observations in the F1 generation female and male mice occurred in one mouse each in the 35 and 175 mg/kg/day dosage groups, respectively. One male mouse had a clear fluid filled cyst in the liver and one female mouse had a dark flat red mass in the mesentery.

8.2. Body Weights and Body Weight Changes (Figures 2 and 3; Summaries - Tables 15 through 18; Individual Data - Tables 38 and 39)

Body weights and body weight gains of the F1 generation male and female mice were unaffected by maternal dosages of the test substance as high as 175 mg/kg/day. No significant differences occurred among the groups during the postweaning period (PND 21 to 41).

8.3. Sexual Maturation (Summary - Table 19; Individual Data - Tables 40 and 41)

Sexual maturation was unaffected by maternal dosages of the test substance as high as 175 mg/kg/day. The average day on which preputial separation or vaginal patency occurred was comparable among the four dosage groups.

8.4. Terminal Body Weights, Liver Weights and Ratios of Liver Weight to Terminal Body Weight (Summaries - Tables 22 and 23; Individual Data - Tables 44 and 45)

Terminal body weights were comparable among the four groups. Maternal dosages of the test substance as high as 175 mg/kg/day did not affect the liver weights or the ratio of liver weights to the terminal body weight. There were no significant differences among the groups.

9. CONCLUSION

On the basis of these data, the maternal no-observable-adverse-effect-level (NOEL) for PFH Ammonium Salt is 175 mg/kg/day (the highest dosage tested.). The NOAEL in the F1 generation is 35 mg/kg/day (the 175 mg/kg/day dosage had an increase in the number of stillborn pups and pups dying day 1 along with a reduction in pup weights on postnatal day 1, two litters in this dosage group also had a corneal opacity). None of the effects observed in the pups preweaning persisted into the postweaning period.

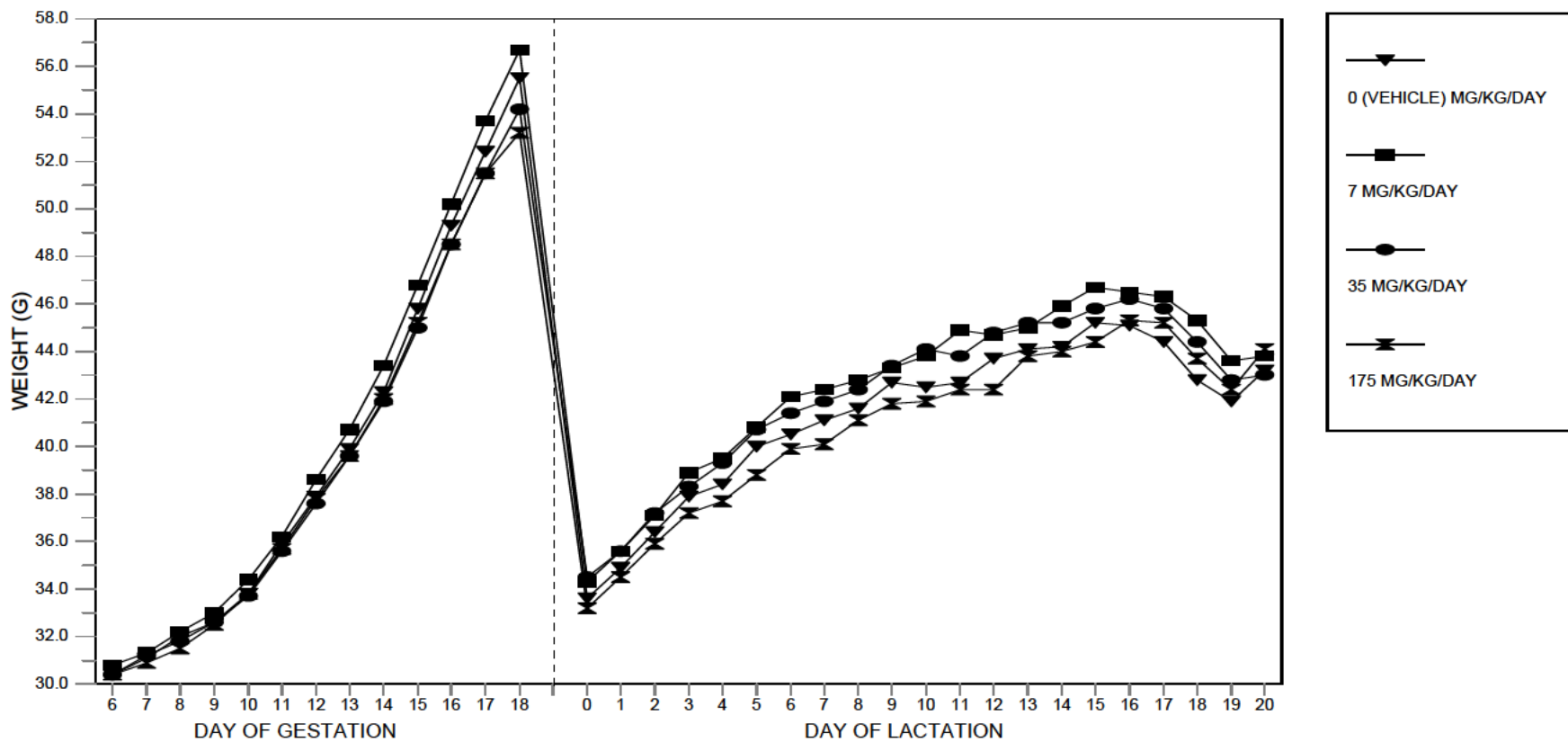
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PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT
(AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

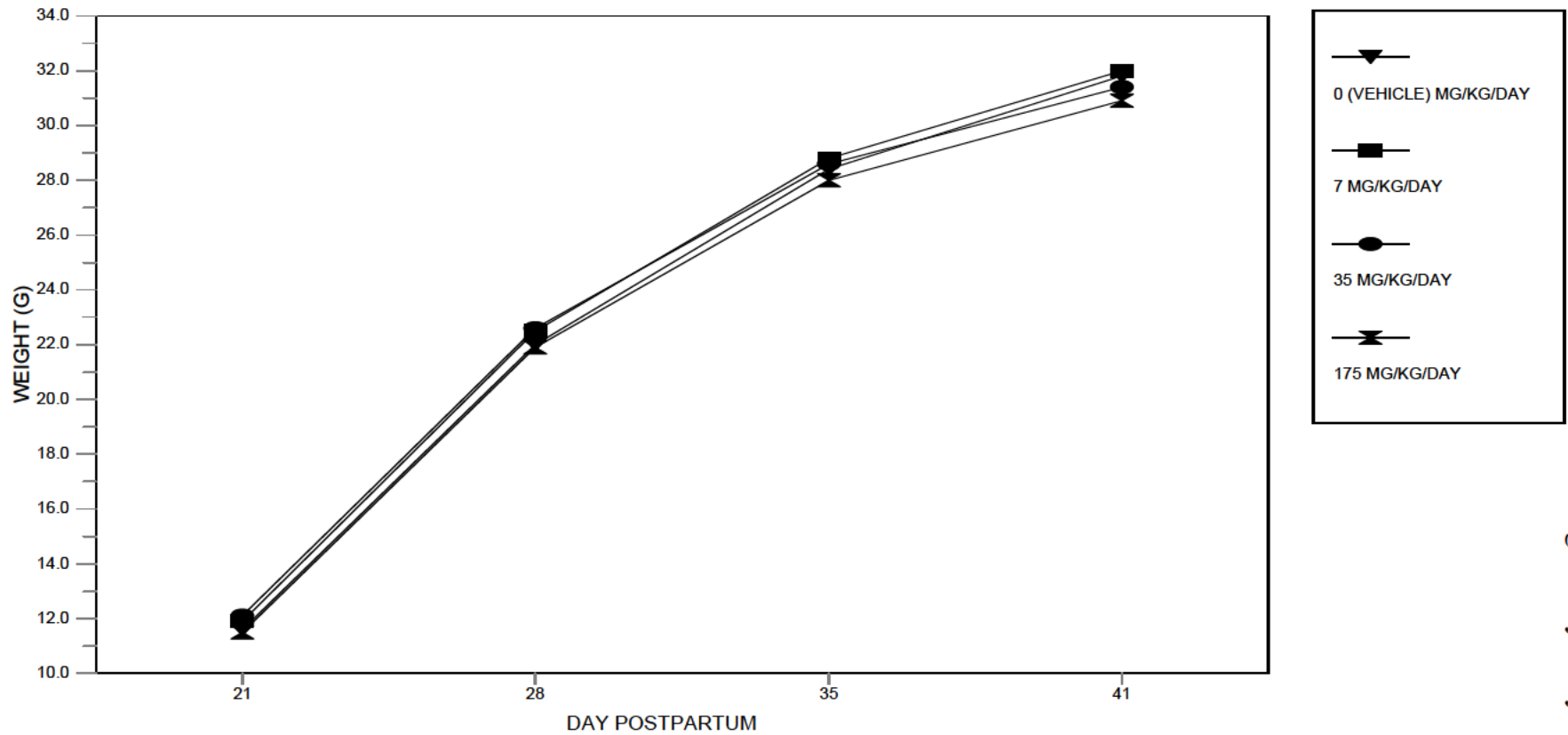
MATERNAL BODY WEIGHTS - F0 GENERATION FEMALE MICE

Figure 1



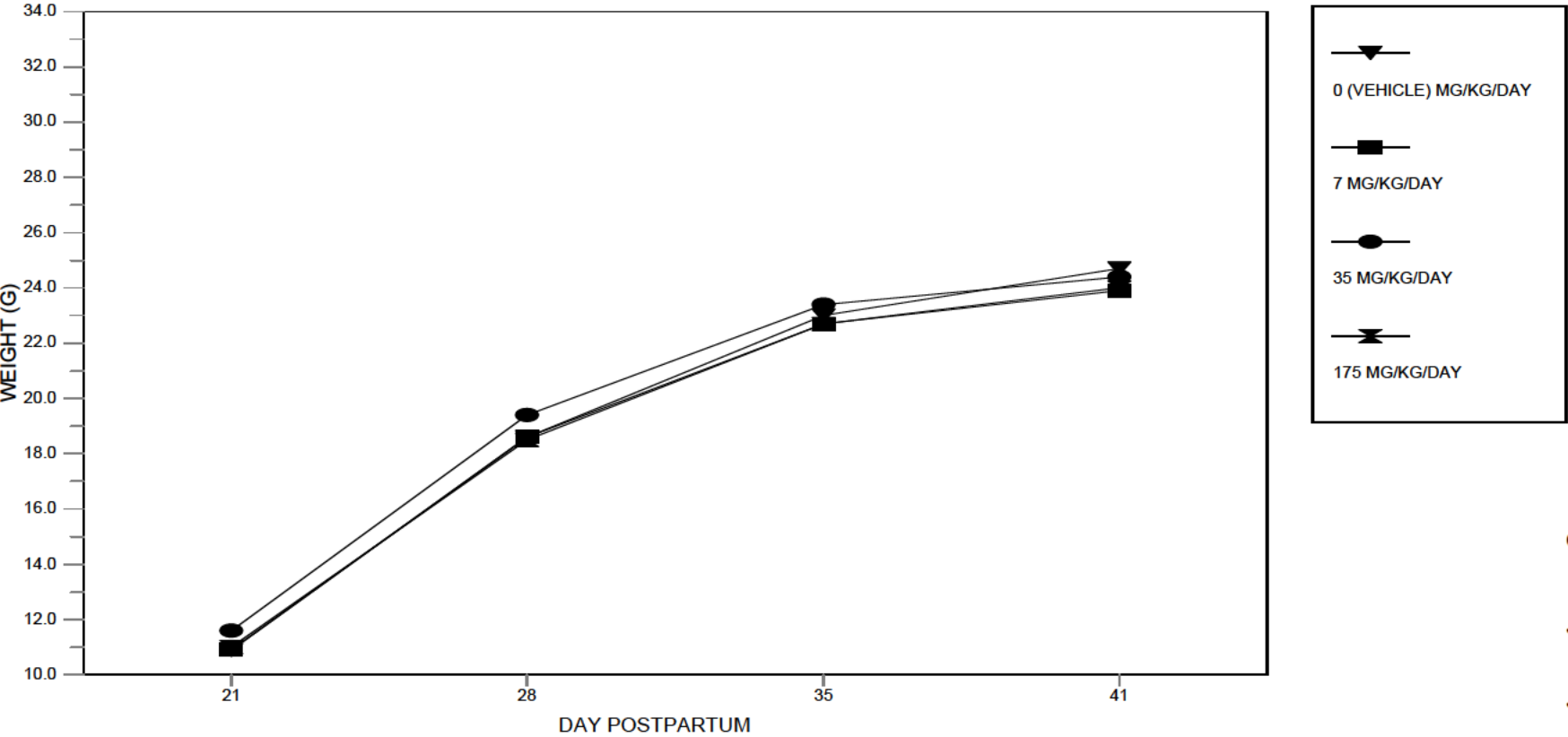
BODY WEIGHTS - F1 GENERATION MALE MICE

Figure 2



BODY WEIGHTS - F1 GENERATION FEMALE MICE

Figure 3



PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 1 (PAGE 1): CLINICAL OBSERVATIONS - SUMMARY - F0 GENERATION FEMALE MICE

DOSAGE GROUP DOSAGE (MG/KG/DAY) a	I 0 (VEHICLE)	II 7	III 35	IV 175
SACRIFICED DUE TO PREMATURE DELIVERY	0	0	1b	0
SACRIFICED DUE TO NO SURVIVING PUPS	0	1c	0	0
<u>PRESUMED GESTATION:</u>				
MAXIMUM POSSIBLE INCIDENCE	255/ 20	275/ 20	257/ 20	257/ 20
RED PERIVAGINAL SUBSTANCE	0/ 0	0/ 0	2/ 1b	1/ 1
URINE-STAINED ABDOMINAL FUR	0/ 0	0/ 0	4/ 1	0/ 0
<u>LACTATION:</u>				
MAXIMUM POSSIBLE INCIDENCE	420/ 20	339/ 17	399/ 19	420/ 20
RED PERIVAGINAL SUBSTANCE	0/ 0	0/ 0	0/ 0	1/ 1

STATISTICAL ANALYSES OF CLINICAL OBSERVATION DATA WERE RESTRICTED TO THE NUMBER OF MICE WITH OBSERVATIONS.

MAXIMUM POSSIBLE INCIDENCE = (DAYS x MICE)/NUMBER OF MICE EXAMINED PER GROUP

N/N = TOTAL NUMBER OF OBSERVATIONS/NUMBER OF MICE WITH OBSERVATION

- Dosage occurred on days 6 through 18 of presumed gestation.
- Mouse 448 was sacrificed on day 17 of gestation due to premature delivery.
- Mouse 430 was sacrificed on day 2 of lactation due to no surviving pups.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 2 (PAGE 1): MATERNAL BODY WEIGHTS - GESTATION - SUMMARY - F0 GENERATION FEMALE MICE

DOSAGE GROUP DOSAGE (MG/KG/DAY) a		I 0 (VEHICLE)	II 7	III 35	IV 175
MICE TESTED	N	20	20	20	20
PREGNANT	N	20	17	20	20
MATERNAL BODY WEIGHT (G)					
DAY 6	MEAN±S.D.	30.4 ± 1.7	30.8 ± 1.9	30.4 ± 1.7	30.4 ± 1.7
DAY 7	MEAN±S.D.	31.1 ± 1.9	31.3 ± 2.0	31.2 ± 1.9	30.9 ± 1.8
DAY 8	MEAN±S.D.	32.0 ± 2.1	32.2 ± 2.0	31.8 ± 1.8	31.5 ± 1.8
DAY 9	MEAN±S.D.	32.6 ± 2.2	33.0 ± 2.2	32.6 ± 1.9	32.5 ± 2.0
DAY 10	MEAN±S.D.	33.8 ± 2.2	34.4 ± 2.2	33.7 ± 2.1	33.8 ± 2.2
DAY 11	MEAN±S.D.	35.9 ± 2.3	36.2 ± 2.1	35.6 ± 2.4	35.7 ± 2.5
DAY 12	MEAN±S.D.	37.9 ± 2.6	38.6 ± 2.0	37.6 ± 2.9	37.8 ± 2.6
DAY 13	MEAN±S.D.	39.9 ± 3.0	40.7 ± 2.3	39.6 ± 3.3	39.6 ± 2.8
DAY 14	MEAN±S.D.	42.3 ± 3.3	43.4 ± 2.7	41.9 ± 3.7	42.0 ± 3.1
DAY 15	MEAN±S.D.	45.8 ± 3.8	46.8 ± 2.9	45.0 ± 4.5	45.2 ± 3.6
DAY 16	MEAN±S.D.	49.3 ± 4.4	50.2 ± 3.4	48.5 ± 5.3	48.5 ± 4.1
DAY 17	MEAN±S.D.	52.4 ± 5.2	53.7 ± 4.0	51.5 ± 6.5	51.5 ± 4.6
DAY 18	MEAN±S.D.	55.5 ± 4.9 [15]b	56.7 ± 4.8 [14]b	54.2 ± 6.3 [17]b,c	53.2 ± 5.6 [15]b

DAY = DAY OF GESTATION

[] = NUMBER OF VALUES AVERAGED

a. Dosage occurred on days 6 through 18 of gestation.

b. Excludes values for mice that were in the process of delivering or had delivered.

c. Excludes values for mouse 448, which was sacrificed on day 17 of gestation due to premature delivery.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 3 (PAGE 1): MATERNAL BODY WEIGHT CHANGES - GESTATION - SUMMARY - F0 GENERATION FEMALE MICE

DOSAGE GROUP		I	II	III	IV
DOSAGE (MG/KG/DAY) a		0 (VEHICLE)	7	35	175
MICE TESTED	N	20	20	20	20
PREGNANT	N	20	17	20	20
MATERNAL BODY WEIGHT CHANGE (G)					
DAYS 6 - 9	MEAN±S.D.	+2.2 ± 0.8	+2.2 ± 0.7	+2.2 ± 0.5	+2.1 ± 0.6
DAYS 9 - 12	MEAN±S.D.	+5.3 ± 1.1	+5.5 ± 1.1	+5.0 ± 1.4	+5.3 ± 1.0
DAYS 12 - 15	MEAN±S.D.	+7.9 ± 1.6	+8.3 ± 1.5	+7.4 ± 2.0	+7.4 ± 1.4
DAYS 15 - 18	MEAN±S.D.	+9.9 ± 1.9	+10.2 ± 2.1	+8.6 ± 5.0	+8.6 ± 3.3
DAYS 6 - 18	MEAN±S.D.	+25.1 ± 3.8	+26.0 ± 4.6	+23.7 ± 5.6	+22.8 ± 4.8
		[15]b	[14]b	[17]b	[15]b
		[15]b	[14]b	[17]b,c	[15]b

DAYS = DAYS OF GESTATION

[] = NUMBER OF VALUES AVERAGED

a. Dosage occurred on days 6 through 18 of gestation.

b. Excludes values for mice that were in the process of delivering or had delivered.

c. Excludes values for mouse 448, which was sacrificed on day 17 of gestation due to premature delivery.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 4 (PAGE 1): MATERNAL BODY WEIGHTS - LACTATION - SUMMARY - F0 GENERATION FEMALE MICE

DOSAGE GROUP		I	II	III	IV
DOSAGE (MG/KG/DAY) a		0 (VEHICLE)	7	35	175
MICE TESTED	N	20	20	20	20
PREGNANT	N	20	17	20	20
DELIVERED A LITTER	N	20	17	20	20
INCLUDED IN ANALYSES	N	20	17	19b	20
MATERNAL BODY WEIGHT (G)					
DAY 0	MEAN±S.D.	33.6 ± 2.2	34.3 ± 1.8	34.5 ± 2.1	33.2 ± 2.4
DAY 1	MEAN±S.D.	34.9 ± 2.9	35.6 ± 2.0	35.6 ± 1.9	34.5 ± 2.8
DAY 2	MEAN±S.D.	36.4 ± 3.1	37.1 ± 2.0	37.2 ± 2.2	35.9 ± 3.1
DAY 3	MEAN±S.D.	37.9 ± 3.2	38.9 ± 2.2	38.3 ± 2.2	37.2 ± 3.2
DAY 4	MEAN±S.D.	38.4 ± 3.3	39.5 ± 2.0 [16]c	39.3 ± 2.6	37.7 ± 3.4
DAY 5	MEAN±S.D.	40.0 ± 3.4	40.8 ± 2.2 [16]c	40.7 ± 2.3	38.8 ± 3.2
DAY 6	MEAN±S.D.	40.5 ± 3.6	42.1 ± 2.0 [16]c	41.4 ± 2.2	39.9 ± 3.5
DAY 7	MEAN±S.D.	41.1 ± 4.0	42.4 ± 2.0 [16]c	41.9 ± 2.6	40.1 ± 3.5
DAY 8	MEAN±S.D.	41.6 ± 3.5	42.8 ± 1.7 [16]c	42.4 ± 2.4	41.1 ± 3.9
DAY 9	MEAN±S.D.	42.7 ± 4.2	43.3 ± 1.7 [16]c	43.4 ± 2.1	41.8 ± 4.0
DAY 10	MEAN±S.D.	42.5 ± 4.0	43.8 ± 2.0 [16]c	44.1 ± 2.4	41.9 ± 3.5
DAY 11	MEAN±S.D.	42.7 ± 4.2	44.9 ± 2.3 [16]c	43.8 ± 2.9	42.4 ± 4.1
DAY 12	MEAN±S.D.	43.7 ± 3.8	44.7 ± 2.5 [16]c	44.8 ± 2.8	42.4 ± 4.0

DAY = DAY OF LACTATION

[] = NUMBER OF VALUES AVERAGED

a. Dosage occurred on days 6 through 18 of gestation.

b. Excludes values for mouse 448, which was sacrificed on day 17 of gestation due to premature delivery.

c. Excludes values for mouse 430, which was sacrificed on day 2 of lactation due to no surviving pups.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 4 (PAGE 2): MATERNAL BODY WEIGHTS - LACTATION - SUMMARY - F0 GENERATION FEMALE MICE

DOSAGE GROUP		I	II	III	IV
DOSAGE (MG/KG/DAY) a		0 (VEHICLE)	7	35	175
MICE TESTED	N	20	20	20	20
PREGNANT	N	20	17	20	20
DELIVERED A LITTER	N	20	17	20	20
INCLUDED IN ANALYSES	N	20	16b	19c	20
MATERNAL BODY WEIGHT (G)					
DAY 13	MEAN±S.D.	44.1 ± 3.6	45.0 ± 2.9	45.2 ± 2.6	43.8 ± 4.3
DAY 14	MEAN±S.D.	44.2 ± 4.2	45.9 ± 2.7	45.2 ± 2.4	44.0 ± 4.3
DAY 15	MEAN±S.D.	45.2 ± 4.3	46.7 ± 2.7	45.8 ± 3.0	44.4 ± 4.1
DAY 16	MEAN±S.D.	45.1 ± 4.0	46.5 ± 2.9	46.2 ± 2.6	45.3 ± 4.4
DAY 17	MEAN±S.D.	44.4 ± 4.6	46.3 ± 2.9	45.8 ± 2.3	45.2 ± 4.7
DAY 18	MEAN±S.D.	42.8 ± 3.9	45.3 ± 3.2	44.4 ± 3.3	43.7 ± 3.8
DAY 19	MEAN±S.D.	41.9 ± 3.6	43.6 ± 4.2	42.8 ± 3.5	42.4 ± 4.2
DAY 20	MEAN±S.D.	43.2 ± 4.3	43.8 ± 4.8	43.0 ± 4.0	44.1 ± 4.7

DAY = DAY OF LACTATION

a. Dosage occurred on days 6 through 18 of gestation.

b. Excludes values for mouse 430, which was sacrificed on day 2 of lactation due to no surviving pups.

c. Excludes values for mouse 448, which was sacrificed on day 17 of gestation due to premature delivery.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 5 (PAGE 1): MATERNAL BODY WEIGHT CHANGES - LACTATION - SUMMARY - F0 GENERATION FEMALE MICE

DOSAGE GROUP		I	II	III	IV
DOSAGE (MG/KG/DAY) a		0 (VEHICLE)	7	35	175
MICE TESTED		20	20	20	20
PREGNANT	N	20	17	20	20
DELIVERED A LITTER	N	20	17	20	20
INCLUDED IN ANALYSES	N	20	16b	19c	20
MATERNAL BODY WEIGHT CHANGE (G)					
DAYS 0 - 3	MEAN±S.D.	+4.3 ± 1.7	+4.5 ± 1.5	+3.7 ± 1.2	+4.0 ± 1.7
DAYS 3 - 6	MEAN±S.D.	+2.6 ± 1.3	+3.2 ± 1.0	+3.1 ± 0.8	+2.8 ± 1.0
DAYS 6 - 13	MEAN±S.D.	+3.6 ± 1.6	+2.9 ± 2.3	+3.8 ± 2.1	+3.9 ± 2.5
DAYS 13 - 20	MEAN±S.D.	-1.0 ± 3.4	-1.1 ± 3.6	-2.2 ± 3.1	+0.2 ± 4.3
DAYS 0 - 20	MEAN±S.D.	+9.5 ± 3.3	+9.4 ± 4.0	+8.5 ± 2.8	+10.9 ± 3.6

DAYS = DAYS OF LACTATION

[] = NUMBER OF VALUES AVERAGED

a. Dosage occurred on days 6 through 18 of gestation.

b. Excludes values for mouse 430, which was sacrificed on day 2 of lactation due to no surviving pups.

c. Excludes values for mouse 448, which was sacrificed on day 17 of gestation due to premature delivery.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 6 (PAGE 1): NATURAL DELIVERY OBSERVATIONS - SUMMARY - F0 GENERATION FEMALE MICE

DOSAGE GROUP		I	II	III	IV
DOSAGE (MG/KG/DAY) a		0 (VEHICLE)	7	35	175
MICE ASSIGNED TO NATURAL DELIVERY	N	20	20	20	20
PREGNANT	N	20	17	20	20
DELIVERED A LITTER	N(%)	20(100.0)	17(100.0)	20(100.0)	20(100.0)
INCLUDED IN ANALYSES	N	20	17	19b	20
DURATION OF GESTATION c	MEAN±S.D.	19.6 ± 0.5	19.8 ± 0.8	19.8 ± 0.4	19.7 ± 0.5
IMPLANTATION SITES PER DELIVERED LITTER	N MEAN±S.D.	261 13.0 ± 2.3	220 12.9 ± 2.5	239 12.6 ± 1.8	252 12.6 ± 1.7
MICE WITH STILLBORN PUPS	N(%)	0(0.0)	0(0.0)	0(0.0)	1(5.0)
MICE WITH NO LIVEBORN PUPS	N	0	0	0	0
GESTATION INDEX d	% N/N	100.0 20/ 20	100.0 17/ 17	100.0 19/ 19	100.0 20/ 20
MICE WITH ALL PUPS DYING DAYS 0-3 POSTPARTUM	N(%)	0(0.0)	1(5.9)	0(0.0)	0(0.0)
MICE WITH ALL PUPS DYING DAYS 4-20 POSTPARTUM	N(%)	0(0.0)	0(0.0)	0(0.0)	0(0.0)

- a. Dosage occurred on days 6 through 18 of gestation.
b. Excludes values for mouse 448, which was sacrificed on day 17 of gestation due to premature delivery.
c. Calculated (in days) as the time elapsed between confirmed mating (arbitrarily defined as day 0 of gestation) and the day the first pup was delivered.
d. Number of mice with live offspring/number of pregnant mice.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 7 (PAGE 1): LITTER OBSERVATIONS (NATURALLY DELIVERED PUPS) - SUMMARY - F1 GENERATION LITTERS

DOSAGE GROUP DOSAGE (MG/KG/DAY) a		I 0 (VEHICLE)	II 7	III 35	IV 175
DELIVERED A LITTER WITH ONE OR MORE LIVEBORN PUPS	N	20	17	19	20
PUPS DELIVERED (TOTAL)	N	249	213	232	241
	MEAN±S.D.	12.4 ± 2.5	12.5 ± 3.0	12.2 ± 1.7	12.0 ± 2.1
LIVEBORN	MEAN±S.D. N(%)	12.4 ± 2.5 249(100.0)	12.4 ± 3.4 211(99.1)	12.2 ± 1.7 232(100.0)	11.9 ± 2.5 238(98.8)
STILLBORN	MEAN±S.D. N(%)	0.0 ± 0.0 0(0.0)	0.0 ± 0.0 0(0.0)	0.0 ± 0.0 0(0.0)	0.2 ± 0.7 3(1.2)**
UNKNOWN VITAL STATUS	N	0	2	0	0
PUPS FOUND DEAD OR PRESUMED CANNIBALIZED					
DAY 0	N/N(%)	0/249(0.0)	0/211(0.0)	0/232(0.0)	4/238(1.7)**
DAYS 1- 4	N/N(%)	3/249(1.2)	6/211(2.8)	2/232(0.9)	3/234(1.3)
DAYS 5- 7	N/N(%)	1/246(0.4)	0/205(0.0)	0/230(0.0)	3/231(1.3)
DAYS 8-14	N/N(%)	0/245(0.0)	0/205(0.0)	0/230(0.0)	0/228(0.0)
DAYS 15-20	N/N(%)	0/245(0.0)	0/205(0.0)	0/230(0.0)	1/228(0.4)
DAY 4 VIABILITY INDEX b	% N/N	98.8 246/249	97.2 205/211	99.1 230/232	97.0 231/238
DAY 7 VIABILITY INDEX c	% N/N	98.4 245/249	97.2 205/211	99.1 230/232	95.8 228/238
LACTATION INDEX d	% N/N	99.6 245/246	97.2 205/211**	100.0 230/230	98.3 227/231

DAY(S) = DAY(S) POSTPARTUM

a. Dosage occurred on days 6 through 18 of gestation.

b. Number of live pups on day 4 postpartum/number of liveborn pups on day 0 postpartum.

c. Number of live pups on day 7 postpartum/number of liveborn pups on day 0 postpartum.

d. Number of live pups on day 20 (weaning) postpartum/number of live pups on day 4 postpartum.

** Significantly different from the vehicle control group value (p≤0.01).

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 7 (PAGE 2): LITTER OBSERVATIONS (NATURALLY DELIVERED PUPS) - SUMMARY - F1 GENERATION LITTERS

DOSAGE GROUP		I	II	III	IV
DOSAGE (MG/KG/DAY) a		0 (VEHICLE)	7	35	175
DELIVERED A LITTER WITH ONE OR MORE LIVEBORN PUPS					
N		20	17	19	20
SURVIVING PUPS/LITTER b					
DAY 0	MEAN±S.D.	12.4 ± 2.5	12.4 ± 3.4	12.2 ± 1.7	11.9 ± 2.5
DAY 4	MEAN±S.D.	12.3 ± 2.4	12.0 ± 3.5	12.1 ± 1.7	11.6 ± 3.0
DAY 7	MEAN±S.D.	12.2 ± 2.5	12.0 ± 3.5	12.1 ± 1.7	11.4 ± 3.0
DAY 14	MEAN±S.D.	12.2 ± 2.5	12.0 ± 3.5	12.1 ± 1.7	11.4 ± 3.0
DAY 20	MEAN±S.D.	12.2 ± 2.5	12.0 ± 3.5	12.1 ± 1.7	11.4 ± 3.0
PERCENT MALE PUPS PER NUMBER OF PUPS SEXED					
DAY 0	MEAN±S.D.	52.3 ± 13.2	54.0 ± 18.5	52.4 ± 15.0	53.1 ± 12.9
DAY 4	MEAN±S.D.	52.4 ± 13.0	51.4 ± 14.7 [16]c	52.3 ± 15.0	52.6 ± 13.0
DAY 7	MEAN±S.D.	52.8 ± 13.2	51.4 ± 14.7 [16]c	52.3 ± 15.0	53.4 ± 13.7
DAY 14	MEAN±S.D.	52.8 ± 13.2	51.4 ± 14.7 [16]c	52.3 ± 15.0	53.4 ± 13.7
DAY 20	MEAN±S.D.	52.8 ± 13.2	51.4 ± 14.7 [16]c	52.3 ± 15.0	53.2 ± 13.7

DAY = DAY POSTPARTUM

[] = NUMBER OF VALUES AVERAGED

a. Dosage occurred on days 6 through 18 of gestation.

b. Average number of live pups per litter, including litters with no surviving pups.

c. Excludes values for litter 430, which had no surviving pups on day 2 postpartum.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 7 (PAGE 3): LITTER OBSERVATIONS (NATURALLY DELIVERED PUPS) - SUMMARY - F1 GENERATION LITTERS

DOSAGE GROUP		I	II	III	IV
DOSAGE (MG/KG/DAY) a		0 (VEHICLE)	7	35	175
DELIVERED A LITTER WITH ONE OR MORE LIVEBORN PUPS					
N		20	17	19	20
LIVE LITTER SIZE AT WEIGHING					
DAY 0	MEAN±S.D.	12.4 ± 2.5	12.4 ± 3.4	12.2 ± 1.7	11.7 ± 2.8
DAY 4	MEAN±S.D.	12.3 ± 2.4	12.8 ± 1.7	12.1 ± 1.7	11.6 ± 3.0
DAY 7	MEAN±S.D.	12.2 ± 2.5	12.8 ± 1.7 [16]b	12.1 ± 1.7	11.4 ± 3.0
DAY 14	MEAN±S.D.	12.2 ± 2.5	12.8 ± 1.7 [16]b	12.1 ± 1.7	11.4 ± 3.0
DAY 20	MEAN±S.D.	12.2 ± 2.5	12.8 ± 1.7 [16]b	12.1 ± 1.7	11.4 ± 3.0
PUP WEIGHT/LITTER (GRAMS)					
DAY 0	MEAN±S.D.	1.6 ± 0.1	1.6 ± 0.1	1.6 ± 0.1	1.4 ± 0.2*
DAY 4	MEAN±S.D.	2.8 ± 0.3	2.8 ± 0.3 [16]b	3.0 ± 0.3	2.7 ± 0.5
DAY 7	MEAN±S.D.	4.2 ± 0.6	4.2 ± 0.4 [16]b	4.4 ± 0.4	4.2 ± 0.6
DAY 14	MEAN±S.D.	6.8 ± 1.2	6.7 ± 0.6 [16]b	7.0 ± 0.7	6.8 ± 0.9
DAY 20	MEAN±S.D.	10.2 ± 1.8	10.0 ± 1.2 [16]b	10.8 ± 1.3	10.4 ± 1.4

DAY = DAY POSTPARTUM

[] = NUMBER OF VALUES AVERAGED

a. Dosage occurred on days 6 through 18 of gestation.

b. Excludes values for litter 430, which had no surviving pups on day 2 postpartum.

* Significantly different from the vehicle control group value (p≤0.05).

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 8 (PAGE 1): NECROPSY OBSERVATIONS - SUMMARY - F0 GENERATION FEMALE MICE

DOSAGE GROUP DOSAGE (MG/KG/DAY) a		I 0 (VEHICLE)	II 7	III 35	IV 175
MICE EXAMINED b	N	20	20	20	20
SACRIFICED DUE TO PREMATURE DELIVERY	N	0	0	1c	0
SACRIFICED DUE TO NO SURVIVING PUPS	N	0	1d	0	0
APPEARED NORMAL	N	20	18	18	20
LIVER: ALL LOBES, NUMEROUS CLEAR FLUID-FILLED CYSTS	N	0	1	0	0
KIDNEYS: LEFT, SURFACE OF CAPSULE, CLEAR FLUID-FILLED CYST	N	0	0	1	0
UTERUS: BOTH HORNS, WALLS, THICK	N	0	1	0	0
RIGHT AND LEFT HORN, CLEAR FLUID-FILLED CYST(S)	N	0	0	1	0

a. Dosage occurred on days 6 through 18 of gestation.

b. Refer to the individual clinical observations table (Table 24) for external observations confirmed at necropsy.

c. Mouse 448 was sacrificed on day 17 of gestation due to premature delivery.

d. Mouse 430 was sacrificed on day 2 of lactation due to no surviving pups.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 9 (PAGE 1): TERMINAL BODY WEIGHTS, LIVER WEIGHTS AND RATIOS (%) OF LIVER WEIGHT TO TERMINAL BODY WEIGHT - SUMMARY - F0 GENERATION FEMALE MICE

DOSAGE GROUP		I	II	III	IV
DOSAGE (MG/KG/DAY) a		0 (VEHICLE)	7	35	175
MICE TESTED	N	5	9	6	5
PREGNANT	N	5	6	6	5
INCLUDED IN ANALYSES	N	5	5b	5c	5
TERMINAL BODY WEIGHT	MEAN±S.D.	42.4 ± 4.4	43.1 ± 5.1	44.0 ± 4.4	45.8 ± 2.8
LIVER (G)	MEAN±S.D.	3.030 ± 0.208	3.194 ± 0.356	3.506 ± 0.517	3.172 ± 0.345
LIVER (%)	MEAN±S.D.	7.172 ± 0.361	7.418 ± 0.497	7.970 ± 0.964	6.906 ± 0.362

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. Dosage occurred on days 6 through 18 of gestation.
b. Excludes values for mouse 430, which was sacrificed on day 2 of lactation due to no surviving pups.
c. Excludes values for mouse 448, which was sacrificed on day 17 of gestation due to premature delivery.

RATIOS (%) = (ORGAN WEIGHT/TERMINAL BODY WEIGHT) X 100.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 10 (PAGE 1): CLINICAL OBSERVATIONS FROM BIRTH TO DAY 20 POSTPARTUM - SUMMARY - F1 GENERATION PUPS

MATERNAL DOSAGE GROUP		I	II	III	IV
MATERNAL DOSAGE (MG/KG/DAY)		0 (VEHICLE)	7	35	175
LITTERS EXAMINED (N)		20	17	19	20
TRANSIENT CLINICAL OBSERVATIONS: a		TOTAL FREQUENCY (DAYS X PUPS)/LITTERS WITH OBSERVATIONS			
DEHYDRATION, TOTAL	N/N	12/4	26/4	1/1	33/3
MILD	N/N	12/4	24/4	1/1	23/3
MODERATE	N/N	0/0	2/2	0/0	10/2
COLD TO TOUCH	N/N	0/0	1/1	0/0	3/3
CORNEAL OPACITY	N/N	0/0	0/0	0/0	17/2
MICROPTHALMIA	N/N	0/0	0/0	0/0	13/2
TIP OF TAIL, RED	N/N	0/0	0/0	0/0	1/1
LENTICULAR OPACITY	N/N	0/0	0/0	0/0	1/1
WHOLE BODY, PALE	N/N	0/0	1/1	0/0	0/0
NOT NESTING	N/N	0/0	1/1	0/0	0/0
LOWER MIDLINE OR HEAD, SCAB	N/N	19/2	0/0	0/0	0/0
HEAD, LACERATION	N/N	2/1	0/0	0/0	0/0
BACK, MASS	N/N	1/1	0/0	0/0	0/0

a. Tabulation restricted to adverse observations; all other pups appeared normal.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 11 (PAGE 1): EYE OPENING BY LITTER - SUMMARY - F1 GENERATION LITTERS

DOSAGE GROUP		I		II		III		IV	
DOSAGE (MG/KG/DAY)		0 (VEHICLE)		7		35		175	
LITTERS TESTED		N	20	16		19		20	
DAY	10	MEAN±S.D.	0.4 ± 1.7	2.1 ± 4.8		1.0 ± 2.9		1.3 ± 3.2	
DAY	11	MEAN±S.D.	0.4 ± 1.7	2.2 ± 4.1		1.7 ± 3.5		1.2 ± 3.1	
DAY	12	MEAN±S.D.	3.5 ± 6.5	7.0 ± 10.7		5.5 ± 6.6		2.8 ± 4.0	
DAY	13	MEAN±S.D.	37.6 ± 34.1	35.3 ± 23.5		50.4 ± 35.5		29.7 ± 25.6	
DAY	14	MEAN±S.D.	85.5 ± 22.7	87.6 ± 24.4		89.3 ± 22.7		78.9 ± 27.4	
DAY	15	MEAN±S.D.	99.6 ± 1.6	99.2 ± 3.3		99.6 ± 1.9		94.2 ± 22.3	
DAY	16	MEAN±S.D.	100.0 ± 0.0	100.0 ± 0.0		100.0 ± 0.0		100.0 ± 0.0	
CRITERION DAY a		MEAN±S.D.	13.8 ± 0.7	13.8 ± 0.6		13.4 ± 0.6		14.0 ± 0.8	

DAY = DAY POSTPARTUM

a. The average day postpartum that at least 50% of the pups had the developmental measure present.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 12 (PAGE 1): NECROPSY OBSERVATIONS - SUMMARY - F1 GENERATION PUPS

MATERNAL DOSAGE GROUP		I	II	III	IV
MATERNAL DOSAGE (MG/KG/DAY)		0 (VEHICLE)	7	35	175
LITTERS EVALUATED	N	20	17	20	20
TOTAL PUPS STILLBORN					
OR FOUND DEAD a,b	N	0	1	1	7
STILLBORN	N	0	0	0	2
FOUND DEAD	N	0	1	1	5
NO MILK IN STOMACH c	N(%)	0 (0.0)	0 (0.0)	1(100.0)	1 (20.0)
APPEARED NORMAL	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	6 (85.7)
INTESTINES, FILLED WITH GAS	N(%)	0 (0.0)	1(100.0)**	0 (0.0)	0 (0.0)
PUPS SACRIFICED AND NECROPSIED ON DAY 20 POSTPARTUM b					
LITTERS EVALUATED	N	20	16	19	19
PUPS EVALUATED	N	205	165	190	187
APPEARED NORMAL					
LITTER INCIDENCE	N(%)	20(100.0)	16(100.0)	19(100.0)	19(100.0)
PUP INCIDENCE	N(%)	205(100.0)	165(100.0)	190(100.0)	187(100.0)

- a. Restricted to pups in which complete necropsies were performed. Complete necropsies were not performed on pups in which autolysis or cannibalization precluded full evaluation.
- b. Refer to the individual pup clinical observations table (Table 33) for external clinical observations confirmed at necropsy.
- c. Analysis restricted to pups found dead and necropsied.
- ** Significantly different from the vehicle control group value ($p \leq 0.01$).

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 13 (PAGE 1): CLINICAL OBSERVATIONS - SUMMARY - F1 GENERATION MALE MICE

MATERNAL DOSAGE GROUP	I	II	III	IV
MATERNAL DOSAGE (MG/KG/DAY)	0 (VEHICLE)	7	35	175
MAXIMUM POSSIBLE INCIDENCE	401/ 20	400/ 20	402/ 20	402/ 20
MORTALITY	0	0	0	0
LACRIMATION	0/ 0	0/ 0	0/ 0	4/ 1
PTOSIS	0/ 0	0/ 0	0/ 0	3/ 1

STATISTICAL ANALYSES OF CLINICAL OBSERVATION DATA WERE RESTRICTED TO THE NUMBER OF MICE WITH OBSERVATIONS.
MAXIMUM POSSIBLE INCIDENCE = (DAYS x MICE)/NUMBER OF MICE EXAMINED PER GROUP
N/N = TOTAL NUMBER OF OBSERVATIONS/NUMBER OF MICE WITH OBSERVATION

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 14 (PAGE 1): CLINICAL OBSERVATIONS - SUMMARY - F1 GENERATION FEMALE MICE

MATERNAL DOSAGE GROUP	I	II	III	IV
MATERNAL DOSAGE (MG/KG/DAY)	0 (VEHICLE)	7	35	175
MAXIMUM POSSIBLE INCIDENCE	401/ 20	400/ 20	402/ 20	402/ 20
MORTALITY	0	0	0	0
TAIL: SCAB	0/ 0	0/ 0	0/ 0	2/ 1
RIGHT EYE: LENTICULAR OPACITY	0/ 0	0/ 0	0/ 0	20/ 1

STATISTICAL ANALYSES OF CLINICAL OBSERVATION DATA WERE RESTRICTED TO THE NUMBER OF MICE WITH OBSERVATIONS.
MAXIMUM POSSIBLE INCIDENCE = (DAYS x MICE)/NUMBER OF MICE EXAMINED PER GROUP
N/N = TOTAL NUMBER OF OBSERVATIONS/NUMBER OF MICE WITH OBSERVATION

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 15 (PAGE 1): BODY WEIGHTS - SUMMARY - F1 GENERATION MALE MICE

MATERNAL DOSAGE GROUP		I	II	III	IV
MATERNAL DOSAGE (MG/KG/DAY)		0 (VEHICLE)	7	35	175
MICE TESTED	N	20	20	20	20
BODY WEIGHT (G)					
DAY 21	MEAN±S.D.	11.6 ± 2.2	11.9 ± 1.3	12.1 ± 1.4	11.5 ± 1.4
DAY 28	MEAN±S.D.	22.0 ± 2.8	22.5 ± 1.9	22.6 ± 2.0	21.9 ± 2.2
DAY 35	MEAN±S.D.	28.4 ± 1.9	28.8 ± 1.4	28.6 ± 1.9	28.0 ± 2.1
DAY 41	MEAN±S.D.	31.8 ± 1.9	32.0 ± 1.6	31.4 ± 2.1	30.9 ± 2.3
DAY = DAY POSTPARTUM					

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 16 (PAGE 1): BODY WEIGHT CHANGES - SUMMARY - F1 GENERATION MALE MICE

MATERNAL DOSAGE GROUP		I	II	III	IV
MATERNAL DOSAGE (MG/KG/DAY)		0 (VEHICLE)	7	35	175
MICE TESTED	N	20	20	20	20
BODY WEIGHT CHANGE (G)					
DAYS 21 - 28	MEAN±S.D.	+10.3 ± 1.1	+10.6 ± 0.9	+10.5 ± 0.8	+10.4 ± 1.0
DAYS 28 - 35	MEAN±S.D.	+6.4 ± 1.6	+6.3 ± 1.2	+6.0 ± 1.0	+6.1 ± 1.0
DAYS 35 - 41	MEAN±S.D.	+3.4 ± 0.9	+3.1 ± 0.9	+2.8 ± 0.8	+2.9 ± 0.9
DAYS 21 - 41	MEAN±S.D.	+20.1 ± 1.4	+20.1 ± 1.4	+19.3 ± 1.8	+19.4 ± 1.7
DAYS = DAYS POSTPARTUM					

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 17 (PAGE 1): BODY WEIGHTS - SUMMARY - F1 GENERATION FEMALE MICE

MATERNAL DOSAGE GROUP		I	II	III	IV
MATERNAL DOSAGE (MG/KG/DAY)		0 (VEHICLE)	7	35	175
MICE TESTED	N	20	20	20	20
BODY WEIGHT (G)					
DAY 21	MEAN±S.D.	10.9 ± 1.8	10.9 ± 1.2	11.6 ± 1.4	11.0 ± 1.7
DAY 28	MEAN±S.D.	18.6 ± 2.2	18.6 ± 1.9	19.4 ± 1.2	18.5 ± 2.4
DAY 35	MEAN±S.D.	23.0 ± 2.1	22.7 ± 1.0	23.4 ± 1.1	22.7 ± 2.2
DAY 41	MEAN±S.D.	24.7 ± 2.4	23.9 ± 1.3	24.4 ± 1.2	24.0 ± 2.4
DAY = POSTNATAL DAY					

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 18 (PAGE 1): BODY WEIGHT CHANGES - SUMMARY - F1 GENERATION FEMALE MICE

MATERNAL DOSAGE GROUP		I	II	III	IV
MATERNAL DOSAGE (MG/KG/DAY)		0 (VEHICLE)	7	35	175
MICE TESTED	N	20	20	20	20
BODY WEIGHT CHANGE (G)					
DAYS 21 - 28	MEAN±S.D.	+7.6 ± 0.9	+7.7 ± 0.8	+7.8 ± 1.0	+7.5 ± 1.0
DAYS 28 - 35	MEAN±S.D.	+4.4 ± 0.8	+4.1 ± 1.1	+4.0 ± 0.8	+4.2 ± 0.9
DAYS 35 - 41	MEAN±S.D.	+1.7 ± 1.2	+1.2 ± 0.8	+1.0 ± 0.9	+1.3 ± 1.1
DAYS 21 - 41	MEAN±S.D.	+13.8 ± 2.0	+13.0 ± 1.1	+12.7 ± 1.4	+13.0 ± 1.6
DAYS = POSTNATAL DAYS					

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 19 (PAGE 1): SEXUAL MATURATION - SUMMARY - F1 GENERATION MICE

MATERNAL DOSAGE GROUP		I	II	III	IV
MATERNAL DOSAGE (MG/KG/DAY)		0 (VEHICLE)	7	35	175
MALE MICE	N	20	20	20	20
PREPUTIAL SEPARATION a	MEAN±S.D.	29.2 ± 1.0	29.0 ± 1.1	28.0 ± 1.0**	28.4 ± 1.0
BODY WEIGHT AT SEPARATION (G)b	MEAN±S.D.	23.6 ± 2.2	23.9 ± 2.1	22.8 ± 2.3	22.6 ± 2.4
FEMALE MICE	N	20	20	20	20
VAGINAL PATENCY c	MEAN±S.D.	26.4 ± 2.8	25.8 ± 2.9	25.8 ± 1.6	25.2 ± 1.9
BODY WEIGHT AT VAGINAL PATENCY (G)d	MEAN±S.D.	16.8 ± 2.6	16.2 ± 2.9	17.2 ± 1.7	15.7 ± 2.4

- a. Average day postpartum that the prepuce was observed to be separated.
b. Average body weight on day prepuce was first observed to be separated.
c. Average day postpartum that the vagina was observed to be patent.
d. Average body weight on day vagina was first observed to be patent.
** Significantly different from the vehicle control group value ($p \leq 0.01$).

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 20 (PAGE 1): NECROPSY OBSERVATIONS - SUMMARY - F1 GENERATION MALE MICE

MATERNAL DOSAGE GROUP		I	II	III	IV
MATERNAL DOSAGE (MG/KG/DAY)		0 (VEHICLE)	7	35	175

MICE EXAMINED a	N	20	20	20	20
MORTALITY	N	0	0	0	0
APPEARED NORMAL	N	20	20	20	19
LIVER:					
MEDIAN LOBE, CLEAR FLUID-FILLED					
CYST	N	0	0	0	1

a. Refer to the individual clinical observations table (Table 36) for external observations confirmed at necropsy.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 21 (PAGE 1): NECROPSY OBSERVATIONS - SUMMARY - F1 GENERATION FEMALE MICE

MATERNAL DOSAGE GROUP		I	II	III	IV
MATERNAL DOSAGE (MG/KG/DAY)		0 (VEHICLE)	7	35	175

MICE EXAMINED a	N	20	20	20	20
MORTALITY	N	0	0	0	0
APPEARED NORMAL	N	20	20	19	20
MESENTERY:					
DARK RED FLAT MASS	N	0	0	1	0

a. Refer to the individual clinical observations table (Table 37) for external observations confirmed at necropsy.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 22 (PAGE 1): TERMINAL BODY WEIGHTS, LIVER WEIGHTS AND RATIOS (%) OF LIVER WEIGHT TO TERMINAL BODY WEIGHT - SUMMARY - F1 GENERATION MALE MICE

MATERNAL DOSAGE GROUP		I	II	III	IV
MATERNAL DOSAGE (MG/KG/DAY)		0 (VEHICLE)	7	35	175
MICE TESTED	N	5	5	5	5
TERMINAL BODY WEIGHT	MEAN±S.D.	31.8 ± 1.7	32.0 ± 0.7	31.4 ± 2.1	31.4 ± 1.4
LIVER (G)	MEAN±S.D.	2.231 ± 0.354	2.365 ± 0.116	2.134 ± 0.080	2.246 ± 0.151
LIVER (%)	MEAN±S.D.	6.976 ± 0.762	7.396 ± 0.452	6.810 ± 0.419	7.156 ± 0.236
ALL WEIGHTS WERE RECORDED IN GRAMS (G) .			RATIOS (%) = (ORGAN WEIGHT/TERMINAL BODY WEIGHT) X 100.		

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 23 (PAGE 1): TERMINAL BODY WEIGHTS, LIVER WEIGHTS AND RATIOS (%) OF LIVER WEIGHT TO TERMINAL BODY WEIGHT - SUMMARY - F1 GENERATION FEMALE MICE

MATERNAL DOSAGE GROUP		I	II	III	IV
MATERNAL DOSAGE (MG/KG/DAY)		0 (VEHICLE)	7	35	175
MICE TESTED	N	5	5	5	5
TERMINAL BODY WEIGHT	MEAN±S.D.	23.9 ± 2.1	23.1 ± 1.6	23.5 ± 1.4	23.9 ± 2.1
LIVER (G)	MEAN±S.D.	1.444 ± 0.184	1.479 ± 0.198	1.380 ± 0.149	1.503 ± 0.167
LIVER (%)	MEAN±S.D.	6.018 ± 0.408	6.398 ± 0.504	5.866 ± 0.359	6.270 ± 0.256
ALL WEIGHTS WERE RECORDED IN GRAMS (G) .			RATIOS (%) = (ORGAN WEIGHT/TERMINAL BODY WEIGHT) X 100.		

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT
(AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 24 (PAGE 1): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

DOSAGE GROUP I		VEHICLE CONTROL		0 (VEHICLE) MG/KG/DAY	
MOUSE #		DESCRIPTION			
401		NO ADVERSE FINDINGS			
402		NO ADVERSE FINDINGS			
403		NO ADVERSE FINDINGS			
404		NO ADVERSE FINDINGS			
405		NO ADVERSE FINDINGS			
406		NO ADVERSE FINDINGS			
407		NO ADVERSE FINDINGS			
408		NO ADVERSE FINDINGS			
409		NO ADVERSE FINDINGS			
410		NO ADVERSE FINDINGS			
411		NO ADVERSE FINDINGS			
412		NO ADVERSE FINDINGS			
413		NO ADVERSE FINDINGS			
414		NO ADVERSE FINDINGS			
415		NO ADVERSE FINDINGS			
416		NO ADVERSE FINDINGS			
417		NO ADVERSE FINDINGS			
418		NO ADVERSE FINDINGS			
419		NO ADVERSE FINDINGS			
420		NO ADVERSE FINDINGS			
CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE					
DG = DAY OF PRESUMED GESTATION		DL = DAY OF LACTATION			

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT
(AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 24 (PAGE 2): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

DOSAGE GROUP II		LOW DOSAGE	7 MG/KG/DAY
MOUSE #		DESCRIPTION	
421		NO ADVERSE FINDINGS	
422		NO ADVERSE FINDINGS	
423		NO ADVERSE FINDINGS	
424		NO ADVERSE FINDINGS	
425		NO ADVERSE FINDINGS	
426		NO ADVERSE FINDINGS	
427		NO ADVERSE FINDINGS	
428		NO ADVERSE FINDINGS	
429		NO ADVERSE FINDINGS	
430	DL (2)	SACRIFICED DUE TO NO SURVIVING PUPS	
431		NO ADVERSE FINDINGS	
432		NO ADVERSE FINDINGS	
433		NO ADVERSE FINDINGS	
434		NO ADVERSE FINDINGS	
435		NO ADVERSE FINDINGS	
436		NO ADVERSE FINDINGS	
437		NO ADVERSE FINDINGS	
438		NO ADVERSE FINDINGS	
439		NO ADVERSE FINDINGS	
440		NO ADVERSE FINDINGS	
CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE			
DG = DAY OF PRESUMED GESTATION		DL = DAY OF LACTATION	

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT
(AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 24 (PAGE 3): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

DOSAGE GROUP III		MIDDLE DOSAGE	35 MG/KG/DAY
MOUSE #		DESCRIPTION	
441		NO ADVERSE FINDINGS	
442		NO ADVERSE FINDINGS	
443		NO ADVERSE FINDINGS	
444		NO ADVERSE FINDINGS	
445		NO ADVERSE FINDINGS	
446		NO ADVERSE FINDINGS	
447		NO ADVERSE FINDINGS	
448	DG (16- 17)	RED PERIVAGINAL SUBSTANCE	
	DG (17)	SACRIFICED DUE TO PREMATURE DELIVERY a	
449		NO ADVERSE FINDINGS	
450		NO ADVERSE FINDINGS	
451		NO ADVERSE FINDINGS	
452		NO ADVERSE FINDINGS	
453		NO ADVERSE FINDINGS	
454		NO ADVERSE FINDINGS	
455		NO ADVERSE FINDINGS	
456		NO ADVERSE FINDINGS	
457		NO ADVERSE FINDINGS	
458		NO ADVERSE FINDINGS	
459		NO ADVERSE FINDINGS	
460	DG (14- 17)	URINE-STAINED ABDOMINAL FUR	

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE

DG = DAY OF PRESUMED GESTATION DL = DAY OF LACTATION

a. Mouse 448 delivered one dead pup and had one early resorption *in utero* on day 17 of gestation.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT
(AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 24 (PAGE 4): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

DOSAGE GROUP IV		HIGH DOSAGE	175 MG/KG/DAY
MOUSE #	DESCRIPTION		
461	DG (15)	NO ADVERSE FINDINGS	
462		NO ADVERSE FINDINGS	
463		RED PERIVAGINAL SUBSTANCE	
464		NO ADVERSE FINDINGS	
465		NO ADVERSE FINDINGS	
466		NO ADVERSE FINDINGS	
467		NO ADVERSE FINDINGS	
468	DL (0)	NO ADVERSE FINDINGS	
469		RED PERIVAGINAL SUBSTANCE	
470		NO ADVERSE FINDINGS	
471		NO ADVERSE FINDINGS	
472		NO ADVERSE FINDINGS	
473		NO ADVERSE FINDINGS	
474		NO ADVERSE FINDINGS	
475		NO ADVERSE FINDINGS	
476		NO ADVERSE FINDINGS	
477		NO ADVERSE FINDINGS	
478		NO ADVERSE FINDINGS	
479		NO ADVERSE FINDINGS	
480	NO ADVERSE FINDINGS		
CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE			
DG = DAY OF PRESUMED GESTATION		DL = DAY OF LACTATION	

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 25 (PAGE 1): MATERNAL BODY WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

MOUSE #	DOSAGE GROUP I	VEHICLE CONTROL 0 (VEHICLE) MG/KG/DAY												
PREGNANCY STATUS	DAY	6	7	8	9	10	11	12	13	14	15	16	17	18
401 P	31.3	32.5	33.6	34.7	35.4	37.8	40.4	41.1	43.1	46.2	50.2	53.8	57.1	
402 P	30.7	31.4	32.8	32.2	33.7	36.1	37.9	40.8	43.4	47.0	51.1	54.2	57.2	
403 P	30.7	31.7	32.9	33.5	34.6	36.6	39.4	42.2	44.9	48.7	52.3	56.3	61.5	
404 P	28.7	28.4	28.8	29.3	30.5	31.4	31.9	33.1	34.2	36.1	38.1	39.2		
405 P	29.3	30.1	30.8	31.6	32.9	35.0	37.0	39.1	40.8	44.2	47.5	50.1	52.7	
406 P	30.8	31.3	32.0	32.3	33.2	33.6	34.7	35.7	37.6	39.9	42.1	43.8	46.1	
407 P	27.5	27.8	28.5	28.9	30.5	32.8	35.2	36.9	39.3	42.9	46.6	49.5	51.9	
408 P	31.0	32.1	33.6	34.6	35.9	37.5	38.8	39.9	42.1	44.8	48.7	51.1	53.6	
409 P	30.0	31.2	31.8	32.5	33.4	36.0	37.7	39.4	42.1	45.6	49.6	53.9	57.8	
410 P	32.2	33.5	35.1	35.5	36.0	37.9	40.4	42.7	45.3	49.7	54.1	58.3	63.1	
411 P	32.1	33.1	34.1	35.0	36.4	38.4	40.4	42.8	45.4	49.1	52.5	56.3	59.3	
412 P	28.5	29.0	29.5	30.2	31.5	33.5	35.6	37.7	40.4	43.3	46.1	48.8	51.5	
413 P	30.7	31.4	31.8	32.8	34.6	36.6	38.8	41.6	44.7	48.1	52.7	56.3		
414 P	34.1	35.2	35.4	36.0	37.3	39.3	42.0	44.1	46.8	50.2	54.0	57.9	61.5	
415 P	27.7	28.3	29.3	29.4	30.9	32.7	34.5	36.5	38.7	41.6	44.8	47.3	49.8	
416 P	32.5	32.5	34.1	34.6	36.0	38.4	40.1	42.5	44.8	47.8	50.9	54.2	57.7	
417 P	28.5	29.1	29.9	30.1	30.9	32.8	35.4	37.1	39.3	42.7	45.9	48.7	52.1	
418 P	31.2	32.0	32.7	34.4	36.0	38.3	41.2	44.1	46.4	51.9	56.1	60.8		
419 P	31.2	31.7	32.2	33.4	34.4	36.5	38.6	41.0	43.7	47.4	51.1	54.3		
420 P	29.8	30.3	30.7	31.6	32.9	36.4	37.8	40.6	43.9	47.8	51.3	53.8		

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G) .

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 25 (PAGE 2): MATERNAL BODY WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

MOUSE #	DOSAGE GROUP II		LOW DOSAGE					7 MG/KG/DAY						
PREGNANCY STATUS	DAY	6	7	8	9	10	11	12	13	14	15	16	17	18
421 P		30.6	31.7	33.2	33.2	33.5	35.2	36.9	38.5	40.5	43.5	45.9	49.2	50.9
422 P		27.1	27.3	28.3	28.9	30.6	32.7	35.5	37.6	39.8	44.0	47.4	51.0	54.6
423 P		31.0	31.6	33.2	33.9	35.2	37.3	39.4	41.9	45.7	50.5	54.3	59.5	64.0
424 NP		29.1	28.4	28.8	27.9	28.0	28.2	28.8	28.9	28.5	28.5	28.8	29.1	28.6
425 NP		30.6	30.8	30.6	29.7	30.2	30.9	30.0	30.7	31.5	31.8	31.2	31.0	30.3
426 NP		30.3	31.1	30.5	29.5	29.5	29.6	29.6	29.8	29.4	29.5	29.7	29.4	29.0
427 P		30.3	31.6	32.7	33.7	35.5	38.0	40.7	43.8	47.4	50.5	54.9	58.9	62.2
428 P		30.1	30.6	31.5	32.7	34.5	36.5	38.6	40.7	43.9	47.3	50.5	53.9	
429 P		32.2	33.2	34.0	35.6	36.5	38.5	40.9	42.7	45.6	49.6	52.7	55.7	59.1
430 P		31.8	31.9	32.8	32.8	34.9	35.5	37.3	38.6	41.3	43.2	45.6	47.2	49.1
431 P		34.4	34.9	35.2	36.1	37.5	39.5	41.5	43.9	46.6	50.1	53.3	57.1	60.4
432 P		29.7	29.9	30.6	31.5	32.5	34.9	37.7	39.8	42.6	47.9	50.7	55.3	58.2
433 P		29.7	30.5	31.3	32.0	33.6	35.8	37.9	40.5	44.1	47.4	52.3	56.4	59.6
434 P		29.1	29.7	29.9	30.8	32.2	34.6	37.8	40.2	42.9	46.5	49.5	53.5	57.4
435 P		31.8	32.4	33.2	34.5	35.3	37.4	39.3	41.6	43.3	45.9	48.9	51.9	54.2
436 P		27.3	27.3	28.0	28.3	29.6	31.2	33.6	35.3	37.0	40.1	42.7	45.3	48.5
437 P		33.2	33.4	34.5	35.8	36.9	37.2	38.8	40.4	42.2	45.0	47.8	51.5	55.7
438 P		32.1	32.3	34.0	34.4	35.9	37.3	40.1	43.3	46.6	49.6	53.4	57.2	
439 P		31.9	32.3	32.6	33.8	35.3	37.3	39.6	41.7	44.7	48.0	52.1	55.1	
440 P		31.3	32.2	33.1	33.5	35.0	37.0	40.2	42.0	43.9	47.5	51.8	55.0	60.0
	DAY	19	20	21	22	23								
424 NP		28.5	28.3	28.7	28.9	30.0								
425 NP		30.4	30.4	30.1	30.4	31.3								
426 NP		28.2	28.1	28.6	28.9	29.3								
430 P		50.6	50.1											

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G) .

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 25 (PAGE 3): MATERNAL BODY WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

MOUSE #	DOSAGE GROUP III	MIDDLE DOSAGE	35 MG/KG/DAY											
PREGNANCY STATUS	DAY	6	7	8	9	10	11	12	13	14	15	16	17	18
441 P	28.7	29.9	30.7	31.0	32.8	34.3	35.3	37.4	38.4	40.9	44.0	47.5	48.6	
442 P	32.5	33.3	34.4	35.0	36.2	38.0	40.3	42.0	44.0	47.4	50.5	54.1	57.3	
443 P	30.0	31.2	31.9	32.4	33.5	35.4	37.8	40.0	42.9	45.8	49.6	53.3	56.7	
444 P	30.5	31.4	32.4	33.4	34.0	35.9	38.8	40.1	42.5	44.9	49.1	51.5	54.5	
445 P	32.4	32.2	33.5	34.3	36.0	38.9	41.8	43.9	47.2	51.2	55.8	58.8		
446 P	29.2	29.6	30.1	30.5	32.0	34.3	35.7	37.7	40.0	43.2	47.1	49.7		
447 P	33.2	34.4	35.2	36.1	38.0	40.3	43.0	45.5	48.3	52.9	56.6	61.2	64.2	
448 P	28.5	28.5	28.9	29.4	29.6	29.8	30.1	29.9	30.5	30.7	31.1	28.8a		
449 P	31.8	33.7	33.4	34.2	35.9	37.4	39.5	41.7	44.0	47.7	51.5	54.4	58.4	
450 P	29.5	30.4	30.8	31.6	32.6	34.9	36.5	38.7	42.4	45.1	49.1	51.7	34.8	
451 P	32.3	33.2	33.2	34.2	34.8	36.9	38.7	41.0	43.1	45.8	49.5	53.2	55.5	
452 P	28.5	28.8	29.3	30.1	30.3	32.1	34.2	35.6	37.8	40.8	44.2	46.7	49.2	
453 P	30.0	30.7	31.4	32.7	34.0	35.7	38.1	40.3	42.7	45.3	48.7	52.2	55.4	
454 P	32.1	32.4	32.7	34.2	35.6	37.5	38.8	40.8	43.2	47.0	49.9	53.0	55.8	
455 P	29.8	30.3	31.1	31.6	33.2	35.3	37.5	39.7	41.8	45.9	48.8	53.2	56.4	
456 P	29.3	30.3	31.1	31.3	32.8	34.2	36.3	38.9	42.0	44.7	48.6	52.2	55.5	
457 P	30.9	32.3	32.2	33.1	34.4	36.8	39.7	42.1	45.3	49.6	54.5	58.5	61.7	
458 P	33.0	34.2	34.3	35.0	35.3	37.1	39.1	40.6	42.2	45.0	48.9	52.0	53.8	
459 P	27.8	28.7	29.1	30.3	31.0	33.2	34.9	37.4	39.8	42.5	46.3	48.8	52.5	
460 P	28.4	29.2	30.0	31.4	32.3	34.2	36.3	38.0	40.1	43.5	46.2	49.5	51.6	

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Mouse 448 was sacrificed on day 17 of gestation due to premature delivery.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 25 (PAGE 4): MATERNAL BODY WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

MOUSE #	DOSAGE GROUP IV	HIGH DOSAGE 175 MG/KG/DAY												
PREGNANCY STATUS	DAY	6	7	8	9	10	11	12	13	14	15	16	17	18
461 P	31.0	31.8	31.8	32.8	34.5	36.5	39.6	41.0	43.5	45.9	49.5	53.1	56.8	
462 P	30.8	31.0	32.2	32.7	35.3	36.4	38.0	40.0	42.2	45.8	48.4	49.1		
463 P	29.4	29.7	30.9	31.2	32.3	34.3	35.9	37.6	39.6	43.1	46.5	49.0	52.2	
464 P	29.0	29.9	30.0	30.7	32.1	34.1	35.9	37.8	39.7	41.9	44.0	46.2		
465 P	29.1	30.0	30.6	31.4	33.0	34.7	36.8	38.9	41.7	45.4	48.3	52.9		
466 P	32.9	33.3	34.8	36.1	37.4	39.8	42.4	44.1	46.4	50.0	54.5	58.3	62.3	
467 P	28.7	29.1	29.2	30.3	31.2	33.4	35.0	36.5	38.9	42.0	45.5	47.1	47.4	
468 P	31.1	31.5	31.8	33.3	34.7	38.5	40.4	43.8	47.2	51.3	55.0	58.9		
469 P	32.6	33.4	34.0	34.5	36.6	38.6	41.0	43.6	46.8	49.8	54.4	58.1	60.2	
470 P	31.0	31.3	31.6	32.5	33.3	35.3	37.2	38.6	39.3	42.5	43.3	45.6	42.4	
471 P	29.6	29.8	30.8	31.2	32.5	33.9	36.5	38.8	41.5	44.6	48.8	52.1	54.3	
472 P	29.3	29.9	30.4	32.0	33.1	35.0	36.9	38.4	40.4	42.9	45.8	47.0	46.3	
473 P	31.4	31.7	32.0	33.1	34.0	35.7	37.8	39.8	42.4	46.5	50.3	53.6	56.0	
474 P	28.8	28.9	29.6	30.0	31.2	33.5	35.2	37.2	39.5	42.1	45.2	48.7	52.8	
475 P	32.9	34.1	34.6	36.6	38.3	40.4	41.6	43.8	45.2	49.3	53.0	56.3	59.1	
476 P	29.5	29.8	30.4	31.9	32.1	32.4	34.7	36.2	38.2	40.6	43.3	46.2	48.1	
477 P	29.3	30.1	30.9	31.7	33.1	35.0	37.2	38.7	41.8	45.6	49.5	53.0	57.0	
478 P	33.3	33.5	34.5	35.7	37.0	39.5	42.5	44.1	47.5	51.7	55.0	58.2		
479 P	31.6	32.3	32.3	33.3	33.7	35.3	37.6	38.7	41.0	43.9	47.0	49.8	53.3	
480 P	26.7	27.6	28.1	28.9	29.9	32.0	34.1	35.5	38.1	39.8	43.4	47.0	49.2	

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G) .

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 26 (PAGE 1): MATERNAL BODY WEIGHTS - LACTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

MOUSE #	DOSAGE GROUP I		VEHICLE CONTROL					0 (VEHICLE) MG/KG/DAY						
	DAY	0	1	2	3	4	5	6	7	8	9	10	11	12
401		34.1	36.3	38.7	40.1	40.2	42.8	42.4	43.8	43.6	45.0	41.1	43.8	46.7
402		34.3	36.1	37.5	39.0	40.0	40.9	41.0	42.1	43.5	45.0	41.7	44.5	44.3
403		35.6	38.4	39.0	40.0	42.4	44.0	43.6	46.0	45.8	45.4	45.2	46.2	47.7
404		31.7	28.0	28.7	29.9	30.6	32.2	31.9	31.7	34.3	33.3	33.0	33.1	34.8
405		34.7	35.5	37.1	38.2	39.8	40.3	43.2	44.8	44.3	44.3	43.4	45.2	45.3
406		30.6	32.2	34.0	35.1	36.2	38.7	40.0	41.3	40.8	41.2	40.5	40.4	43.2
407		31.1	32.0	33.8	35.6	36.8	36.6	39.0	39.9	38.7	38.7	37.9	39.4	41.6
408		32.7	32.5	34.2	35.6	36.5	37.4	37.9	41.5	39.3	40.5	40.6	42.1	46.3
409		33.7	34.8	36.5	38.6	38.8	39.4	42.8	42.0	41.7	45.2	44.9	46.8	44.9
410		36.5	38.9	40.4	42.9	41.7	42.1	43.9	44.1	44.3	45.6	45.3	45.5	45.0
411		35.3	37.1	39.5	41.3	41.0	42.4	42.4	42.2	44.6	46.6	48.3	45.4	47.2
412		32.4	34.2	34.6	37.0	35.8	37.9	37.5	36.3	37.6	39.8	41.7	39.7	38.8
413		35.4	36.5	38.7	40.6	40.4	42.1	44.3	44.4	43.5	45.9	46.5	46.3	44.9
414		38.6	39.7	41.6	42.9	43.9	46.7	46.5	46.7	46.7	50.9	48.3	49.5	50.2
415		30.1	32.2	33.8	35.4	34.1	37.4	36.5	37.0	38.2	38.5	40.8	38.5	39.8
416		35.4	36.9	38.8	40.0	39.7	42.8	42.4	43.1	43.8	46.2	46.9	46.2	46.1
417		30.9	32.7	33.0	35.4	35.3	37.5	37.5	37.5	38.6	38.9	39.4	39.1	39.6
418		35.2	36.6	38.9	40.4	42.2	43.5	43.6	44.2	46.5	46.5	46.2	46.2	46.4
419		32.3	32.8	35.0	35.4	35.9	37.5	37.8	36.9	38.8	38.6	40.7	38.6	39.7
420		32.0	34.4	35.1	34.9	37.0	37.0	36.4	35.9	37.9	38.6	36.9	36.7	41.2

DAY = DAY OF LACTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 26 (PAGE 2): MATERNAL BODY WEIGHTS - LACTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

MOUSE #	DOSAGE GROUP I		VEHICLE CONTROL				0 (VEHICLE) MG/KG/DAY	
	DAY 13	14	15	16	17	18	19	20
401	44.9	44.6	46.8	45.6	46.5	41.8	42.2	43.7
402	44.9	42.7	47.7	45.8	43.7	41.0	38.9	40.0
403	46.3	43.5	47.7	48.9	49.3	47.0	46.1	45.5
404	35.8	35.8	34.8	35.1	33.9	33.7	33.6	35.5
405	47.1	45.3	47.6	46.0	42.6	41.8	43.3	42.0
406	42.0	39.9	42.3	43.8	40.8	39.8	36.8	36.0
407	40.9	40.9	42.7	43.2	41.2	42.0	40.7	41.7
408	41.9	41.6	45.3	44.7	43.6	40.9	44.0	41.1
409	45.8	46.5	46.8	46.1	45.2	46.9	43.0	46.8
410	43.7	48.0	49.4	47.2	45.4	47.4	46.2	49.4
411	48.9	50.3	51.2	49.5	50.7	45.2	46.6	50.4
412	41.8	40.7	41.6	41.2	42.9	40.2	39.5	39.8
413	46.8	49.9	49.6	48.9	47.8	48.5	46.0	49.6
414	50.0	50.5	49.9	52.0	53.0	48.6	44.8	46.9
415	42.0	41.2	41.9	44.5	42.4	43.0	41.9	45.0
416	49.0	48.6	48.4	49.3	50.5	45.1	42.4	42.3
417	41.9	42.0	40.9	40.5	40.3	38.8	37.3	36.7
418	47.2	49.7	48.7	47.7	46.9	45.1	45.3	45.6
419	41.9	41.4	40.6	42.0	41.3	39.9	39.3	43.1
420	39.6	40.7	40.1	39.6	39.4	38.6	39.8	42.2

DAY = DAY OF LACTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 26 (PAGE 3): MATERNAL BODY WEIGHTS - LACTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

MOUSE #	DOSAGE GROUP II		LOW DOSAGE					7 MG/KG/DAY						
	DAY	0	1	2	3	4	5	6	7	8	9	10	11	12
421		32.4	32.6	33.9	35.1	36.5	38.0	38.9	39.4	40.9	41.7	41.6	42.1	43.3
422		31.9	33.4	35.2	36.9	39.5	39.7	40.4	41.9	40.9	42.6	40.6	43.4	43.9
423		36.6	37.7	39.0	42.4	42.4	42.7	43.3	44.1	43.6	43.6	43.5	45.2	48.0
424		NOT PREGNANT												
425		NOT PREGNANT												
426		NOT PREGNANT												
427		36.9	37.9	38.9	40.5	41.1	44.5	44.9	44.6	44.0	44.9	47.2	46.1	47.6
428		34.8	35.5	37.7	37.8	39.8	39.6	41.8	43.5	42.3	41.3	41.9	43.8	44.6
429		35.6	37.1	38.7	39.3	40.1	41.2	41.6	44.4	44.7	44.7	44.6	46.2	46.0
430		32.2	32.4	32.6	SACRIFICED ON DAY 2 OF LACTATION DUE TO NO SURVIVING PUPS									
431		35.9	38.5	40.2	43.6	42.9	44.1	46.4	45.2	45.1	45.4	47.5	49.4	47.1
432		33.5	36.2	37.8	39.3	39.8	40.5	41.8	41.9	41.5	42.8	42.7	45.6	41.6
433		33.4	35.2	37.1	39.7	40.0	39.8	43.0	42.8	43.8	44.8	45.1	47.7	45.2
434		32.7	34.3	35.7	36.5	37.1	37.5	39.9	39.2	41.1	40.6	41.7	42.5	41.3
435		33.3	34.9	38.0	39.5	38.8	43.0	42.0	41.5	43.6	45.1	45.1	43.9	45.2
436		31.9	33.0	35.1	36.3	35.6	37.3	38.7	38.5	39.2	39.8	41.5	39.9	39.9
437		35.0	36.4	37.4	38.7	38.8	40.2	43.2	43.9	43.4	43.9	45.1	44.0	45.8
438		35.3	36.0	37.5	39.4	37.8	41.9	42.1	41.8	42.5	42.7	43.6	46.0	42.8
439		35.5	36.7	37.4	38.9	40.8	40.7	43.7	43.4	42.8	44.1	43.8	45.0	44.3
440		36.7	38.0	38.2	39.1	41.3	41.3	42.0	42.1	45.1	44.9	44.5	47.3	48.2

DAY = DAY OF LACTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 26 (PAGE 4): MATERNAL BODY WEIGHTS - LACTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

MOUSE #	DOSAGE GROUP II		LOW DOSAGE					7 MG/KG/DAY	
	DAY 13	14	15	16	17	18	19	20	
421	42.0	42.0	44.8	44.0	44.0	41.9	39.6	38.6	
422	43.5	44.5	47.6	48.7	45.4	42.8	42.6	40.0	
423	45.0	44.7	46.4	48.1	45.7	47.8	47.9	47.1	
424	NOT PREGNANT								
425	NOT PREGNANT								
426	NOT PREGNANT								
427	46.6	47.7	48.4	49.0	47.3	48.4	49.8	50.5	
428	42.5	43.5	45.4	43.7	44.8	42.5	38.2	41.9	
429	47.5	46.3	48.2	49.9	48.9	47.1	48.6	48.4	
430	SACRIFICED ON DAY 2 OF LACTATION DUE TO NO SURVIVING PUPS								
431	48.8	51.2	52.8	50.9	51.5	52.3	50.0	51.6	
432	43.1	44.6	44.0	44.7	44.0	43.6	39.7	43.6	
433	45.7	47.6	47.6	44.8	47.4	48.2	44.7	47.5	
434	40.5	43.0	42.9	42.3	42.4	41.9	39.7	38.5	
435	49.9	49.7	48.3	50.5	51.7	47.4	45.7	48.2	
436	42.0	41.4	41.6	41.7	41.7	39.7	37.0	34.7	
437	46.4	48.7	48.0	47.9	48.4	45.8	42.6	39.9	
438	42.9	45.5	45.7	45.7	46.7	45.4	43.6	43.4	
439	43.9	46.3	46.8	46.1	45.7	46.1	42.3	45.6	
440	49.4	47.1	48.7	46.1	44.8	44.1	46.4	42.1	

DAY = DAY OF LACTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 26 (PAGE 5): MATERNAL BODY WEIGHTS - LACTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

MOUSE #	DOSAGE GROUP III			MIDDLE DOSAGE			35 MG/KG/DAY							
	DAY 0	1	2	3	4	5	6	7	8	9	10	11	12	
441	31.8	33.1	33.8	35.9	37.4	38.2	39.5	40.8	39.3	39.7	40.0	40.5	43.5	
442	37.2	37.5	39.9	40.1	42.7	43.9	44.2	45.4	46.5	46.4	46.8	47.5	49.6	
443	34.3	35.9	37.8	39.2	41.5	42.1	43.0	45.1	44.5	43.7	44.3	44.5	47.6	
444	34.9	35.5	36.9	37.5	39.8	40.4	41.6	42.4	41.6	44.0	42.0	44.3	46.1	
445	37.9	37.7	38.3	41.2	40.5	43.3	42.8	45.6	45.2	45.7	47.0	46.8	48.1	
446	34.2	32.7	33.9	35.2	36.3	37.2	37.7	38.1	39.5	40.7	41.4	39.4	42.0	
447	38.1	39.3	41.9	42.4	46.1	44.6	44.6	47.1	48.3	47.0	46.3	46.4	49.6	
448	SACRIFICED ON DAY 17 OF GESTATION DUE TO PREMATURE DELIVERY													
449	35.1	36.2	36.7	38.6	39.2	42.3	42.2	41.7	41.5	42.5	45.1	45.8	43.2	
450	34.7	36.8	38.5	40.0	40.6	39.8	42.9	42.7	42.5	43.2	46.4	46.3	44.0	
451	34.7	36.7	38.6	40.2	40.5	41.0	43.8	42.9	44.0	45.0	44.4	49.3	44.6	
452	30.9	33.2	34.4	35.2	36.3	39.1	39.9	39.5	41.4	42.5	44.5	42.4	42.1	
453	36.2	35.6	38.6	39.2	39.4	41.0	41.9	41.6	41.4	44.1	44.5	42.8	44.7	
454	34.7	36.9	39.2	39.8	41.4	41.9	42.5	42.7	43.3	45.0	45.8	44.9	47.0	
455	34.1	35.5	37.2	38.7	38.8	40.5	42.1	41.8	43.2	43.4	45.6	43.1	46.4	
456	33.9	35.6	37.5	38.0	38.0	41.4	40.5	40.7	41.7	43.1	44.7	42.3	43.1	
457	36.8	37.7	39.0	39.2	39.3	43.2	42.9	41.7	42.6	45.3	47.3	43.7	44.7	
458	32.1	33.2	34.1	34.7	35.9	38.0	37.3	38.4	39.5	41.7	41.8	39.4	40.9	
459	31.3	32.9	35.4	35.3	35.5	37.0	38.3	38.1	39.7	39.6	40.5	39.1	40.0	
460	32.9	34.3	35.9	36.6	38.0	38.4	39.0	40.0	41.0	41.5	40.2	43.4	43.6	

DAY = DAY OF LACTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 26 (PAGE 6): MATERNAL BODY WEIGHTS - LACTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

MOUSE #	DOSAGE GROUP III			MIDDLE DOSAGE			35 MG/KG/DAY	
	DAY 13	14	15	16	17	18	19	20
441	40.7	41.6	42.1	43.9	42.8	38.7	36.9	37.2
442	48.1	48.7	49.8	51.4	49.7	47.2	47.3	46.4
443	43.1	46.0	47.9	47.3	45.6	45.7	44.7	43.9
444	43.3	43.5	45.3	45.9	45.1	42.6	44.1	44.3
445	50.8	47.4	48.3	50.9	49.3	51.0	50.8	50.1
446	42.7	40.2	40.0	44.0	42.9	41.7	39.6	40.6
447	46.5	46.0	48.6	45.2	45.7	44.4	42.9	45.4
448	SACRIFICED ON DAY 17 OF GESTATION DUE TO PREMATURE DELIVERY							
449	44.9	46.3	46.3	45.8	48.2	46.6	45.0	49.4
450	43.7	47.3	48.7	45.6	45.0	45.1	41.5	41.0
451	48.4	47.5	50.6	49.0	48.3	50.2	47.9	46.2
452	46.3	45.2	43.5	44.2	45.4	40.8	38.7	38.6
453	46.8	45.7	46.0	47.0	47.8	45.2	43.4	44.7
454	46.1	48.4	47.1	48.7	46.5	45.5	41.7	38.7
455	45.8	46.3	48.8	48.5	47.6	44.1	41.5	38.0
456	45.5	45.1	43.8	45.7	45.9	43.2	41.6	41.0
457	47.4	45.2	46.1	45.7	45.0	43.3	44.1	48.3
458	43.8	42.4	43.5	43.5	44.4	42.5	40.7	42.9
459	41.2	41.0	40.9	42.2	40.9	38.8	37.3	39.5
460	44.0	45.2	43.9	43.0	44.6	47.4	43.3	40.5

DAY = DAY OF LACTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 26 (PAGE 7): MATERNAL BODY WEIGHTS - LACTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

MOUSE #	DOSAGE GROUP IV			HIGH DOSAGE			175 MG/KG/DAY							
	DAY 0	1	2	3	4	5	6	7	8	9	10	11	12	
461	35.4	35.8	37.1	38.9	41.5	40.9	41.9	43.5	44.1	44.3	42.9	44.8	46.5	
462	31.8	33.3	34.7	37.3	39.3	40.4	41.7	40.9	44.0	43.7	42.0	42.9	42.3	
463	34.3	35.2	37.1	36.7	38.8	39.0	39.4	41.4	41.2	44.2	41.3	43.1	43.5	
464	32.5	31.4	32.7	33.7	35.5	36.7	36.9	36.9	39.5	38.0	39.0	37.4	39.1	
465	32.3	35.1	36.2	38.6	38.0	39.4	40.6	40.4	41.5	40.7	41.2	44.4	41.8	
466	38.2	39.7	39.8	42.1	42.4	41.0	44.3	44.3	44.7	46.2	45.5	46.6	44.4	
467	29.4	29.5	29.4	31.5	32.1	32.9	35.5	35.0	35.5	36.8	38.5	40.0	37.3	
468	36.3	36.6	38.3	40.1	38.6	40.2	44.0	43.0	42.9	43.1	43.8	45.9	45.3	
469	36.2	38.0	37.5	40.5	40.7	40.8	42.7	41.8	43.7	43.0	43.9	47.3	44.4	
470	29.4	28.6	29.4	29.7	29.4	30.6	30.9	30.7	30.0	30.8	31.8	31.0	30.1	
471	33.0	35.6	37.1	39.1	37.2	41.0	40.9	40.7	40.2	43.4	43.4	42.3	42.3	
472	30.2	33.1	34.9	36.0	35.5	38.2	37.8	38.3	38.9	40.3	41.9	39.7	39.9	
473	32.1	33.6	36.8	36.6	35.9	37.9	38.7	37.7	39.9	41.9	41.9	41.1	43.2	
474	32.4	33.8	37.3	36.9	38.0	39.2	40.3	40.1	40.2	42.4	43.7	43.0	44.3	
475	35.0	36.5	39.0	38.8	38.1	41.5	41.5	42.0	40.9	43.3	44.4	42.5	43.6	
476	31.4	33.2	34.8	35.7	35.5	38.5	38.7	38.6	39.1	39.9	40.5	40.6	40.7	
477	33.7	34.6	36.2	36.0	38.3	37.9	38.8	40.0	44.0	42.8	41.5	41.2	44.0	
478	34.9	37.5	40.3	42.1	42.1	44.7	46.1	46.3	48.9	49.8	49.5	50.5	49.3	
479	34.2	37.0	37.6	38.4	42.8	40.7	42.1	42.7	43.7	45.1	43.4	44.4	46.3	
480	31.2	31.6	31.7	34.9	34.9	35.0	35.9	37.5	38.8	37.2	37.7	40.0	39.4	

DAY = DAY OF LACTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 26 (PAGE 8): MATERNAL BODY WEIGHTS - LACTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

MOUSE #	DOSAGE GROUP IV		HIGH DOSAGE					175 MG/KG/DAY	
	DAY 13	14	15	16	17	18	19	20	
461	43.8	48.6	47.1	46.1	45.2	45.0	47.7	46.6	
462	46.7	40.6	42.0	46.6	44.7	43.2	38.3	38.6	
463	44.9	44.8	44.7	46.0	43.3	43.1	42.4	44.8	
464	42.4	39.5	39.5	41.2	40.7	39.9	38.9	38.3	
465	42.6	44.6	44.1	42.6	44.2	44.3	41.9	45.9	
466	44.2	50.0	48.3	48.0	48.6	45.9	46.1	49.6	
467	36.9	39.3	40.2	40.4	40.9	41.7	38.2	41.9	
468	43.7	48.2	46.3	48.5	49.1	46.3	45.3	47.0	
469	43.2	45.1	45.7	45.3	49.4	47.5	45.7	50.2	
470	31.9	32.1	32.7	34.6	34.1	34.1	33.9	36.0	
471	44.3	44.2	44.2	46.0	46.0	44.5	44.5	41.9	
472	44.7	41.2	44.6	43.8	42.4	42.1	41.0	42.9	
473	46.5	46.0	45.8	48.4	51.2	47.3	47.0	50.4	
474	45.7	44.8	45.7	47.0	46.9	43.0	41.1	43.9	
475	46.9	46.6	45.8	47.4	47.9	43.6	40.4	43.2	
476	41.9	42.2	43.4	44.9	43.2	40.3	38.6	40.5	
477	45.0	45.7	46.4	45.4	46.8	42.3	43.0	46.9	
478	52.8	50.4	52.4	56.4	55.1	53.4	50.9	53.5	
479	48.5	46.2	49.2	48.9	45.6	44.7	45.4	40.3	
480	40.2	40.9	40.8	39.4	38.7	41.4	37.2	39.1	

DAY = DAY OF LACTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 27 (PAGE 1): NATURAL DELIVERY, IMPLANTATION SITES, AND PUP VIABILITY AND SEX - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE/ F1 GENERATION LITTERS

DOSAGE GROUP I		VEHICLE CONTROL			0 (VEHICLE) MG/KG/DAY												
MOUSE/ LITTER NUMBER	DURATION OF GESTATION (DAYS) N	LITTER DELIVERED			NUMBER OF LIVE PUPS AT COMPLETION OF DAY POSTPARTUM												TOTAL IMPLAN- TATIONS N
		LIVE BORN N	STILL- BORN N	TOTAL BORN N	0		4		7		14		20				
					M	F	M	F	M	F	M	F	M	F			
401	20	13	0	13	9	4	9	4	9	4	9	4	9	4	13		
402	20	15	0	15	8	7	8	6	8	6	8	6	8	6	16		
403	20	13	0	13	6	7	6	7	6	7	6	7	6	7	13		
404	19	4	0	4	3	1	3	1	3	1	3	1	3	1	7		
405	20	9	0	9	5	4	5	4	5	3	5	3	5	3	9		
406	20	10	0	10	5	5	5	5	5	5	5	5	5	5	11		
407	20	14	0	14	5	9	5	8	5	8	5	8	5	8	14		
408	19	12	0	12	9	3	9	3	9	3	9	3	9	3	12		
409	20	13	0	13	4	9	4	9	4	9	4	9	4	9	13		
410	20	15	0	15	7	8	7	8	7	8	7	8	7	8	16		
411	20	14	0	14	9	5	9	5	9	5	9	5	9	5	14		
412	19	12	0	12	6	6	6	6	6	6	6	6	6	6	12		
413	19	12	0	12	4	8	4	8	4	8	4	8	4	8	12		
414	20	13	0	13	7	6	6	6	6	6	6	6	6	6	16		
415	19	12	0	12	6	6	6	6	6	6	6	6	6	6	13		
416	20	12	0	12	5	7	5	7	5	7	5	7	5	7	12		
417	19	13	0	13	7	6	7	6	7	6	7	6	7	6	13		
418	19	14	0	14	10	4	10	4	10	4	10	4	10	4	15		
419	19	15	0	15	6	9	6	9	6	9	6	9	6	9	16		
420	19	14	0	14	7	7	7	7	7	7	7	7	7	7	14		
M = MALE		F = FEMALE															

M = MALE F = FEMALE

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 27 (PAGE 2): NATURAL DELIVERY, IMPLANTATION SITES, AND PUP VIABILITY AND SEX - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE/ F1 GENERATION LITTERS

DOSAGE GROUP II		LOW DOSAGE			7 MG/KG/DAY												TOTAL IMPLAN- TATIONS N
MOUSE/ LITTER NUMBER	DURATION OF GESTATION (DAYS) N	LITTER DELIVERED			NUMBER OF LIVE PUPS AT COMPLETION OF DAY POSTPARTUM												
		LIVE BORN N	STILL- BORN N	TOTAL BORN N	0		4		7		14		20				
					M	F	M	F	M	F	M	F	M	F			
421	20	10	0	10	5	5	5	5	5	5	5	5	5	5	10		
422	20	13	0	13	6	7	6	7	6	7	6	7	6	7	14		
423	20	15	0	15	6	9	6	9	6	9	6	9	6	9	15		
424	NOT PREGNANT																
425	NOT PREGNANT																
426	NOT PREGNANT																
427	20	15	0	15	8	7	7	7	7	7	7	7	7	7	15		
428	19	12	0	12	4	8	4	8	4	8	4	8	4	8	12		
429	20	13	0	13	7	6	6	6	6	6	6	6	6	6	13		
430	22	1	0	3[2]	1	-	-	-	-	-	-	-	-	-	6		
431	20	14	0	14	9	5	9	5	9	5	9	5	9	5	14		
432	19	14	0	14	7	7	7	7	7	7	7	7	7	7	14		
433	20	15	0	15	7	8	7	8	7	8	7	8	7	8	15		
434	19	14	0	14	8	6	8	5	8	5	8	5	8	5	14		
435	20	13	0	13	6	7	6	6	6	6	6	6	6	6	13		
436	20	9	0	9	2	7	2	7	2	7	2	7	2	7	10		
437	19	12	0	12	10	2	10	2	10	2	10	2	10	2	12		
438	19	16	0	16	7	9	7	8	7	8	7	8	7	8	17		
439	19	13	0	13	7	6	7	6	7	6	7	6	7	6	14		
440	20	12	0	12	9	3	9	3	9	3	9	3	9	3	12		

M = MALE F = FEMALE

[] = NUMBER OF PUPS IN WHICH CANNIBALIZATION AND/OR AUTOLYSIS PRECLUDED THE DETERMINATION OF VIABILITY.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 27 (PAGE 3): NATURAL DELIVERY, IMPLANTATION SITES, AND PUP VIABILITY AND SEX - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE/ F1 GENERATION LITTERS

DOSAGE GROUP III		MIDDLE DOSAGE			35 MG/KG/DAY												TOTAL IMPLAN- TATIONS N
MOUSE/ LITTER NUMBER	DURATION OF GESTATION (DAYS) N	LITTER DELIVERED			NUMBER OF LIVE PUPS AT COMPLETION OF DAY POSTPARTUM												
		LIVE BORN N	STILL- BORN N	TOTAL BORN N	0		4		7		14		20				
					M	F	M	F	M	F	M	F					
441	20	9	0	9	4	5	4	5	4	5	4	5	4	5	9		
442	20	11	0	11	9	2	9	2	9	2	9	2	9	2	11		
443	20	12	0	12	7	5	7	5	7	5	7	5	7	5	12		
444	20	11	0	11	7	4	7	4	7	4	7	4	7	4	11		
445	19	15	0	15	7	8	7	7	7	7	7	7	7	7	15		
446	19	12	0	12	5	7	5	7	5	7	5	7	5	7	12		
447	20	15	0	15	5	10	5	10	5	10	5	10	5	10	16		
448a	b	0	0	1 ^c	-	-	-	-	-	-	-	-	-	-	2		
449	20	14	0	14	6	8	6	8	6	8	6	8	6	8	15		
450	19	12	0	12	9	3	9	3	9	3	9	3	9	3	12		
451	20	13	0	13	8	5	8	5	8	5	8	5	8	5	13		
452	20	11	0	11	4	7	4	7	4	7	4	7	4	7	12		
453	20	11	0	11	8	3	8	3	8	3	8	3	8	3	13		
454	20	12	0	12	3	9	3	9	3	9	3	9	3	9	12		
455	20	12	0	12	6	6	6	6	6	6	6	6	6	6	12		
456	20	12	0	12	7	5	7	5	7	5	7	5	7	5	12		
457	20	16	0	16	7	9	7	9	7	9	7	9	7	9	16		
458	20	11	0	11	7	4	7	4	7	4	7	4	7	4	12		
459	20	12	0	12	5	7	5	7	5	7	5	7	5	7	13		
460	19	11	0	11	6	5	5	5	5	5	5	5	5	5	11		

M = MALE F = FEMALE

- a. Mouse 448 was sacrificed on day 17 of gestation due to premature delivery; values were excluded from summarization and statistical analyses.
 b. Value could not be calculated.
 c. Vital status could not be determined due to degree of cannibalization.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 27 (PAGE 4): NATURAL DELIVERY, IMPLANTATION SITES, AND PUP VIABILITY AND SEX - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE/ F1 GENERATION LITTERS

DOSAGE GROUP IV		HIGH DOSAGE		175 MG/KG/DAY													
MOUSE/ LITTER NUMBER	DURATION OF GESTATION (DAYS) N	LITTER DELIVERED			NUMBER OF LIVE PUPS AT COMPLETION OF DAY POSTPARTUM												TOTAL IMPLAN- TATIONS N
		LIVE BORN N	STILL- BORN N	TOTAL N	0		4		7		14		20				
					M	F	M	F	M	F	M	F	M	F			
461	20	13	0	13	5	8	5	8	5	8	5	8	5	8	13		
462	19	12	0	12	8	4	8	3	8	2	8	2	8	2	13		
463	20	12	0	12	6	6	6	6	6	6	6	6	6	6	13		
464	19	8	0	8	4	4	4	4	4	4	4	4	4	4	9		
465	19	14	0	14	8	6	8	6	8	6	8	6	8	6	14		
466	20	14	0	14	9	5	9	5	9	5	9	5	9	5	14		
467	20	11 (1)	0	11	5	5	5	5	5	5	5	5	5	5	12		
468	19	15	0	15	7	8	7	8	7	8	7	8	7	8	15		
469	20	13	0	13	6	7	6	7	6	7	6	7	6	7	13		
470	20	5 (2)	3	8	1	2	1	1	1	1	1	1	1	1	12		
471	20	13	0	13	9	4	9	4	9	4	9	4	9	4	13		
472	19	11	0	11	7	4	7	4	7	4	7	4	7	4	11		
473	20	15 (1)	0	15	7	7	7	7	7	5	7	5	7	5	15		
474	20	11	0	11	4	7	4	7	4	7	4	7	4	7	13		
475	20	13	0	13	3	10	3	10	3	10	3	10	3	10	13		
476	20	9	0	9	6	3	5	3	5	3	5	3	5	3	9		
477	20	14	0	14	5	9	5	9	5	9	5	9	5	9	14		
478	19	14	0	14	10	4	10	4	10	4	10	4	10	4	14		
479	20	11	0	11	6	5	6	5	6	5	6	5	5	5	11		
480	20	10	0	10	6	4	6	4	6	4	6	4	6	4	11		

M = MALE F = FEMALE

() = NUMBER OF PUPS DYING PRIOR TO WEIGHING ON DAY 0 POSTPARTUM.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 28 (PAGE 1): PUP BODY WEIGHT LITTER AVERAGES FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION LITTERS

MATERNAL DOSAGE GROUP I				VEHICLE CONTROL			0 (VEHICLE) MG/KG/DAY								
MOUSE/ LITTER NUMBER	DAY 0			DAY 4			DAY 7			DAY 14			DAY 20		
	M	F	T	M	F	T	M	F	T	M	F	T	M	F	T
401	1.6	1.6	1.6	3.1	3.0	3.1	4.6	4.6	4.6	6.6	6.6	6.6	9.4	9.1	9.3
402	1.5	1.4	1.5	2.9	2.7	2.8	4.3	4.0	4.2	6.9	6.4	6.7	11.0	10.1	10.6
403	1.8	1.7	1.7	3.0	2.9	2.9	4.6	4.3	4.4	6.9	6.8	6.8	10.7	10.6	10.6
404	1.8	1.8	1.8	3.6	3.6	3.6	5.8	5.9	5.8	10.7	10.5	10.6	14.7	15.0	14.8
405	1.7	1.7	1.7	3.3	2.6	3.0	5.4	4.7	5.2	9.7	8.4	9.2	14.1	11.6	13.2
406	1.5	1.4	1.4	2.7	2.6	2.7	4.4	4.4	4.4	7.5	7.4	7.4	10.8	11.4	11.1
407	1.4	1.4	1.4	2.6	2.4	2.5	3.9	3.6	3.7	6.3	5.9	6.0	9.4	8.9	9.1
408	1.6	1.7	1.6	2.8	2.7	2.8	4.2	4.1	4.2	6.7	7.1	6.8	9.6	10.1	9.7
409	1.6	1.5	1.5	2.9	2.7	2.8	4.0	3.9	3.9	6.3	6.2	6.2	9.5	9.0	9.2
410	1.6	1.5	1.6	3.2	2.8	3.0	4.5	4.2	4.4	6.5	6.2	6.3	10.1	9.4	9.7
411	1.6	1.6	1.6	3.0	2.7	2.9	4.1	3.7	3.9	6.4	5.4	6.1	9.4	8.1	8.9
412	1.6	1.5	1.5	3.2	2.9	3.0	4.5	4.2	4.4	6.6	6.3	6.4	10.2	9.7	10.0
413	1.6	1.6	1.6	2.9	2.8	2.8	4.4	4.3	4.3	7.1	6.8	6.9	10.5	10.1	10.2
414	1.6	1.6	1.6	3.3	3.2	3.3	5.0	4.9	5.0	7.8	7.8	7.8	12.8	12.4	12.6
415	1.5	1.5	1.5	2.7	2.6	2.7	3.6	3.8	3.7	6.2	6.1	6.2	9.9	9.3	9.6
416	1.7	1.6	1.7	3.1	3.0	3.0	4.5	4.3	4.4	6.9	6.9	6.9	11.5	11.0	11.2
417	1.4	1.4	1.4	2.7	2.6	2.7	3.8	3.8	3.8	5.8	5.8	5.8	8.4	8.6	8.5
418	1.6	1.6	1.6	2.8	2.6	2.7	4.1	4.0	4.0	6.7	6.2	6.6	11.2	9.1	10.6
419	1.3	1.3	1.3	2.1	2.1	2.1	3.0	3.0	3.0	5.1	4.9	5.0	6.6	6.6	6.6
420	1.5	1.4	1.5	2.6	2.5	2.6	3.9	3.7	3.8	5.7	5.5	5.6	8.1	8.0	8.0
M = MALE F = FEMALE T = TOTAL (SUM OF PUP WEIGHTS/NUMBER OF LIVE PUPS) DAY = DAY POSTPARTUM															
ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.															

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 28 (PAGE 2): PUP BODY WEIGHT LITTER AVERAGES FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION LITTERS

MATERNAL DOSAGE GROUP II				LOW DOSAGE			7 MG/KG/DAY								
MOUSE/ LITTER NUMBER	DAY 0			DAY 4			DAY 7			DAY 14			DAY 20		
	M	F	T	M	F	T	M	F	T	M	F	T	M	F	T
421	1.5	1.4	1.4	2.5	2.4	2.4	4.2	3.7	4.0	6.9	6.7	6.8	9.7	9.0	9.4
422	1.5	1.5	1.5	2.9	2.8	2.8	4.5	4.2	4.3	7.0	6.6	6.8	10.5	10.0	10.2
423	1.7	1.5	1.6	2.9	2.6	2.7	4.3	4.0	4.1	6.6	5.8	6.1	9.6	8.2	8.7
424	NOT PREGNANT														
425	NOT PREGNANT														
426	NOT PREGNANT														
427	1.6	1.5	1.5	2.8	2.8	2.8	4.4	4.3	4.3	6.9	6.7	6.8	10.6	9.8	10.2
428	1.7	1.8	1.8	3.1	2.9	3.0	4.5	4.4	4.4	6.8	6.8	6.8	10.3	10.2	10.2
429	1.6	1.5	1.5	2.6	2.4	2.5	4.4	4.1	4.2	7.4	7.2	7.3	10.9	10.5	10.7
430	1.6	---	1.6	NO SURVIVING PUPS ON DAY 2 OF LACTATION											
431	1.6	1.6	1.6	2.8	2.8	2.8	4.2	4.0	4.2	6.2	6.3	6.3	9.5	9.5	9.5
432	1.6	1.5	1.6	3.0	2.8	2.9	4.3	4.2	4.3	6.4	6.0	6.2	9.5	9.2	9.4
433	1.6	1.5	1.5	2.8	2.7	2.8	4.1	3.9	4.0	6.2	5.8	6.0	9.0	8.3	8.6
434	1.5	1.5	1.5	2.6	2.7	2.7	4.0	4.1	4.0	6.2	6.2	6.2	9.3	9.5	9.4
435	1.5	1.4	1.5	2.9	2.7	2.8	4.1	4.1	4.1	6.4	6.7	6.6	10.7	10.4	10.5
436	1.8	1.7	1.7	3.6	3.6	3.6	5.2	5.1	5.1	7.8	7.9	7.9	12.7	11.6	11.8
437	1.6	1.6	1.6	3.2	3.2	3.2	4.7	4.8	4.7	7.4	7.4	7.4	12.1	11.6	12.0
438	1.3	1.3	1.3	2.4	2.3	2.3	3.5	3.4	3.4	5.5	5.2	5.4	7.7	7.3	7.5
439	1.6	1.4	1.5	3.0	2.6	2.8	4.6	4.1	4.4	7.2	6.7	7.0	10.8	10.0	10.4
440	1.8	1.7	1.8	3.4	3.2	3.3	4.7	4.4	4.6	7.5	7.1	7.4	11.6	11.1	11.5
M = MALE F = FEMALE T = TOTAL (SUM OF PUP WEIGHTS/NUMBER OF LIVE PUPS) DAY = DAY POSTPARTUM															
ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.															

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TABLE 28 (PAGE 3): PUP BODY WEIGHT LITTER AVERAGES FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION LITTERS

MATERNAL DOSAGE GROUP III				MIDDLE DOSAGE			35 MG/KG/DAY								
MOUSE/ LITTER NUMBER	DAY 0			DAY 4			DAY 7			DAY 14			DAY 20		
	M	F	T	M	F	T	M	F	T	M	F	T	M	F	T
441	1.7	1.6	1.7	3.0	2.9	3.0	4.8	4.7	4.7	7.6	7.3	7.4	11.5	11.6	11.6
442	1.8	1.7	1.7	3.3	3.2	3.3	5.0	4.8	5.0	8.1	7.5	8.0	12.7	11.7	12.5
443	1.8	1.6	1.7	3.1	2.8	3.0	4.8	4.4	4.7	7.5	6.9	7.2	11.7	10.6	11.2
444	1.8	1.6	1.7	3.2	2.9	3.1	4.6	4.2	4.4	7.2	6.8	7.0	11.3	10.4	11.0
445	1.4	1.3	1.3	2.6	2.5	2.5	4.1	3.8	3.9	7.0	6.3	6.6	10.1	9.0	9.6
446	1.5	1.3	1.4	2.4	2.1	2.2	3.9	3.5	3.6	6.2	5.8	6.0	9.1	8.3	8.6
447	1.7	1.7	1.7	3.1	3.0	3.0	4.5	4.5	4.5	6.9	6.6	6.7	10.9	10.5	10.6
448	SACRIFICED ON DAY 17 OF GESTATION DUE TO PREMATURE DELIVERY														
449	1.5	1.5	1.5	2.8	2.8	2.8	4.0	4.1	4.0	6.2	6.3	6.2	9.7	9.7	9.7
450	1.5	1.5	1.5	2.9	2.7	2.8	4.3	4.0	4.2	6.7	6.4	6.7	10.7	10.2	10.6
451	1.6	1.4	1.5	2.9	2.7	2.8	4.3	3.9	4.2	6.8	6.3	6.6	10.6	10.0	10.4
452	1.5	1.5	1.5	2.8	2.7	2.8	4.3	4.1	4.2	7.0	6.7	6.8	10.1	9.9	10.0
453	1.7	1.4	1.6	3.8	3.5	3.7	5.4	5.2	5.4	8.5	8.3	8.5	13.4	12.6	13.2
454	1.7	1.6	1.6	3.3	3.1	3.1	4.6	4.5	4.5	7.4	7.1	7.2	10.7	11.0	11.0
455	1.7	1.7	1.7	3.2	3.2	3.2	4.5	4.4	4.4	7.0	6.7	6.8	10.4	10.4	10.4
456	1.7	1.7	1.7	3.4	3.2	3.3	4.6	4.5	4.6	7.2	7.1	7.2	11.4	11.4	11.4
457	1.5	1.4	1.4	2.8	2.6	2.7	4.0	3.7	3.9	5.9	5.7	5.8	8.5	8.0	8.2
458	1.6	1.5	1.6	2.9	2.8	2.9	4.4	4.2	4.4	7.2	7.1	7.2	11.4	10.8	11.2
459	1.6	1.6	1.6	3.0	3.0	3.0	4.5	4.4	4.4	6.9	7.1	7.0	11.3	11.1	11.2
460	1.6	1.6	1.6	3.4	3.3	3.3	5.0	5.1	5.1	8.4	8.4	8.4	13.5	12.8	13.2
M = MALE F = FEMALE T = TOTAL (SUM OF PUP WEIGHTS/NUMBER OF LIVE PUPS) DAY = DAY POSTPARTUM															
ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.															

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 28 (PAGE 4): PUP BODY WEIGHT LITTER AVERAGES FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION LITTERS

MATERNAL DOSAGE GROUP IV				HIGH DOSAGE						175 MG/KG/DAY					
MOUSE/ LITTER NUMBER	DAY 0			DAY 4			DAY 7			DAY 14			DAY 20		
	M	F	T	M	F	T	M	F	T	M	F	T	M	F	T
461	1.7	1.6	1.6	2.7	2.6	2.6	4.4	4.2	4.3	7.0	6.4	6.6	10.4	9.5	9.8
462	1.3	1.2	1.3	2.4	2.3	2.3	4.5	4.4	4.4	8.0	8.0	8.0	11.8	11.3	11.7
463	1.5	1.5	1.5	2.8	2.7	2.7	4.5	4.3	4.4	7.1	6.9	7.0	10.7	10.4	10.6
464	1.4	1.3	1.4	3.0	2.9	3.0	5.0	4.9	5.0	8.3	8.2	8.3	12.8	12.1	12.4
465	1.4	1.4	1.4	2.9	2.7	2.8	4.1	4.0	4.0	6.1	6.2	6.1	9.0	8.9	9.0
466	1.8	1.6	1.7	3.1	3.1	3.1	4.7	4.5	4.6	7.0	6.8	7.0	11.3	10.6	11.0
467	1.3	1.3	1.3	2.4	2.4	2.4	3.7	3.7	3.7	6.7	6.7	6.7	9.1	9.7	9.4
468	1.5	1.4	1.5	2.7	2.7	2.7	4.0	3.9	3.9	6.0	5.8	5.9	9.2	9.3	9.2
469	1.6	1.6	1.6	2.8	2.6	2.7	3.9	3.9	3.9	6.7	6.4	6.5	10.2	9.7	9.9
470	1.0	0.8	0.9	1.4	1.1	1.2	2.5	1.8	2.2	6.9	2.7	4.8	10.4	7.2	8.8
471	1.4	1.4	1.4	2.8	2.7	2.8	4.2	4.0	4.2	6.8	6.5	6.7	10.4	9.6	10.1
472	1.2	1.2	1.2	2.8	2.6	2.8	4.3	4.0	4.2	6.9	6.5	6.7	10.5	9.6	10.2
473	1.4	1.4	1.4	2.6	2.6	2.6	4.0	3.9	4.0	6.8	7.0	6.9	9.7	10.1	9.9
474	1.6	1.6	1.6	3.0	3.0	3.0	4.2	4.3	4.3	7.0	7.0	7.0	10.9	11.0	11.0
475	1.7	1.5	1.6	3.0	2.8	2.8	4.2	4.0	4.0	6.9	6.2	6.4	10.4	9.4	9.7
476	1.6	1.6	1.6	3.4	3.3	3.4	5.3	5.3	5.3	8.8	8.9	8.8	13.6	13.5	13.6
477	1.5	1.5	1.5	3.0	2.8	2.9	4.4	4.1	4.2	6.7	6.6	6.6	10.9	10.5	10.6
478	1.4	1.4	1.4	2.4	2.4	2.4	3.6	3.6	3.6	6.3	5.8	6.2	8.3	7.8	8.1
479	1.6	1.5	1.6	3.4	3.1	3.3	4.7	4.6	4.6	7.7	7.5	7.6	12.5	12.0	12.3
480	1.5	1.5	1.5	3.1	3.0	3.1	4.4	4.6	4.5	7.2	7.2	7.2	11.4	11.7	11.5

M = MALE F = FEMALE T = TOTAL (SUM OF PUP WEIGHTS/NUMBER OF LIVE PUPS) DAY = DAY POSTPARTUM
ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 1): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP I					VEHICLE CONTROL					0 (VEHICLE) MG/KG/DAY					DAY 0 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
401	1.5	1.6	1.6	1.7	1.7	1.6	1.6	1.7	1.5	1.6	1.7	1.6	1.6				
402	1.6	1.5	1.6	1.4	1.6	1.7	1.2	1.4	1.4	1.3	1.5	1.5	1.5	1.4	1.4		
403	1.8	1.9	1.8	1.7	1.9	1.7	1.7	1.7	1.6	1.6	1.7	1.6	1.8				
404	1.8	1.8	1.7	1.8													
405	1.5	1.8	1.9	1.7	1.8	1.7	1.8	1.6	1.7								
406	1.5	1.4	1.5	1.4	1.5	1.4	1.4	1.4	1.3	1.4							
407	1.4	1.5	1.3	1.4	1.3	1.6	1.5	1.4	1.3	1.4	1.4	1.4	1.3	1.4			
408	1.5	1.6	1.6	1.6	1.6	1.7	1.7	1.8	1.6	1.7	1.6	1.8					
409	1.7	1.6	1.6	1.6	1.5	1.6	1.4	1.4	1.5	1.4	1.5	1.3	1.6				
410	1.7	1.8	1.8	1.6	1.4	1.7	1.5	1.7	1.5	1.6	1.3	1.4	1.2	1.6	1.5		
411	1.7	1.6	1.7	1.6	1.5	1.6	1.6	1.6	1.7	1.6	1.6	1.4	1.7	1.6			
412	1.6	1.6	1.6	1.5	1.7	1.6	1.5	1.5	1.4	1.5	1.4	1.6					
413	1.6	1.6	1.6	1.6	1.5	1.6	1.6	1.5	1.6	1.5	1.6	1.5					
414	1.0	1.7	1.9	1.7	1.6	1.6	1.6	1.6	1.6	1.6	1.5	1.7	1.6				
415	1.6	1.5	1.5	1.6	1.6	1.4	1.5	1.5	1.4	1.6	1.5	1.6					
416	1.7	1.7	1.7	1.8	1.7	1.6	1.6	1.7	1.6	1.7	1.7	1.7					
417	1.5	1.4	1.5	1.4	1.4	1.3	1.5	1.4	1.5	1.4	1.4	1.4	1.4				
418	1.6	1.5	1.7	1.7	1.6	1.7	1.7	1.7	1.6	1.7	1.7	1.6	1.6	1.6			
419	1.3	1.3	1.3	1.4	1.4	1.3	1.3	1.3	1.4	1.3	1.3	1.3	1.4	1.3	1.4		
420	1.4	1.4	1.6	1.5	1.5	1.5	1.6	1.4	1.6	1.4	1.4	1.4	1.4	1.5			

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 2): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP II					LOW DOSAGE					7 MG/KG/DAY				DAY 0 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
421	1.5	1.6	1.5	1.5	1.4	1.3	1.4	1.5	1.3	1.4						
422	1.5	1.7	1.4	1.5	1.5	1.6	1.6	1.6	1.5	1.5	1.5	1.5	1.6			
423	1.6	1.7	1.8	1.7	1.8	1.7	1.7	1.6	1.5	1.4	1.4	1.6	1.5	1.6	1.5	
424	NOT PREGNANT															
425	NOT PREGNANT															
426	NOT PREGNANT															
427	1.5	1.5	1.7	1.6	1.9	1.4	1.7	1.4	1.6	1.4	1.6	1.6	1.4	1.4	1.5	
428	1.8	1.7	1.7	1.7	1.7	1.9	1.8	1.8	1.7	1.9	2.0	1.6				
429	1.5	1.4	1.7	1.5	1.6	1.6	1.6	1.5	1.4	1.5	1.5	1.4	1.6			
430	1.6	MU	UU													
431	1.5	1.6	1.6	1.6	1.7	1.6	1.5	1.6	1.6	1.6	1.5	1.7	1.6	1.5		
432	1.8	1.7	1.6	1.2	1.6	1.7	1.6	1.5	1.6	1.6	1.5	1.6	1.5	1.5		
433	1.5	1.6	1.7	1.5	1.6	1.4	1.7	1.3	1.5	1.5	1.5	1.6	1.6	1.6	1.5	
434	1.3	1.6	1.5	1.5	1.5	1.6	1.6	1.5	1.5	1.5	1.5	1.5	1.6	1.6		
435	1.6	1.5	1.6	1.5	1.3	1.7	1.6	1.5	1.4	1.4	1.1	1.4	1.4			
436	1.7	1.8	1.8	1.7	1.7	1.7	1.6	1.6	1.6							
437	1.7	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.5	1.6				
438	1.3	1.3	1.2	1.4	1.3	1.3	1.3	1.4	1.2	1.3	1.3	1.2	1.1	1.4	1.2	1.3
439	1.6	1.7	1.6	1.5	1.6	1.5	1.6	1.5	0.9	1.4	1.5	1.5	1.4			
440	1.8	1.7	1.7	1.8	1.9	1.9	1.8	1.8	1.9	1.6	1.7	1.7				

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 3): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP III					MIDDLE DOSAGE					35 MG/KG/DAY				DAY 0 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
441	1.7	1.7	1.6	1.8	1.6	1.6	1.7	1.7	1.6							
442	1.7	1.8	1.7	1.7	1.8	1.9	1.7	1.9	1.6	1.7	1.7					
443	1.8	1.7	1.9	1.6	1.7	2.0	1.7	1.7	1.9	1.6	1.5	1.5				
444	1.7	1.8	1.7	1.7	1.8	1.8	1.8	1.7	1.6	1.7	1.6					
445	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.2	1.3	1.4	1.3	1.3	1.3	1.3	1.4	
446	1.4	1.5	1.4	1.5	1.5	1.2	1.2	1.3	1.3	1.5	1.2	1.3				
447	1.7	1.7	1.8	1.6	1.7	1.6	1.5	1.8	1.8	1.7	1.8	1.7	1.7	1.5	1.6	
448	SACRIFICED ON DAY 17 OF GESTATION DUE TO PREMATURE DELIVERY															
449	1.6	1.5	1.5	1.5	1.4	1.6	1.5	1.5	1.4	1.6	1.5	1.7	1.6	1.5		
450	1.5	1.5	1.4	1.5	1.5	1.7	1.5	1.7	1.4	1.5	1.4	1.5				
451	1.8	1.5	1.6	1.5	1.5	1.5	1.6	1.5	1.4	1.4	1.4	1.5	1.5			
452	1.6	1.5	1.5	1.4	1.5	1.4	1.5	1.5	1.5	1.5	1.5					
453	1.7	1.6	1.7	1.7	1.7	1.7	1.6	1.6	1.5	1.3	1.5					
454	1.6	1.7	1.7	1.5	1.5	1.6	1.6	1.7	1.5	1.5	1.6	1.7				
455	1.7	1.6	1.8	1.7	1.6	1.6	1.8	1.8	1.5	1.7	1.5	1.7				
456	1.7	1.8	1.6	1.6	1.7	1.7	1.6	1.7	1.5	1.7	1.7	1.7				
457	1.5	1.5	1.4	1.5	1.6	1.4	1.5	1.4	1.4	1.4	1.4	1.5	1.4	1.5	1.4	1.4
458	1.6	1.6	1.7	1.5	1.5	1.6	1.7	1.4	1.6	1.5	1.5					
459	1.6	1.6	1.6	1.6	1.5	1.6	1.6	1.5	1.6	1.6	1.6	1.4				
460	1.6	1.4	1.7	1.7	1.6	1.7	1.5	1.6	1.7	1.6	1.6					

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 4): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP IV					HIGH DOSAGE					175 MG/KG/DAY				DAY 0 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
461	1.8	1.7	1.6	1.7	1.7	1.6	1.6	1.5	1.8	1.5	1.7	1.5	1.6			
462	1.3	1.4	1.3	1.2	1.3	1.3	1.3	1.4	1.2	1.3	1.4	1.1				
463	1.5	1.5	1.4	1.6	1.5	1.4	1.5	1.5	1.5	1.4	1.4	1.5				
464	1.5	1.5	1.4	1.4	1.3	1.4	1.3	1.3								
465	1.4	1.5	1.3	1.5	1.6	1.5	1.4	1.4	1.6	1.4	1.5	1.3	1.4	1.4		
466	1.8	1.8	1.8	1.7	1.8	1.7	1.8	1.8	1.6	1.5	1.7	1.7	1.6	1.6		
467	1.4	1.3	1.4	1.3	1.3	MD 0	1.4	1.3	1.3	1.2	1.1					
468	1.5	1.4	1.6	1.5	1.3	1.6	1.6	1.5	1.4	1.6	1.4	1.4	1.3	1.4	1.5	
469	1.7	1.7	1.8	1.6	1.7	1.4	1.4	1.7	1.6	1.5	1.6	1.5	1.6			
470	1.0	MS	MD 0	MD 0	MS	0.9	0.8	FS								
471	1.4	1.3	1.4	1.3	1.4	1.4	1.5	1.3	1.5	1.3	1.3	1.4	1.4			
472	1.3	1.3	1.3	1.1	1.2	1.2	1.1	1.2	1.2	1.2	1.1					
473	1.3	1.4	1.3	1.4	1.5	1.3	1.5	1.5	1.4	1.4	1.3	1.4	1.4	1.5	FD 0	
474	1.7	1.5	1.6	1.6	1.5	1.6	1.7	1.6	1.5	1.5	1.5					
475	1.7	1.7	1.7	1.5	1.6	1.6	1.3	1.6	1.4	1.5	1.7	1.5	1.7			
476	1.3	1.7	1.7	1.7	1.7	1.4	1.6	1.6	1.7							
477	1.5	1.5	1.6	1.5	1.5	1.5	1.4	1.5	1.5	1.5	1.4	1.6	1.5	1.5		
478	1.3	1.5	1.4	1.6	1.5	1.4	1.4	1.4	1.5	1.5	1.5	1.3	1.5	1.5		
479	1.6	1.6	1.5	1.5	1.7	1.7	1.4	1.6	1.4	1.6	1.5					
480	1.4	1.5	1.6	1.5	1.5	1.5	1.4	1.4	1.6	1.5						

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 5): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP I					VEHICLE CONTROL					0 (VEHICLE) MG/KG/DAY					DAY 4 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
401	3.7	3.1	3.0	3.3	3.2	3.0	3.1	3.0	2.7	3.1	3.0	3.1	2.9				
402	2.9	2.6	3.0	3.0	2.8	3.1	2.8	3.2	FD 4	2.5	2.5	3.1	2.7	2.9	2.3		
403	3.0	3.1	2.9	3.2	3.1	2.9	2.9	2.8	2.9	2.9	3.0	2.7	2.9				
404	3.7	3.5	3.5	3.6													
405	3.4	3.4	3.3	3.1	3.3	1.6	3.5	3.1	2.3								
406	2.7	2.7	2.8	2.7	2.7	2.5	2.7	2.8	2.6	2.6							
407	2.5	2.6	2.4	2.5	2.8	2.5	2.3	2.4	2.6	2.8	2.6	2.1	2.3	FM 4			
408	2.8	2.4	3.0	2.7	2.7	2.7	2.9	3.0	2.8	3.0	2.6	2.6					
409	2.8	2.8	3.2	2.7	2.8	2.7	2.5	2.6	2.6	2.8	2.8	2.8	2.8				
410	3.0	3.7	3.0	3.2	3.0	3.0	3.3	3.3	2.1	2.8	2.9	3.4	2.7	2.4	2.6		
411	2.9	2.9	2.6	3.1	3.1	3.0	3.0	3.2	2.8	2.9	2.8	2.7	2.7	2.5			
412	3.3	3.2	3.1	3.1	3.3	3.1	2.8	2.9	2.9	3.0	3.1	2.8					
413	3.0	2.9	2.8	2.8	2.7	2.9	2.8	2.7	2.8	2.7	2.6	2.9					
414	3.4	3.6	3.2	3.2	3.4	3.1	MM 2	3.2	3.2	3.3	3.5	3.0	3.3				
415	2.8	2.5	2.7	2.6	2.7	2.8	2.6	2.9	2.4	2.6	2.6	2.8					
416	3.1	3.1	3.2	3.2	3.0	2.9	3.0	3.0	3.1	2.9	3.0	3.1					
417	2.6	2.6	2.8	2.8	2.6	2.8	2.7	2.7	2.6	2.7	2.7	2.4	2.7				
418	2.7	2.8	2.8	2.3	3.0	2.7	3.1	2.8	2.7	2.7	2.8	2.5	2.7	2.6			
419	2.1	2.1	2.1	2.2	2.0	2.1	2.0	2.3	2.0	2.0	2.2	1.9	2.2	1.9	2.3		
420	2.7	2.4	3.0	2.5	3.0	2.5	2.5	2.4	2.2	2.8	2.5	2.5	2.5	2.7			

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

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TABLE 29 (PAGE 6): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP II					LOW DOSAGE					7 MG/KG/DAY				DAY 4 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
421	2.7	2.6	2.2	2.4	2.4	2.6	2.6	2.5	2.1	2.3						
422	3.1	3.2	2.6	2.8	2.9	3.0	2.7	3.0	2.6	2.7	2.8	2.8	2.8			
423	2.9	3.2	3.1	2.7	2.8	2.8	2.7	2.4	2.5	2.6	2.3	2.8	2.9	3.0	2.5	
424	NOT PREGNANT															
425	NOT PREGNANT															
426	NOT PREGNANT															
427	2.8	3.3	2.9	3.2	2.3	2.8	2.6	MM 5	2.9	2.8	2.7	2.8	2.7	2.8	2.8	
428	3.3	3.0	3.0	3.1	2.8	3.0	3.0	3.0	2.8	2.7	2.8	3.0				
429	2.7	2.7	2.7	2.4	2.6	2.4	MM 2	2.5	2.3	2.5	2.5	2.4	2.5			
430	MD 2	MU	UU													
431	3.0	2.7	2.7	2.7	2.8	3.1	3.0	2.8	2.9	2.8	2.8	2.8	2.7	2.8		
432	3.1	3.3	3.4	3.1	1.8	3.5	3.2	2.9	2.8	2.7	2.7	2.8	2.9	3.0		
433	2.4	3.1	2.7	2.8	2.9	2.8	2.9	2.7	2.8	2.8	3.1	2.7	2.7	2.5	2.6	
434	2.7	3.0	2.4	2.6	2.5	2.8	2.7	2.5	2.8	2.5	2.9	2.6	2.6	FD 4		
435	3.1	3.0	2.9	2.5	2.9	2.9	2.8	2.7	2.3	3.1	2.8	2.5	FM 4			
436	3.5	3.6	3.4	3.6	3.6	3.8	3.4	3.6	3.6							
437	3.4	3.1	3.1	3.4	3.5	3.3	3.1	3.3	2.9	3.2	3.1	3.4				
438	2.5	2.5	2.5	2.3	2.4	2.2	2.1	2.4	2.2	2.3	1.9	2.2	2.5	2.3	2.4	FD 1
439	3.0	3.1	2.9	3.2	2.9	3.0	3.2	2.8	1.8	2.8	2.7	2.7	2.9			
440	3.3	3.2	3.5	3.2	3.5	3.5	3.5	3.4	3.2	3.1	3.4	3.1				

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

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TABLE 29 (PAGE 7): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP III					MIDDLE DOSAGE					35 MG/KG/DAY				DAY 4 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
441	3.0	2.9	3.0	3.1	2.9	2.9	3.0	2.8	3.1							
442	3.2	3.3	3.4	3.3	3.3	3.2	3.3	3.1	3.5	3.1	3.3					
443	3.1	3.3	3.1	2.9	3.2	2.9	3.1	2.7	2.8	2.9	2.9	2.7				
444	3.2	3.3	3.2	3.1	3.2	3.2	3.3	3.0	3.0	2.8	2.9					
445	2.6	2.6	2.8	2.5	2.6	2.6	2.5	2.3	2.6	2.6	2.3	2.4	2.7	2.4	FD 1	
446	2.4	2.3	2.4	2.2	2.5	1.8	2.1	2.4	2.1	2.1	2.2	1.9				
447	3.4	3.2	3.0	2.9	3.0	3.1	3.3	2.8	2.9	2.5	3.1	3.1	3.2	2.6	3.1	
448	SACRIFICED ON DAY 17 OF GESTATION DUE TO PREMATURE DELIVERY															
449	2.8	2.8	3.0	2.8	2.8	2.7	2.7	3.1	2.7	2.9	3.0	3.0	2.7	2.7		
450	2.9	2.8	3.2	2.6	3.1	2.9	2.8	2.8	2.7	2.7	2.7	2.7				
451	3.0	2.8	2.7	3.0	2.9	2.9	3.0	2.8	2.8	2.8	2.6	2.6	2.5			
452	2.8	2.8	2.7	3.1	2.7	2.8	2.8	2.7	2.7	2.6	2.6					
453	3.7	3.9	4.0	3.7	3.9	3.9	3.7	3.7	3.8	3.2	3.6					
454	3.2	3.5	3.2	3.3	2.8	3.0	3.2	3.0	3.0	2.9	3.1	3.3				
455	3.0	3.2	3.2	3.2	3.4	3.3	3.3	3.3	2.9	3.3	3.1	3.5				
456	3.5	3.5	3.3	3.4	3.4	3.2	3.3	3.1	3.3	3.1	3.2	3.3				
457	2.8	2.9	2.7	2.9	2.7	2.8	3.1	2.4	2.7	2.6	2.4	2.5	2.5	2.6	2.5	2.8
458	2.8	3.1	2.9	3.0	2.8	2.9	3.0	2.9	2.6	2.8	2.8					
459	3.0	3.0	2.9	3.0	3.2	2.8	3.2	2.8	2.8	3.0	3.2	2.9				
460	3.4	3.6	3.5	3.2	3.4	MD 2	3.1	3.5	3.3	3.2	3.2					

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 8): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP IV					HIGH DOSAGE					175 MG/KG/DAY				DAY 4 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
461	2.8	2.8	2.6	2.8	2.7	2.7	2.7	2.7	2.5	2.7	2.8	2.3	2.4			
462	2.5	2.3	2.5	2.3	2.3	2.3	2.5	2.2	2.1	2.3	2.4	FM 4				
463	2.8	2.7	2.6	2.6	2.9	2.9	2.7	2.7	2.7	2.9	2.4	2.7				
464	3.1	3.0	2.9	3.0	2.8	2.9	3.0	2.9								
465	2.7	2.8	2.6	2.9	2.9	2.8	3.1	3.1	2.4	2.9	2.6	2.8	2.8	2.6		
466	2.9	3.0	3.3	3.2	3.4	3.1	3.0	3.0	3.4	2.8	3.2	3.0	3.1	3.2		
467	2.4	2.4	2.3	2.3	2.6	MD 0	2.5	2.4	2.3	2.1	2.5					
468	2.9	2.7	2.7	2.7	2.2	2.8	2.9	3.0	2.8	2.8	2.4	2.6	2.8	2.4	2.8	
469	2.7	2.7	2.9	2.8	2.9	2.7	2.5	2.3	2.7	2.7	2.7	2.7	2.7			
470	1.4	MS	MD 0	MD 0	MS	1.1	FM 4	FS								
471	2.9	2.9	2.8	2.7	3.0	3.0	2.9	2.7	2.7	2.5	2.8	2.8	2.7			
472	3.0	3.0	2.9	2.9	2.6	2.8	2.6	2.8	2.6	2.4	2.7					
473	2.8	2.5	2.8	2.7	2.5	2.4	2.4	2.8	2.4	2.6	2.7	2.5	2.3	2.6	FD 0	
474	2.9	3.0	3.0	2.9	3.2	3.0	3.1	3.0	2.8	2.9	2.9					
475	3.0	3.0	2.9	2.7	3.0	2.4	2.8	2.6	3.0	3.0	3.0	2.6	2.7			
476	3.2	3.6	3.4	3.5	3.4	MM 2	3.3	3.4	3.3							
477	3.1	3.0	3.1	3.0	3.0	2.7	2.8	3.1	2.9	2.9	2.5	2.9	2.5	2.9		
478	2.6	2.7	2.7	2.3	2.4	2.5	2.6	1.9	2.5	2.3	2.3	2.2	2.5	2.5		
479	3.5	3.6	3.1	3.5	3.5	3.2	3.2	2.9	3.2	3.1	3.1					
480	3.1	3.2	2.9	3.1	3.0	3.1	3.2	3.0	3.1	2.9						

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 9): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP I					VEHICLE CONTROL					0 (VEHICLE) MG/KG/DAY					DAY 7 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
401	5.0	4.6	4.3	4.8	4.6	5.3	4.3	4.7	4.1	4.6	4.7	5.0	4.2				
402	4.5	4.4	4.1	4.6	4.0	4.5	4.4	3.6	FD 4	4.1	4.6	3.6	4.4	3.8	3.5		
403	4.6	4.6	4.5	4.8	4.4	4.4	4.2	4.3	4.3	4.3	4.4	4.4	4.4				
404	6.1	5.7	5.7	5.9													
405	5.2	5.6	5.6	5.5	5.3	5.1	5.5	3.5	FD 5								
406	4.6	4.4	4.3	4.4	4.5	4.7	4.6	4.2	4.1	4.3							
407	3.9	3.7	3.7	4.3	3.9	3.8	3.8	3.8	3.2	3.6	3.7	3.0	3.8	FM 4			
408	4.6	3.8	4.2	4.2	3.8	4.3	4.2	4.2	4.1	4.0	4.3	4.1					
409	3.7	3.7	4.2	4.3	3.9	4.1	3.8	3.6	3.5	4.0	3.5	4.3	4.1				
410	4.7	4.8	4.5	5.1	4.1	4.3	4.2	5.0	4.2	3.9	4.1	4.9	3.4	4.4	4.0		
411	4.4	4.0	4.3	4.3	4.2	3.8	3.4	4.3	4.2	3.5	4.0	4.1	3.1	3.6			
412	4.7	4.3	4.8	4.6	4.5	4.3	3.9	4.2	4.5	4.1	4.0	4.4					
413	4.6	4.2	4.5	4.3	4.4	4.3	4.2	3.9	4.5	4.4	4.1	4.4					
414	4.9	5.3	5.0	5.1	4.6	5.4	MM 2	4.9	4.6	5.2	4.6	5.0	5.1				
415	3.7	3.5	3.7	3.8	3.5	3.5	3.9	3.9	4.0	3.5	3.6	3.7					
416	4.3	4.7	4.5	4.5	4.4	4.1	4.1	4.3	4.3	4.5	4.5	4.4					
417	4.0	3.8	3.8	3.8	3.8	3.8	4.0	4.1	3.8	3.8	3.5	4.0	3.6				
418	4.6	4.1	4.3	4.5	4.0	4.0	3.4	3.8	4.0	4.0	3.7	4.3	3.8	4.1			
419	3.0	2.9	2.8	3.2	3.1	3.3	3.2	2.9	3.2	2.8	3.3	3.2	3.3	2.8	2.5		
420	3.9	4.2	4.1	3.5	3.5	3.9	4.0	4.4	3.7	3.7	3.3	3.7	3.4	3.5			

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 10): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP II					LOW DOSAGE					7 MG/KG/DAY				DAY 7 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
421	4.1	4.2	4.4	3.9	4.2	3.3	3.5	4.0	4.1	3.8						
422	4.6	4.1	4.9	4.7	4.4	4.3	4.3	4.1	4.3	4.0	4.2	4.4	3.9			
423	3.8	4.3	4.4	5.0	4.3	4.1	4.3	4.0	4.0	4.2	3.4	4.4	3.7	4.3	3.5	
424	NOT PREGNANT															
425	NOT PREGNANT															
426	NOT PREGNANT															
427	4.2	4.3	4.2	5.0	4.2	5.1	3.5	MM 5	4.1	4.3	4.5	3.9	4.6	4.3	4.4	
428	4.4	4.6	4.5	4.4	4.2	4.6	4.8	4.4	4.7	4.2	4.2	4.5				
429	4.5	4.0	4.6	4.6	4.2	4.3	MM 2	4.1	4.0	4.2	4.2	4.0	4.0			
430	MD 2	MU	UU													
431	4.1	4.2	4.1	4.4	4.2	3.9	4.4	4.7	4.1	3.8	4.0	4.0	4.2	4.2		
432	4.7	4.6	4.6	5.0	4.3	2.4	4.6	4.4	4.5	4.1	4.1	4.1	4.6	4.0		
433	3.9	4.6	4.0	4.4	3.7	4.3	4.0	3.7	3.8	4.2	3.7	4.1	3.7	3.9	4.1	
434	4.4	4.0	3.3	4.0	4.0	4.2	4.1	3.9	4.0	4.2	4.0	4.3	4.1	FD 4		
435	4.4	4.2	4.1	4.3	3.8	4.0	3.6	4.5	4.3	4.2	3.9	4.1	FM 4			
436	5.4	5.0	5.2	5.0	5.4	5.4	4.9	5.0	5.0							
437	4.4	4.9	4.6	4.9	5.0	5.0	4.6	4.4	4.7	4.9	4.7	4.8				
438	3.5	3.6	3.9	3.2	3.4	3.6	3.2	3.7	3.6	3.2	3.7	3.2	3.3	3.6	2.7	FD 1
439	4.7	4.4	4.6	5.0	4.5	4.6	4.5	4.3	4.1	2.6	4.7	4.2	4.6			
440	4.6	5.0	4.5	4.5	4.8	4.8	5.0	4.2	4.7	4.2	4.6	4.5				

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 11): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP III					MIDDLE DOSAGE					35 MG/KG/DAY				DAY 7 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
441	4.9	4.4	4.9	4.8	4.8	4.9	4.7	4.6	4.5							
442	5.3	5.2	5.0	4.8	5.2	5.1	4.5	5.0	5.0	4.7	4.8					
443	4.8	4.9	4.5	4.7	5.4	4.8	4.9	4.4	4.5	4.2	4.3	4.7				
444	4.7	4.5	4.6	4.5	4.5	4.5	4.7	4.1	4.3	4.3	4.1					
445	4.1	4.1	4.0	4.4	4.2	4.0	4.0	4.2	3.8	3.6	4.0	3.6	3.7	3.5	FD 1	
446	4.0	3.6	4.2	3.7	3.9	3.7	3.8	3.6	3.3	3.7	2.9	3.4				
447	4.2	4.5	4.2	5.0	4.8	5.2	4.1	3.8	4.8	4.8	4.8	3.4	4.8	4.4	4.5	
448	SACRIFICED ON DAY 17 OF GESTATION DUE TO PREMATURE DELIVERY															
449	3.9	4.1	4.1	3.7	4.4	4.0	4.5	4.0	4.2	4.2	4.1	4.0	3.6	3.9		
450	4.6	3.9	5.1	4.1	4.4	4.1	4.1	4.6	4.1	3.7	4.0	4.2				
451	4.5	4.0	4.7	4.5	3.8	4.3	4.1	4.4	3.8	4.3	3.7	4.0	3.9			
452	4.5	4.1	4.3	4.2	4.1	4.3	4.2	4.1	4.1	4.0	4.0					
453	5.5	5.5	5.5	5.5	5.1	5.5	5.7	5.2	4.9	5.4	5.4					
454	4.6	4.5	4.6	4.4	4.6	4.7	4.3	4.8	4.3	4.5	4.2	4.5				
455	4.0	4.5	4.6	4.4	4.7	4.6	4.5	4.3	4.7	4.5	4.7	3.9				
456	4.8	4.7	4.5	4.4	4.6	4.9	4.7	4.6	4.7	4.6	4.1	4.3				
457	3.8	4.2	4.6	4.2	4.0	3.8	3.7	4.0	3.5	3.8	4.1	3.8	3.5	3.4	3.7	3.7
458	4.1	4.5	4.7	4.5	4.5	4.6	4.1	4.4	4.2	4.2	4.1					
459	4.6	4.7	4.4	4.3	4.5	4.4	4.3	4.8	4.3	4.3	4.1	4.7				
460	5.1	5.0	5.2	5.0	4.9	MD 2	5.4	5.0	5.3	4.9	4.8					

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

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TABLE 29 (PAGE 12): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP IV					HIGH DOSAGE					175 MG/KG/DAY				DAY 7 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
461	4.6	4.5	4.1	4.5	4.1	4.4	3.9	4.1	4.9	4.2	4.1	3.7	4.3			
462	4.6	4.1	4.5	4.7	4.4	4.4	4.6	4.4	4.6	4.1	FM 6	FM 4				
463	4.4	4.3	4.7	4.6	4.3	4.5	4.6	4.0	4.2	4.4	4.3	4.4				
464	4.8	5.0	5.1	5.1	4.9	5.0	4.9	4.8								
465	4.2	4.1	3.5	4.6	4.3	3.9	3.8	4.5	3.9	4.3	3.9	4.2	4.0	3.6		
466	4.8	5.2	4.2	4.8	4.3	4.4	4.8	4.4	5.2	4.9	4.6	4.3	4.4	4.5		
467	3.6	3.6	3.8	3.8	3.8	MD 0	3.6	3.8	3.8	3.4	4.0					
468	3.5	4.1	4.0	4.2	4.1	3.8	4.0	4.2	3.3	4.0	3.8	4.2	3.9	4.2	3.6	
469	3.6	3.8	4.2	3.9	4.0	4.1	4.0	4.1	4.0	4.0	4.3	3.4	3.7			
470	2.5	MS	MD 0	MD 0	MS	1.8	FM 4	FS								
471	4.0	4.3	4.4	3.9	4.3	4.1	4.3	4.4	4.5	3.9	4.1	4.2	3.8			
472	4.1	4.3	4.0	4.4	4.3	4.6	4.5	4.3	4.0	4.0	3.6					
473	4.1	4.4	4.1	3.3	3.9	4.4	4.1	4.1	4.1	4.0	3.9	3.6	FM 8	FM 6	FD 0	
474	4.3	4.1	4.2	4.3	4.4	4.2	4.3	4.2	4.6	4.2	4.3					
475	4.4	4.1	4.1	4.2	4.2	4.0	4.0	3.8	4.1	3.7	4.5	4.2	3.3			
476	5.0	5.3	5.4	5.6	5.4	MM 2	5.3	5.4	5.2							
477	4.5	4.4	4.4	4.3	4.5	3.6	4.1	4.3	3.9	4.2	4.1	4.4	3.8	4.5		
478	4.2	3.6	2.6	3.6	3.7	3.4	4.0	3.6	3.9	3.5	3.4	3.5	3.8	3.6		
479	4.3	4.8	5.1	4.2	4.8	4.9	4.8	4.6	4.8	4.4	4.4					
480	4.6	4.4	4.3	4.5	4.3	4.2	4.8	4.5	4.6	4.5						

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

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TABLE 29 (PAGE 13): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP I					VEHICLE CONTROL					0 (VEHICLE) MG/KG/DAY					DAY 14 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
401	6.6	7.4	6.1	7.1	6.2	6.7	6.0	6.9	6.2	6.8	6.0	6.8	7.0				
402	7.7	6.6	7.4	7.3	6.2	7.4	6.1	6.6	FD 4	5.7	8.0	5.9	7.4	5.8	5.8		
403	7.3	6.5	7.0	7.3	6.7	6.5	6.7	6.7	6.7	7.2	6.2	6.8	7.2				
404	10.9	10.5	10.7	10.5													
405	9.7	9.7	9.9	9.7	9.4	8.9	6.6	9.8	FD 5								
406	8.0	7.5	7.4	7.4	7.0	7.7	7.4	7.1	7.3	7.3							
407	6.4	6.1	6.4	5.8	6.7	5.6	4.7	6.3	6.9	6.2	6.2	6.0	5.3	FM 4			
408	7.5	6.3	7.1	6.2	6.5	6.5	7.0	6.8	6.8	6.4	7.6	7.2					
409	6.2	6.7	5.6	6.8	6.3	5.9	6.4	6.6	6.0	6.8	5.1	6.5	6.4				
410	7.2	5.7	6.7	7.0	5.7	7.1	6.2	6.2	5.2	5.9	6.0	6.5	7.3	6.3	5.8		
411	5.9	6.8	7.3	6.9	6.7	6.4	6.5	4.9	6.6	6.1	5.8	4.4	4.7	5.9			
412	6.6	6.7	6.5	6.5	6.6	6.6	6.6	6.5	6.1	6.2	6.5	5.9					
413	7.5	6.7	7.1	7.2	6.3	7.5	7.1	6.7	7.0	6.8	6.1	6.8					
414	7.8	7.1	7.9	7.8	8.6	7.7	MM 2	7.5	7.9	7.6	7.7	8.3	7.7				
415	5.7	6.3	6.2	6.7	6.0	6.3	6.5	6.1	6.2	5.9	6.1	5.8					
416	7.0	6.9	6.9	6.7	7.0	7.1	7.0	7.0	6.8	6.6	6.7	6.9					
417	6.2	5.1	6.0	5.4	6.5	5.4	6.0	6.3	5.3	5.4	5.9	5.8	6.0				
418	6.7	6.7	6.9	7.5	6.7	6.9	6.4	5.4	7.9	6.0	6.4	7.1	6.2	5.3			
419	5.0	5.4	5.3	5.0	5.2	4.8	4.7	4.2	5.4	5.8	5.0	4.3	5.1	5.0	4.7		
420	6.2	6.1	5.7	5.1	6.3	5.4	5.1	5.4	5.2	5.1	6.5	5.9	5.7	4.8			

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 14): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP II					LOW DOSAGE					7 MG/KG/DAY				DAY 14 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
421	7.1	6.7	7.5	5.5	7.6	7.4	6.7	6.9	5.3	7.0						
422	7.6	6.1	7.4	6.7	7.0	7.4	5.5	6.7	7.0	7.4	6.7	6.6	6.4			
423	6.2	6.7	6.7	7.8	6.1	6.1	5.5	5.5	5.9	6.2	5.9	6.4	5.2	4.5	7.0	
424	NOT PREGNANT															
425	NOT PREGNANT															
426	NOT PREGNANT															
427	6.5	8.0	8.0	6.7	7.0	6.7	5.7	MM 5	6.3	7.0	6.9	6.4	6.5	7.0	6.7	
428	6.9	6.7	6.7	6.9	6.3	7.3	7.1	6.7	6.6	6.7	6.7	7.0				
429	7.3	7.2	7.3	7.2	7.7	7.7	MM 2	7.3	7.5	7.1	7.4	7.1	6.7			
430	MD 2	MU	UU													
431	6.5	5.5	6.3	6.3	5.9	7.1	6.1	6.4	5.9	6.1	6.5	7.0	5.8	6.3		
432	6.8	6.5	7.4	3.4	7.2	6.4	7.0	6.0	6.1	5.9	5.9	5.7	6.4	6.1		
433	6.6	6.3	6.6	6.5	6.2	5.7	5.8	5.7	5.6	5.7	6.2	5.7	5.4	6.5	5.7	
434	5.6	6.1	6.7	6.2	6.4	6.4	6.7	5.5	6.0	6.0	6.6	6.1	6.5	FD 4		
435	6.6	6.3	5.7	6.8	6.5	6.7	6.5	7.1	6.8	6.7	6.6	6.7	FM 4			
436	7.8	7.7	8.2	7.6	8.1	7.6	7.8	8.2	7.9							
437	7.6	7.5	7.2	7.2	7.1	7.0	7.6	7.2	7.5	7.9	7.2	7.7				
438	5.7	6.2	4.9	4.6	6.0	6.0	5.3	6.0	5.8	5.1	5.2	5.3	5.6	4.9	3.9	FD 1
439	6.9	7.4	7.2	7.2	7.4	6.8	7.4	6.9	6.8	7.6	4.7	7.2	7.1			
440	7.9	7.0	7.5	7.3	7.3	8.7	6.3	8.1	7.8	6.3	7.7	7.4				

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 15): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP III					MIDDLE DOSAGE					35 MG/KG/DAY				DAY 14 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
441	7.7	7.4	7.8	7.7	7.5	7.5	7.2	7.3	6.9							
442	8.1	8.1	7.8	8.1	7.6	8.0	8.3	8.2	8.4	7.5	7.5					
443	7.5	7.7	8.0	7.6	6.7	7.4	7.4	6.9	7.4	6.4	6.6	7.1				
444	7.3	7.4	7.0	7.2	7.2	7.1	7.2	6.6	7.4	6.5	6.5					
445	7.0	6.9	6.5	6.8	7.4	7.4	7.1	6.7	5.9	6.3	6.0	6.2	6.1	6.8	FD 1	
446	6.3	6.7	5.7	5.7	6.5	6.6	5.5	6.3	4.7	6.1	6.1	5.5				
447	6.5	6.8	7.4	6.8	6.8	6.5	7.5	7.5	7.2	6.2	5.8	6.3	5.1	6.8	6.8	
448	SACRIFICED ON DAY 17 OF GESTATION DUE TO PREMATURE DELIVERY															
449	6.3	6.0	6.2	6.2	6.5	6.2	6.1	5.9	6.4	6.5	6.9	5.9	6.4	6.1		
450	6.6	6.7	6.3	6.9	6.6	6.2	6.8	7.2	7.4	6.6	6.3	6.4				
451	7.1	6.7	7.4	7.0	6.6	6.2	7.3	6.3	6.3	6.1	6.5	6.4	6.1			
452	7.3	6.9	7.1	6.7	6.9	6.5	7.2	6.7	6.3	6.4	6.9					
453	8.9	8.6	8.7	8.9	8.6	8.0	8.5	8.0	8.6	8.6	7.7					
454	6.8	8.1	7.2	7.1	7.0	7.2	7.0	7.7	7.1	6.7	7.6	6.9				
455	7.1	7.3	7.0	7.0	6.4	6.9	6.9	6.5	6.4	7.2	6.5	6.8				
456	7.6	7.6	7.3	7.2	6.3	7.3	7.4	6.9	6.6	7.5	7.4	7.0				
457	6.5	6.3	5.8	5.8	5.8	5.9	5.5	5.7	6.0	6.1	6.7	5.3	4.6	5.9	5.6	5.3
458	7.4	7.1	6.5	7.4	7.6	7.4	6.9	6.9	7.1	7.3	7.1					
459	6.7	6.9	6.6	7.2	7.3	7.3	6.7	7.0	7.5	6.4	6.9	7.8				
460	8.2	8.1	8.5	8.6	8.5	MD 2	7.8	8.0	8.5	8.8	8.9					

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 16): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP IV					HIGH DOSAGE					175 MG/KG/DAY				DAY 14 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
461	7.4	6.7	7.1	6.7	7.1	6.4	6.4	7.0	5.9	5.4	7.3	6.4	6.7			
462	7.8	8.4	8.0	7.9	7.6	8.0	8.1	8.2	7.7	8.3	FM 6	FM 4				
463	7.0	7.3	7.0	7.4	6.7	7.2	7.4	7.0	7.0	6.8	6.4	6.7				
464	8.4	8.2	8.4	8.2	8.4	8.1	8.4	8.0								
465	6.6	7.0	7.2	5.9	5.5	6.3	5.8	4.5	5.7	5.8	6.1	6.7	6.5	6.3		
466	7.8	7.0	7.1	7.2	7.2	6.5	7.3	6.5	6.7	6.5	6.9	6.6	7.2	7.0		
467	6.3	7.2	6.6	6.8	6.4	MD 0	6.8	6.6	7.0	7.0	5.9					
468	5.7	6.4	5.8	6.1	5.7	6.1	6.1	5.9	6.0	6.2	6.3	5.8	4.7	5.8	5.8	
469	7.1	7.0	6.8	6.6	5.9	6.6	6.2	6.4	6.7	6.7	7.1	6.3	5.6			
470	6.9	MS	MD 0	MD 0	MS	2.7	FM 4	FS								
471	7.3	6.7	6.9	6.7	7.0	6.3	6.7	7.0	6.2	6.9	6.1	6.9	6.1			
472	6.8	7.0	7.0	6.9	7.0	7.3	6.3	6.7	6.1	6.9	6.2					
473	7.2	6.6	7.1	6.2	6.7	7.0	6.9	6.5	7.3	7.1	7.0	6.9	FM 8	FM 6	FD 0	
474	7.2	7.3	6.7	6.9	7.1	6.9	7.3	7.3	6.9	7.4	6.5					
475	6.6	7.6	6.4	7.2	6.4	7.2	5.9	6.0	4.7	6.7	6.3	6.2	5.7			
476	8.8	9.0	8.6	8.8	8.8	MM 2	8.9	8.8	9.0							
477	6.7	6.7	7.1	6.5	6.7	6.8	6.2	6.8	7.2	6.1	6.9	7.2	6.1	6.2		
478	6.6	6.0	7.1	6.3	7.0	6.0	7.2	6.7	4.9	5.3	5.4	6.1	5.5	6.4		
479	6.9	7.7	7.2	8.1	8.2	8.0	7.4	7.5	8.0	7.4	7.4					
480	7.8	7.1	6.9	7.0	7.1	7.4	7.3	7.8	7.5	6.4						

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 17): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP I					VEHICLE CONTROL					0 (VEHICLE) MG/KG/DAY					DAY 20 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
401	8.4	10.2	12.0	9.3	9.4	9.0	7.7	8.4	9.9	9.4	9.6	9.5	7.8				
402	11.8	12.1	10.8	11.9	9.9	11.0	10.8	10.0	FD 4	9.4	8.9	9.4	9.9	11.1	11.7		
403	11.4	10.8	10.9	10.3	10.3	10.4	10.8	10.5	10.6	11.3	9.4	10.6	10.8				
404	15.4	14.3	14.4	15.0													
405	13.8	14.4	14.7	13.9	13.8	8.0	12.7	14.2	FD 5								
406	11.2	10.8	10.6	11.2	10.3	11.2	12.0	10.8	10.5	12.4							
407	9.8	10.6	8.5	9.4	8.7	8.2	9.7	9.6	8.9	8.7	10.0	7.0	9.0	FM 4			
408	9.7	8.6	10.4	10.3	9.9	9.4	9.9	9.1	9.0	9.3	10.4	10.6					
409	8.8	8.8	10.3	10.0	10.5	8.4	9.5	9.4	9.6	8.7	7.0	9.2	9.1				
410	8.8	9.1	10.8	11.1	11.0	9.3	10.6	10.2	11.1	7.2	9.0	10.2	9.8	8.9	8.4		
411	8.1	9.9	6.8	9.6	9.5	9.3	9.9	10.7	11.0	9.3	6.4	8.7	8.9	7.0			
412	10.7	9.9	9.7	10.7	10.3	9.8	10.4	9.1	9.5	9.7	9.7	9.9					
413	10.6	10.5	10.9	9.9	10.3	9.8	9.7	10.3	10.6	10.3	10.7	9.4					
414	12.0	13.1	14.0	12.5	12.4	12.6	MM 2	13.3	11.8	12.2	12.6	12.3	12.3				
415	11.1	9.8	10.2	9.4	9.6	9.2	9.4	10.5	8.8	9.9	8.4	8.7					
416	11.2	11.9	11.4	11.6	11.4	11.0	11.2	11.1	10.7	11.2	11.1	11.0					
417	7.7	9.8	7.3	6.8	9.4	9.1	8.7	8.5	7.4	7.9	9.6	9.2	8.9				
418	11.6	11.5	13.3	13.5	11.8	10.6	8.4	10.1	10.2	10.6	9.5	9.3	7.7	9.9			
419	6.4	6.7	6.5	6.3	6.7	6.7	6.9	5.8	5.3	6.1	5.8	6.6	7.3	7.3	8.1		
420	9.0	7.9	9.2	7.5	8.3	8.2	6.4	9.6	7.4	7.0	7.9	8.9	6.9	8.2			

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

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TABLE 29 (PAGE 18): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP II					LOW DOSAGE					7 MG/KG/DAY				DAY 20 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
421	7.2	10.4	10.6	10.0	10.2	8.9	10.6	9.7	9.4	6.5						
422	11.5	10.8	10.5	9.3	9.6	11.3	10.5	10.2	8.5	11.0	10.1	10.1	9.8			
423	10.3	8.2	11.5	9.0	10.2	8.4	9.5	10.6	8.6	6.3	8.7	8.3	7.1	7.2	7.1	
424	NOT PREGNANT															
425	NOT PREGNANT															
426	NOT PREGNANT															
427	10.3	9.1	13.1	9.6	10.0	11.7	10.6	MM 5	9.8	9.6	8.9	10.3	10.2	10.4	9.6	
428	10.5	10.6	10.5	9.6	9.9	11.3	10.5	9.4	9.9	10.1	9.8	10.5				
429	11.4	10.9	10.5	12.1	9.7	11.0	MM 2	10.8	11.6	10.4	10.1	10.1	10.2			
430	MD 2	MU	UU													
431	9.7	10.7	9.1	10.0	9.1	8.9	9.9	9.9	8.0	8.5	8.6	10.0	9.8	10.8		
432	3.7	11.5	9.1	11.2	9.9	10.1	11.3	9.1	9.4	8.5	10.2	9.1	9.1	8.9		
433	7.2	9.3	8.8	9.2	9.2	9.6	9.5	8.7	8.9	8.8	8.4	8.2	7.6	7.4	8.4	
434	7.2	9.7	8.5	9.1	10.0	9.6	10.0	10.1	9.7	9.7	9.8	9.4	8.9	FD 4		
435	10.4	10.9	11.3	11.2	10.0	10.2	10.6	9.9	9.6	11.3	10.6	10.5	FM 4			
436	12.4	13.0	11.0	11.9	11.8	11.6	11.7	11.6	11.6							
437	13.7	11.7	12.3	12.0	12.0	12.0	11.5	12.4	12.3	11.4	11.5	11.6				
438	9.5	5.2	6.6	8.2	8.6	7.2	8.8	7.2	4.7	8.6	7.5	8.3	7.9	6.6	7.4	FD 1
439	11.2	10.4	10.8	11.2	10.7	11.0	10.7	10.5	6.8	10.8	10.3	11.3	10.0			
440	12.8	12.5	12.0	11.7	11.8	11.6	10.9	11.0	10.0	10.3	11.4	11.6				

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 19): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP III					MIDDLE DOSAGE					35 MG/KG/DAY				DAY 20 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
441	11.7	9.9	12.0	12.3	11.8	11.3	11.4	11.7	12.0							
442	13.4	12.8	13.2	11.6	11.4	13.1	13.0	13.6	12.5	11.7	11.7					
443	11.8	11.6	11.6	11.6	12.0	10.9	12.6	10.9	9.9	10.8	10.9	10.3				
444	10.8	11.3	11.4	12.3	10.9	11.0	11.4	10.2	11.2	10.5	9.7					
445	10.2	10.5	9.3	11.2	10.2	9.6	9.8	9.6	9.0	9.7	9.2	8.8	8.6	8.5	FD 1	
446	9.5	9.3	8.7	8.6	9.4	7.0	9.1	8.4	8.1	9.1	8.9	7.6				
447	10.2	11.7	11.2	10.7	10.7	11.6	11.5	10.9	11.6	9.6	8.7	11.2	11.2	8.8	10.1	
448	SACRIFICED ON DAY 17 OF GESTATION DUE TO PREMATURE DELIVERY															
449	9.2	10.2	9.7	9.7	10.0	9.3	9.9	10.0	8.7	10.0	10.5	9.6	9.9	9.0		
450	10.5	9.7	10.7	12.2	10.6	11.2	10.3	9.5	11.4	10.9	9.7	9.9				
451	9.4	10.5	11.2	10.2	11.0	11.5	10.5	10.6	10.3	9.0	10.2	10.4	9.9			
452	10.4	9.9	10.3	9.9	10.1	10.1	9.9	10.2	10.0	9.4	9.5					
453	13.1	14.0	12.8	12.8	13.8	13.8	12.9	14.4	11.5	13.2	13.0					
454	12.2	10.1	9.9	11.0	11.8	10.9	11.6	10.6	11.5	10.9	11.1	9.9				
455	11.0	10.8	11.1	10.3	9.2	10.0	9.5	9.7	10.0	11.7	10.7	10.6				
456	11.6	11.7	11.9	12.0	10.7	10.8	11.2	11.5	11.9	11.5	11.0	11.1				
457	9.7	9.3	7.8	8.0	8.2	9.1	7.4	8.3	8.3	8.4	9.7	7.3	8.2	8.3	6.2	7.7
458	11.2	10.8	11.8	11.6	11.2	11.3	11.7	11.3	10.7	10.1	11.3					
459	10.9	11.3	10.8	11.6	12.0	11.6	10.1	11.3	10.3	10.9	11.7	12.0				
460	13.3	14.2	13.2	13.5	13.3	MD 2	12.3	12.8	12.9	13.9	12.2					

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 29 (PAGE 20): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP IV					HIGH DOSAGE					175 MG/KG/DAY				DAY 20 POSTPARTUM	
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
461	9.9	11.2	11.3	9.6	10.0	9.3	10.0	7.9	7.6	10.0	9.7	10.3	11.0			
462	11.5	12.0	12.2	11.9	11.1	12.1	11.4	11.8	11.4	11.2	FM 6	FM 4				
463	10.6	10.7	10.8	10.5	10.8	10.7	10.5	10.9	10.3	10.6	10.0	10.2				
464	12.2	12.4	13.5	12.9	12.0	11.5	12.2	12.6								
465	6.5	9.7	9.7	10.6	8.7	8.4	10.6	8.0	8.8	10.2	8.7	8.4	8.7	8.4		
466	12.1	10.3	12.2	10.4	11.3	11.1	12.3	11.7	10.3	10.9	10.3	10.4	11.4	9.9		
467	8.3	9.2	8.7	8.9	10.6	MD 0	7.8	9.9	10.4	10.0	10.4					
468	8.4	9.5	9.8	9.6	8.5	8.5	9.9	9.5	9.3	9.3	9.4	9.6	9.2	7.5	10.8	
469	9.0	10.7	10.7	10.3	11.0	9.6	8.0	10.3	10.0	9.5	9.8	11.0	9.4			
470	10.4	MS	MD 0	MD 0	MS	7.2	FM 4	FS								
471	11.8	9.9	10.1	10.1	11.6	10.6	10.4	9.3	9.5	9.0	10.6	9.7	9.1			
472	10.2	10.1	10.8	11.0	11.2	10.1	10.2	9.8	9.6	9.7	9.3					
473	9.9	9.7	9.9	9.1	9.4	10.5	9.5	9.2	9.6	10.9	10.8	10.1	FM 8	FM 6	FD 0	
474	11.2	10.3	10.7	11.5	10.7	10.9	11.2	10.8	11.3	11.2	11.3					
475	10.3	11.3	9.7	9.5	11.3	9.0	9.8	9.8	9.6	10.9	8.0	6.1	10.3			
476	13.3	13.8	13.6	13.0	14.4	MM 2	13.4	13.4	13.7							
477	10.2	11.4	11.4	10.9	10.4	9.6	10.3	12.0	10.4	9.9	10.4	11.2	9.8	10.9		
478	9.8	7.0	9.1	7.6	9.2	6.3	8.9	8.5	8.0	8.6	8.8	7.2	7.8	7.2		
479	13.5	13.5	11.7	12.9	11.1	MD20	12.6	12.7	11.2	11.5	12.1					
480	10.7	10.4	12.6	10.9	12.1	11.8	11.9	12.5	10.5	11.8						

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 30 (PAGE 1): PUP VITAL STATUS AND SEX FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP I								VEHICLE CONTROL				0 (VEHICLE) MG/KG/DAY			
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
401	M A	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A			
402	M A	M A	M A	M A	M A	M A	M A	M A	M A	FD 4	F A	F A	F A	F A	F A	
403	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A			
404	M A	M A	M A	F A												
405	M A	M A	M A	M A	M A	F A	F A	F A	FD 5							
406	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A						
407	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A	FM 4		
408	M A	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A				
409	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A	F A			
410	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A	
411	M A	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A		
412	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A				
413	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A				
414	M A	M A	M A	M A	M A	M A	MM 2	F A	F A	F A	F A	F A	F A			
415	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A				
416	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A				
417	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A			
418	M A	M A	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A		
419	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A	F A	
420	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A		

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 30 (PAGE 2): PUP VITAL STATUS AND SEX FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP II							LOW DOSAGE					7 MG/KG/DAY			
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
421	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A						
422	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A			
423	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A	F A	
424	NOT PREGNANT															
425	NOT PREGNANT															
426	NOT PREGNANT															
427	M A	M A	M A	M A	M A	M A	M A	MM 5	F A	F A	F A	F A	F A	F A	F A	
428	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A				
429	M A	M A	M A	M A	M A	M A	MM 2	F A	F A	F A	F A	F A	F A			
430	MD 2	M U	U U													
431	M A	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	
432	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A	
433	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A	
434	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	FD 4		
435	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	FM 4			
436	M A	M A	F A	F A	F A	F A	F A	F A	F A							
437	M A	M A	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A				
438	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	FD 1	
439	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A			
440	M A	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A				

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 30 (PAGE 3): PUP VITAL STATUS AND SEX FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP III								MIDDLE DOSAGE				35 MG/KG/DAY			
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
441	M A	M A	M A	M A	F A	F A	F A	F A	F A							
442	M A	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A					
443	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A				
444	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A					
445	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	FD 1	
446	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A				
447	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A	F A	F A	
448	SACRIFICED ON DAY 17 OF GESTATION DUE TO PREMATURE DELIVERY															
449	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A	F A	
450	M A	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A				
451	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A			
452	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A					
453	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A					
454	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A	F A				
455	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A				
456	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A			
457	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A	
458	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A					
459	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A				
460	M A	M A	M A	M A	M A	MD 2	F A	F A	F A	F A	F A					

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.

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TABLE 30 (PAGE 4): PUP VITAL STATUS AND SEX FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MOUSE/ LITTER #	MATERNAL DOSAGE GROUP IV								HIGH DOSAGE				175 MG/KG/DAY			
PUP #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
461	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A			
462	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	FM 6	FM 4				
463	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A				
464	M A	M A	M A	M A	F A	F A	F A	F A								
465	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A		
466	M A	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	
467	M A	M A	M A	M A	M A	MD 0	F A	F A	F A	F A	F A					
468	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A	
469	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A			
470	M A	M S	MD 0	MD 0	M S	F A	FM 4	F S								
471	M A	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A			
472	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A					
473	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	FM 8	FM 6	FD 0	
474	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A					
475	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A	F A	F A			
476	M A	M A	M A	M A	M A	MM 2	F A	F A	F A							
477	M A	M A	M A	M A	M A	F A	F A	F A	F A	F A	F A	F A	F A	F A	F A	
478	M A	M A	M A	M A	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A		
479	M A	M A	M A	M A	M A	MD30	F A	F A	F A	F A	F A					
480	M A	M A	M A	M A	M A	M A	F A	F A	F A	F A						

FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE

SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, M-MISSING (PRESUMED CANNIBALIZED)

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TABLE 31 (PAGE 1): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

DOSAGE GROUP DOSAGE (MG/KG/DAY)	MOUSE NUMBER	DAY OF NECROPSY	PREGNANCY STATUS	DOSES ADMINISTERED	OBSERVATIONS a
I 0 (VEHICLE)	401	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	402	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	403	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	404	DL 20	P	12	ALL TISSUES APPEARED NORMAL.
	405	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	406	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	407	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	408	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	409	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	410	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	411	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	412	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	413	DL 20	P	12	ALL TISSUES APPEARED NORMAL.
	414	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	415	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	416	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	417	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	418	DL 20	P	12	ALL TISSUES APPEARED NORMAL.
	419	DL 20	P	12	ALL TISSUES APPEARED NORMAL.
	420	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
DG = DAY OF PRESUMED GESTATION DL = DAY OF LACTATION P = PREGNANT NP = NOT PREGNANT					
a. Refer to the individual clinical observations table (Table 24) for external observations confirmed at necropsy.					

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 31 (PAGE 2): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

DOSAGE GROUP DOSAGE (MG/KG/DAY)	MOUSE NUMBER	DAY OF NECROPSY	PREGNANCY STATUS	DOSES ADMINISTERED	OBSERVATIONS a
II					
7	421	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	422	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	423	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	424	DG 23	NP	13	UTERUS: BOTH HORNS, WALLS, THICK. ALL OTHER TISSUES APPEARED NORMAL.
	425	DG 23	NP	13	ALL TISSUES APPEARED NORMAL.
	426	DG 23	NP	13	ALL TISSUES APPEARED NORMAL.
	427	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	428	DL 20	P	12	ALL TISSUES APPEARED NORMAL.
	429	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	430	DL 2	P	13	SACRIFICED ON DAY 2 OF LACTATION DUE TO NO SURVIVING PUPS. ALL TISSUES APPEARED NORMAL.
	431	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	432	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	433	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	434	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	435	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	436	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	437	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	438	DL 20	P	12	LIVER: ALL LOBES, NUMEROUS CLEAR FLUID-FILLED CYSTS (≤ 1.0 MM IN DIAMETER TO 2.0 MM X 2.0 MM X 1.0 MM). KIDNEYS: LEFT, CLEAR FLUID-FILLED CYST (1.0 MM IN DIAMETER). ALL OTHER TISSUES APPEARED NORMAL.
	439	DL 20	P	12	ALL TISSUES APPEARED NORMAL.
	440	DL 20	P	13	ALL TISSUES APPEARED NORMAL.

DG = DAY OF PRESUMED GESTATION DL = DAY OF LACTATION
P = PREGNANT NP = NOT PREGNANT

a. Refer to the individual clinical observations table (Table 24) for external observations confirmed at necropsy.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 31 (PAGE 3): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

DOSAGE GROUP DOSAGE (MG/KG/DAY)	MOUSE NUMBER	DAY OF NECROPSY	PREGNANCY STATUS	DOSES ADMINISTERED	OBSERVATIONS a
III					
35	441	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	442	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	443	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	444	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	445	DL 20	P	12	KIDNEYS: LEFT, SURFACE OF CAPSULE, CLEAR FLUID-FILLED CYST (1.0 MM X 1.0 MM X 1.0 MM). ALL OTHER TISSUES APPEARED NORMAL.
	446	DL 20	P	12	ALL TISSUES APPEARED NORMAL.
	447	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	448	DG 17	P	11	SACRIFICED ON DAY 17 OF GESTATION DUE TO PREMATURE DELIVERY.b ALL TISSUES APPEARED NORMAL.
	449	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	450	DL 20	P	12	ALL TISSUES APPEARED NORMAL.
	451	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	452	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	453	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	454	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	455	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	456	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	457	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	458	DL 20	P	13	UTERUS: RIGHT HORN, ONE FLUID-FILLED CYST (0.3 CM IN DIAMETER); LEFT HORN, TWO FLUID-FILLED CYSTS (BOTH 0.3 CM IN DIAMETER). ALL OTHER TISSUES APPEARED NORMAL.
	459	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	460	DL 20	P	13	ALL TISSUES APPEARED NORMAL.

DG = DAY OF PRESUMED GESTATION DL = DAY OF LACTATION
P = PREGNANT NP = NOT PREGNANT

a. Refer to the individual clinical observations table (Table 24) for external observations confirmed at necropsy.

b. Mouse 448 delivered one dead pup and had one early resorption *in utero* on day 17 of gestation.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 31 (PAGE 4): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

DOSAGE GROUP DOSAGE (MG/KG/DAY)	MOUSE NUMBER	DAY OF NECROPSY	PREGNANCY STATUS	DOSES ADMINISTERED	OBSERVATIONS a
IV 175	461	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	462	DL 20	P	12	ALL TISSUES APPEARED NORMAL.
	463	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	464	DL 20	P	12	ALL TISSUES APPEARED NORMAL.
	465	DL 20	P	12	ALL TISSUES APPEARED NORMAL.
	466	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	467	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	468	DL 20	P	12	ALL TISSUES APPEARED NORMAL.
	469	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	470	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	471	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	472	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	473	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	474	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	475	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	476	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	477	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	478	DL 20	P	12	ALL TISSUES APPEARED NORMAL.
	479	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
	480	DL 20	P	13	ALL TISSUES APPEARED NORMAL.
DG = DAY OF PRESUMED GESTATION DL = DAY OF LACTATION P = PREGNANT NP = NOT PREGNANT a. Refer to the individual clinical observations table (Table 24) for external observations confirmed at necropsy.					

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 32 (PAGE 1): TERMINAL BODY WEIGHTS, LIVER WEIGHTS AND RATIOS (%) OF LIVER WEIGHT TO TERMINAL BODY WEIGHT - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

MOUSE NUMBER	PREGNANCY STATUS	TERMINAL BODY WEIGHT	LIVER	
			ABS. WT.	REL. % TBW
DOSAGE GROUP I		VEHICLE CONTROL		0 (VEHICLE) MG/KG/DAY
401	P	43.7	3.170	7.25
402	P	40.0	2.837	7.09
403	P	45.5	3.230	7.10
406	P	36.0	2.776	7.71
409	P	46.8	3.140	6.71
DOSAGE GROUP II		LOW DOSAGE		7 MG/KG/DAY
421	P	38.6	2.762	7.16
422	P	40.0	2.907	7.27
424	NP	30.0	1.548	5.16
425	NP	31.3	1.478	4.72
426	NP	29.3	1.549	5.29
428	P	41.9	3.462	8.26
430a	P	32.6	2.113	6.48
431	P	51.6	3.600	6.98
432	P	43.6	3.237	7.42
DOSAGE GROUP III		MIDDLE DOSAGE		35 MG/KG/DAY
441	P	37.2	2.817	7.57
443	P	43.9	3.743	8.53
444	P	44.3	4.150	9.37
447	P	45.4	3.183	7.01
448b	P	28.8	1.728	6.00
449	P	49.4	3.640	7.37
DOSAGE GROUP IV		HIGH DOSAGE		175 MG/KG/DAY
463	P	44.8	2.907	6.49
465	P	45.9	3.094	6.74
466	P	49.6	3.680	7.42
467	P	41.9	2.836	6.77
468	P	47.0	3.342	7.11

ALL WEIGHTS WERE RECORDED IN GRAMS (G). ABS. WT. = ORGAN WEIGHT. REL. % TBW = (ORGAN WEIGHT/TERMINAL BODY WEIGHT) X 100.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

- a. Mouse 430 was sacrificed on day 2 of lactation due to no surviving pups; values were excluded from summarization and statistical analyses.
- b. Mouse 448 was sacrificed on day 17 of gestation due to premature delivery; values were excluded from summarization and statistical analyses.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 33 (PAGE 1): CLINICAL OBSERVATIONS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	LITTER NUMBER	DAY (S) POSTPARTUM	OBSERVATIONS a
I 0 (VEHICLE)	405	4 7- 9 20	1/ 9 PUPS: DEHYDRATION, MILD. 1/ 8 PUPS: DEHYDRATION, MILD. 1/ 8 PUPS: BACK, MASS (10 MM X 10 MM X 5 MM) .
	407	7- 8	2/13 PUPS: DEHYDRATION, MILD.
	410	10-12	1/15 PUPS: DEHYDRATION, MILD.
	416	0- 2	1/12 PUPS: LOWER MIDLINE, SCAB (DID NOT EXCEED 0.5 MM X 0.2 MM) .
	419	11	1/15 PUPS: DEHYDRATION, MILD.
	420	11 12-19	2/14 PUPS: HEAD, LACERATION (3 MM X 1 MM) . 2/14 PUPS: HEAD, SCAB (1 MM IN DIAMETER) .
II 7	422b		
	423	8	1/15 PUPS: DEHYDRATION, MILD.
	429	0	1/13 PUPS: WHOLE BODY, PALE.
	431	4 6 14	1/14 PUPS: DEHYDRATION, MILD; NOT NESTING. 1/14 PUPS: DEHYDRATION, MODERATE. 1/14 PUPS: DEHYDRATION, MILD.
	432	7 8-18	1/14 PUPS: DEHYDRATION, MODERATE. 1/14 PUPS: DEHYDRATION, MILD.
	437	2	1/12 PUPS: COLD TO TOUCH.
	439c	5-11 14-16	1/13 PUPS: DEHYDRATION, MILD. 1/13 PUPS: DEHYDRATION, MILD.

a. Tabulation restricted to adverse observations; all other pups appeared normal.

b. Nesting and nursing activity were not recorded on day 7 postpartum.

c. Nesting and nursing activity of the dehydrated pup was not recorded on day 7 postpartum.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 33 (PAGE 2): CLINICAL OBSERVATIONS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	LITTER NUMBER	DAY (S) POSTPARTUM	OBSERVATIONS a
III 35	457	15	1/16 PUPS: DEHYDRATION, MILD.
IV 175	463	10-14 15-20	1/12 PUPS: LEFT EYE, CORNEAL OPACITY. 1/12 PUPS: LEFT EYE, CORNEAL OPACITY b; LEFT EYE, MICROPHTHALMIA b.
		20	1/12 PUPS: TIP OF TAIL, RED.b
	465	4 15 16	1/14 PUPS: COLD TO TOUCH. 1/14 PUPS: DEHYDRATION, MILD. 1/14 PUPS: DEHYDRATION, MODERATE.
	469	5	1/13 PUPS: COLD TO TOUCH.
	470	2 3 4- 6 7- 8 12 13-17 20	3/ 3 PUPS: DEHYDRATION, MODERATE. 2/ 2 PUPS: DEHYDRATION, MILD. 2/ 2 PUPS: DEHYDRATION, MODERATE. 2/ 2 PUPS: DEHYDRATION, MILD. 2/ 2 PUPS: DEHYDRATION, MILD. 1/ 2 PUPS: DEHYDRATION, MILD. 1/ 2 PUPS: RIGHT EYE, LENTICULAR OPACITY.
	474	1 14 15-20	1/11 PUPS: COLD TO TOUCH. 1/11 PUPS: LEFT EYE, MICROPHTHALMIA. 1/11 PUPS: BOTH EYES, MICROPHTHALMIA b; BOTH EYES, CORNEAL OPACITY b.
	478c	6-10 13-16	1/14 PUPS: DEHYDRATION, MILD. 1/14 PUPS: DEHYDRATION, MILD.

a. Tabulation restricted to adverse observations; all other pups appeared normal.

b. Observation confirmed at necropsy.

c. Pup clinical observations were not recorded on day 5 postpartum.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 34 (PAGE 1): EYE OPENING BY LITTER - INDIVIDUAL DATA - F1 GENERATION PUPS

MATERNAL/LITTER #	DOSAGE GROUP I			VEHICLE CONTROL		0 (VEHICLE) MG/KG/DAY	
POSTPARTUM DAY	10	11	12	13	14	15	16
401	1/13 7.7%	1/13 7.7%	0/13 0.0%	4/13 30.8%	13/13 100.0%		
402	0/14 0.0%	0/14 0.0%	0/14 0.0%	6/14 42.8%	14/14 100.0%		
403	0/13 0.0%	0/13 0.0%	0/13 0.0%	12/13 92.3%	13/13 100.0%		
404	0/ 4 0.0%	0/ 4 0.0%	0/ 4 0.0%	4/ 4 100.0%			
405	0/ 8 0.0%	0/ 8 0.0%	0/ 8 0.0%	7/ 8 87.5%	7/ 8 87.5%	8/ 8 100.0%	
406	0/10 0.0%	0/10 0.0%	0/10 0.0%	9/10 90.0%	10/10 100.0%		
407	0/13 0.0%	0/13 0.0%	3/13 23.1%	4/13 30.8%	11/13 84.6%	13/13 100.0%	
408	0/12 0.0%	0/12 0.0%	0/12 0.0%	1/12 8.3%	12/12 100.0%		
409	0/13 0.0%	0/13 0.0%	1/13 7.7%	1/13 7.7%	9/13 69.2%	13/13 100.0%	
410	0/15 0.0%	0/15 0.0%	1/15 6.7%	2/15 13.3%	12/15 80.0%	15/15 100.0%	
411	0/14 0.0%	0/14 0.0%	1/14 7.1%	5/14 35.7%	12/14 85.7%	14/14 100.0%	
412	0/12 0.0%	0/12 0.0%	1/12 8.3%	2/12 16.7%	12/12 100.0%		
413	0/12 0.0%	0/12 0.0%	0/12 0.0%	2/12 16.7%	11/12 91.7%	12/12 100.0%	
414	0/12 0.0%	0/12 0.0%	0/12 0.0%	6/12 50.0%	12/12 100.0%		
415	0/12 0.0%	0/12 0.0%	2/12 16.7%	2/12 16.7%	12/12 100.0%		
416	0/12 0.0%	0/12 0.0%	0/12 0.0%	10/12 83.3%	12/12 100.0%		
417	0/13 0.0%	0/13 0.0%	0/13 0.0%	3/13 23.1%	13/13 100.0%		
418	0/14 0.0%	0/14 0.0%	0/14 0.0%	0/14 0.0%	6/14 42.8%	14/14 100.0%	
419	0/15 0.0%	0/15 0.0%	0/15 0.0%	0/15 0.0%	6/15 40.0%	15/15 100.0%	
420	0/14 0.0%	0/14 0.0%	0/14 0.0%	1/14 7.1%	4/14 28.6%	13/14 92.8%	14/14 100.0%

N/N = NUMBER OF PUPS IN EACH LITTER WITH DEVELOPMENTAL MEASURE/TOTAL NUMBER OF PUPS IN THE LITTER

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 34 (PAGE 2): EYE OPENING BY LITTER - INDIVIDUAL DATA - F1 GENERATION PUPS

MATERNAL/LITTER #	DOSAGE GROUP II		LOW DOSAGE				7 MG/KG/DAY	
POSTPARTUM DAY	10	11	12	13	14	15	16	
421	0/10 0.0%	0/10 0.0%	0/10 0.0%	2/10 20.0%	10/10 100.0%			
422	0/13 0.0%	0/13 0.0%	0/13 0.0%	6/13 46.2%	13/13 100.0%			
423	0/15 0.0%	0/15 0.0%	0/15 0.0%	8/15 53.3%	14/15 93.3%	15/15 100.0%		
427	0/14 0.0%	0/14 0.0%	3/14 21.4%	5/14 35.7%	13/14 92.8%	14/14 100.0%		
428	1/12 8.3%	1/12 8.3%	1/12 8.3%	8/12 66.7%	12/12 100.0%			
429	1/12 8.3%	1/12 8.3%	1/12 8.3%	1/12 8.3%	8/12 66.7%	12/12 100.0%		
430	NO SURVIVING PUPS ON DAY 2 POSTPARTUM							
431	0/14 0.0%	0/14 0.0%	0/14 0.0%	1/14 7.1%	14/14 100.0%			
432	0/14 0.0%	0/14 0.0%	5/14 35.7%	10/14 71.4%	14/14 100.0%			
433	0/15 0.0%	0/15 0.0%	0/15 0.0%	1/15 6.7%	10/15 66.7%	15/15 100.0%		
434	0/13 0.0%	0/13 0.0%	0/13 0.0%	4/13 30.8%	13/13 100.0%			
435	0/12 0.0%	0/12 0.0%	0/12 0.0%	4/12 33.3%	10/12 83.3%	12/12 100.0%		
436	0/ 9 0.0%	1/ 9 11.1%	2/ 9 22.2%	2/ 9 22.2%	9/ 9 100.0%			
437	2/12 16.7%	1/12 8.3%	1/12 8.3%	8/12 66.7%	12/12 100.0%			
438	0/15 0.0%	0/15 0.0%	0/15 0.0%	0/15 0.0%	1/15 6.7%	13/15 86.7%	15/15 100.0%	
439	0/13 0.0%	0/13 0.0%	1/13 7.7%	5/13 38.5%	12/13 92.3%	13/13 100.0%		
440	0/12 0.0%	0/12 0.0%	0/12 0.0%	7/12 58.3%	12/12 100.0%			

N/N = NUMBER OF PUPS IN EACH LITTER WITH DEVELOPMENTAL MEASURE/TOTAL NUMBER OF PUPS IN THE LITTER

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 34 (PAGE 3): EYE OPENING BY LITTER - INDIVIDUAL DATA - F1 GENERATION PUPS

MATERNAL/LITTER #	DOSAGE GROUP III			MIDDLE DOSAGE		35 MG/KG/DAY	
POSTPARTUM DAY	10	11	12	13	14	15	16
441	0/ 9 0.0%	0/ 9 0.0%	0/ 9 0.0%	1/ 9 11.1%	9/ 9 100.0%		
442	0/11 0.0%	0/11 0.0%	0/11 0.0%	11/11 100.0%			
443	0/12 0.0%	0/12 0.0%	0/12 0.0%	4/12 33.3%	12/12 100.0%		
444	1/11 9.1%	1/11 9.1%	1/11 9.1%	7/11 63.6%	11/11 100.0%		
445	0/14 0.0%	0/14 0.0%	0/14 0.0%	0/14 0.0%	7/14 50.0%	14/14 100.0%	
446	0/12 0.0%	1/12 8.3%	1/12 8.3%	0/12 0.0%	2/12 16.7%	11/12 91.7%	12/12 100.0%
447	0/15 0.0%	1/15 6.7%	2/15 13.3%	15/15 100.0%			
449	0/14 0.0%	0/14 0.0%	1/14 7.1%	8/14 57.1%	14/14 100.0%		
450	0/12 0.0%	0/12 0.0%	1/12 8.3%	6/12 50.0%	11/12 91.7%	12/12 100.0%	
451	0/13 0.0%	0/13 0.0%	1/13 7.7%	2/13 15.4%	9/13 69.2%	13/13 100.0%	
452	0/11 0.0%	0/11 0.0%	0/11 0.0%	9/11 81.8%	11/11 100.0%		
453	1/11 9.1%	1/11 9.1%	1/11 9.1%	8/11 72.7%	11/11 100.0%		
454	0/12 0.0%	0/12 0.0%	3/12 25.0%	12/12 100.0%			
455	0/12 0.0%	0/12 0.0%	0/12 0.0%	7/12 58.3%	12/12 100.0%		
456	0/12 0.0%	0/12 0.0%	1/12 8.3%	7/12 58.3%	12/12 100.0%		
457	0/16 0.0%	0/16 0.0%	0/16 0.0%	1/16 6.2%	11/16 68.8%	16/16 100.0%	
458	0/11 0.0%	0/11 0.0%	0/11 0.0%	1/11 9.1%	11/11 100.0%		
459	0/12 0.0%	0/12 0.0%	1/12 8.3%	11/12 91.7%	12/12 100.0%		
460	0/10 0.0%	0/10 0.0%	0/10 0.0%	5/10 50.0%	10/10 100.0%		

N/N = NUMBER OF PUPS IN EACH LITTER WITH DEVELOPMENTAL MEASURE/TOTAL NUMBER OF PUPS IN THE LITTER

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 34 (PAGE 4): EYE OPENING BY LITTER - INDIVIDUAL DATA - F1 GENERATION PUPS

MATERNAL/LITTER #	DOSAGE GROUP IV			HIGH DOSAGE				175 MG/KG/DAY
POSTPARTUM DAY	10	11	12	13	14	15	16	
461	0/13 0.0%	0/13 0.0%	0/13 0.0%	0/13 0.0%	6/13 46.2%	12/13 92.3%	13/13 100.0%	
462	0/10 0.0%	0/10 0.0%	0/10 0.0%	3/10 30.0%	10/10 100.0%			
463	1/12 8.3%	1/12 8.3%	1/12 8.3%	5/12 41.7%	12/12 100.0%			
464	0/ 8 0.0%	0/ 8 0.0%	0/ 8 0.0%	1/ 8 12.5%	7/ 8 87.5%	8/ 8 100.0%		
465	0/14 0.0%	0/14 0.0%	1/14 7.1%	1/14 7.1%	5/14 35.7%	13/14 92.8%	14/14 100.0%	
466	0/14 0.0%	0/14 0.0%	0/14 0.0%	5/14 35.7%	13/14 92.8%	14/14 100.0%		
467	0/10 0.0%	0/10 0.0%	0/10 0.0%	1/10 10.0%	7/10 70.0%	10/10 100.0%		
468	0/15 0.0%	0/15 0.0%	1/15 6.7%	6/15 40.0%	14/15 93.3%	15/15 100.0%		
469	0/13 0.0%	0/13 0.0%	0/13 0.0%	2/13 15.4%	10/13 76.9%	13/13 100.0%		
470	0/ 2 0.0%	0/ 2 0.0%	0/ 2 0.0%	0/ 2 0.0%	0/ 2 0.0%	0/ 2 0.0%	2/ 2 100.0%	
471	0/13 0.0%	0/13 0.0%	0/13 0.0%	8/13 61.5%	13/13 100.0%			
472	1/11 9.1%	0/11 0.0%	1/11 9.1%	2/11 18.2%	9/11 81.8%	11/11 100.0%		
473	0/12 0.0%	0/12 0.0%	0/12 0.0%	1/12 8.3%	10/12 83.3%	12/12 100.0%		
474	1/11 9.1%	1/11 9.1%	1/11 9.1%	6/11 54.5%	11/11 100.0%			
475	0/13 0.0%	1/13 7.7%	1/13 7.7%	4/13 30.8%	10/13 76.9%	13/13 100.0%		
476	0/ 8 0.0%	0/ 8 0.0%	0/ 8 0.0%	3/ 8 37.5%	8/ 8 100.0%			
477	0/14 0.0%	0/14 0.0%	0/14 0.0%	9/14 64.3%	14/14 100.0%			
478	0/14 0.0%	0/14 0.0%	0/14 0.0%	1/14 7.1%	6/14 42.8%	14/14 100.0%		
479	0/11 0.0%	0/11 0.0%	1/11 9.1%	11/11 100.0%				
480	0/10 0.0%	0/10 0.0%	0/10 0.0%	2/10 20.0%	9/10 90.0%	10/10 100.0%		

N/N = NUMBER OF PUPS IN EACH LITTER WITH DEVELOPMENTAL MEASURE/TOTAL NUMBER OF PUPS IN THE LITTER

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 35 (PAGE 1): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION PUPS

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	LITTER NUMBER	DAY POSTPARTUM	OBSERVATIONS a
I 0 (VEHICLE)	401	20	11 PUPS: APPEARED NORMAL.
	402	4	1 PUP: FOUND DEAD. PARTIALLY CANNIBALIZED. ALL OTHER TISSUES APPEARED NORMAL.
		20	12 PUPS: APPEARED NORMAL.
	403	20	11 PUPS: APPEARED NORMAL.
	404	20	2 PUPS: APPEARED NORMAL.
	405	5	1 PUP: FOUND DEAD. NO MILK IN STOMACH. AUTOLYSIS PRECLUDED FURTHER EVALUATION.
		20	6 PUPS: APPEARED NORMAL.
	406	20	8 PUPS: APPEARED NORMAL.
	407	20	11 PUPS: APPEARED NORMAL.
	408	20	10 PUPS: APPEARED NORMAL.
	409	20	11 PUPS: APPEARED NORMAL.
	410	20	13 PUPS: APPEARED NORMAL.
	411	20	12 PUPS: APPEARED NORMAL.
	412	20	10 PUPS: APPEARED NORMAL.
	413	20	10 PUPS: APPEARED NORMAL.
	414	20	10 PUPS: APPEARED NORMAL.
	415	20	10 PUPS: APPEARED NORMAL.
	416	20	10 PUPS: APPEARED NORMAL.
	417	20	11 PUPS: APPEARED NORMAL.
	418	20	12 PUPS: APPEARED NORMAL.
	419	20	13 PUPS: APPEARED NORMAL.
	420	20	12 PUPS: APPEARED NORMAL.

a. Complete necropsies were not performed on pups in which autolysis or cannibalization precluded full evaluation. Refer to the individual pup clinical observations table (Table 33) for external clinical observations confirmed at necropsy.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 35 (PAGE 2): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION PUPS

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	LITTER NUMBER	DAY POSTPARTUM	OBSERVATIONS a
II			
7	421	20	8 PUPS: APPEARED NORMAL.
	422	20	11 PUPS: APPEARED NORMAL.
	423	20	13 PUPS: APPEARED NORMAL.
	427	20	12 PUPS: APPEARED NORMAL.
	428	20	10 PUPS: APPEARED NORMAL.
	429	20	8 PUPS: APPEARED NORMAL.
	430	0	1 PUP: FOUND DEAD. PARTIALLY CANNIBALIZED. VIABILITY COULD NOT BE DETERMINED. ALL OTHER TISSUES APPEARED NORMAL.
			1 PUP: FOUND DEAD. PARTIALLY CANNIBALIZED. SEX AND VIABILITY COULD NOT BE DETERMINED. ALL OTHER TISSUES APPEARED NORMAL.
		2	1 PUP: FOUND DEAD. INTESTINES, FILLED WITH GAS. ALL OTHER TISSUES APPEARED NORMAL.
	431	20	12 PUPS: APPEARED NORMAL.
	432	20	12 PUPS: APPEARED NORMAL.
	433	20	11 PUPS: APPEARED NORMAL.
	434	4	1 PUP: FOUND DEAD. PARTIALLY CANNIBALIZED. ALL OTHER TISSUES APPEARED NORMAL.
		20	11 PUPS: APPEARED NORMAL.
	435	20	8 PUPS: APPEARED NORMAL.
	436	20	7 PUPS: APPEARED NORMAL.
	437	20	10 PUPS: APPEARED NORMAL.
	438	1	1 PUP: FOUND DEAD. AUTOLYSIS PRECLUDED FURTHER EVALUATION.
		20	13 PUPS: APPEARED NORMAL.
	439	20	9 PUPS: APPEARED NORMAL.
	440	20	10 PUPS: APPEARED NORMAL.

a. Complete necropsies were not performed on pups in which autolysis or cannibalization precluded full evaluation. Refer to the individual pup clinical observations table (Table 33) for external clinical observations confirmed at necropsy.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 35 (PAGE 3): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION PUPS

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	LITTER NUMBER	DAY POSTPARTUM	OBSERVATIONS a
III 35	441	20	7 PUPS: APPEARED NORMAL.
	442	20	7 PUPS: APPEARED NORMAL.
	443	20	10 PUPS: APPEARED NORMAL.
	444	20	9 PUPS: APPEARED NORMAL.
	445	1 20	1 PUP: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. 12 PUPS: APPEARED NORMAL.
	446	20	10 PUPS: APPEARED NORMAL.
	447	20	13 PUPS: APPEARED NORMAL.
	448	b	1 PUP: FOUND DEAD. CANNIBALIZATION AND AUTOLYSIS PRECLUDED DETERMINATION OF SEX AND VIABILITY.
	449	20	12 PUPS: APPEARED NORMAL.
	450	20	10 PUPS: APPEARED NORMAL.
	451	20	11 PUPS: APPEARED NORMAL.
	452	20	9 PUPS: APPEARED NORMAL.
	453	20	9 PUPS: APPEARED NORMAL.
	454	20	10 PUPS: APPEARED NORMAL.
	455	20	10 PUPS: APPEARED NORMAL.
	456	20	10 PUPS: APPEARED NORMAL.
	457	20	14 PUPS: APPEARED NORMAL.
	458	20	9 PUPS: APPEARED NORMAL.
	459	20	10 PUPS: APPEARED NORMAL.
	460	2 20	1 PUP: FOUND DEAD. AUTOLYSIS PRECLUDED FURTHER EVALUATION. 8 PUPS: APPEARED NORMAL.

- a. Complete necropsies were not performed on pups in which autolysis or cannibalization precluded full evaluation. Refer to the individual pup clinical observations table (Table 33) for external clinical observations confirmed at necropsy.
- b. Mouse 448 delivered one dead pup and had one early resorption *in utero* on day 17 of gestation.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 35 (PAGE 4): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION PUPS

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	LITTER NUMBER	DAY POSTPARTUM	OBSERVATIONS a
IV 175	461	20	11 PUPS: APPEARED NORMAL.
	462	20	8 PUPS: APPEARED NORMAL.
	463	20	10 PUPS: APPEARED NORMAL.
	464	20	6 PUPS: APPEARED NORMAL.
	465	20	12 PUPS: APPEARED NORMAL.
	466	20	12 PUPS: APPEARED NORMAL.
	467	0	1 PUP: FOUND DEAD. ALL TISSUES APPEARED NORMAL.
		20	8 PUPS: APPEARED NORMAL.
	468	20	13 PUPS: APPEARED NORMAL.
	469	20	11 PUPS: APPEARED NORMAL.
	470	0	2 PUPS: STILLBORN. ALL TISSUES APPEARED NORMAL.
			1 PUP: STILLBORN. AUTOLYSIS PRECLUDED FURTHER EVALUATION.
			1 PUP: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL.
			1 PUP: FOUND DEAD. ALL TISSUES APPEARED NORMAL.
	471	20	11 PUPS: APPEARED NORMAL.
	472	20	9 PUPS: APPEARED NORMAL.
	473	0	1 PUP: FOUND DEAD. ALL TISSUES APPEARED NORMAL.
		20	10 PUPS: APPEARED NORMAL.
	474	20	9 PUPS: APPEARED NORMAL.
	475	20	11 PUPS: APPEARED NORMAL.
	476	20	6 PUPS: APPEARED NORMAL.
	477	20	12 PUPS: APPEARED NORMAL.
	478	20	12 PUPS: APPEARED NORMAL.
	479	20	1 PUP: FOUND DEAD. ALL TISSUES APPEARED NORMAL.
			8 PUPS: APPEARED NORMAL.
	480	20	8 PUPS: APPEARED NORMAL.

a. Complete necropsies were not performed on pups in which autolysis or cannibalization precluded full evaluation. Refer to the individual pup clinical observations table (Table 33) for external clinical observations confirmed at necropsy.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 36 (PAGE 1): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION MALE MICE

MATERNAL DOSAGE GROUP I	VEHICLE CONTROL	0 (VEHICLE) MG/KG/DAY
MOUSE #	DESCRIPTION	
501	NO ADVERSE FINDINGS	
502a	NO ADVERSE FINDINGS	
503a	NO ADVERSE FINDINGS	
504a	NO ADVERSE FINDINGS	
505a	NO ADVERSE FINDINGS	
506a	NO ADVERSE FINDINGS	
507a	NO ADVERSE FINDINGS	
508a	NO ADVERSE FINDINGS	
509b	NO ADVERSE FINDINGS	
510b	NO ADVERSE FINDINGS	
511b	NO ADVERSE FINDINGS	
512c	NO ADVERSE FINDINGS	
513c	NO ADVERSE FINDINGS	
514c	NO ADVERSE FINDINGS	
515c	NO ADVERSE FINDINGS	
516c	NO ADVERSE FINDINGS	
517c	NO ADVERSE FINDINGS	
518c	NO ADVERSE FINDINGS	
519c	NO ADVERSE FINDINGS	
520d	NO ADVERSE FINDINGS	

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE

DP = DAY POSTPARTUM

- a. Clinical observations were not recorded on day 34 postpartum.
- b. Clinical observations were not recorded on day 33 postpartum.
- c. Clinical observations were not recorded on day 32 postpartum.
- d. Clinical observations were not recorded on day 31 postpartum.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT
(AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 36 (PAGE 2): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION MALE MICE

MATERNAL DOSAGE GROUP II	LOW DOSAGE	7 MG/KG/DAY
MOUSE #	DESCRIPTION	
521a	NO ADVERSE FINDINGS	
522a	NO ADVERSE FINDINGS	
523a	NO ADVERSE FINDINGS	
524a	NO ADVERSE FINDINGS	
525a	NO ADVERSE FINDINGS	
526a	NO ADVERSE FINDINGS	
527a	NO ADVERSE FINDINGS	
528b	NO ADVERSE FINDINGS	
529b	NO ADVERSE FINDINGS	
530b	NO ADVERSE FINDINGS	
531b	NO ADVERSE FINDINGS	
532b	NO ADVERSE FINDINGS	
533b	NO ADVERSE FINDINGS	
534b	NO ADVERSE FINDINGS	
535b	NO ADVERSE FINDINGS	
536c	NO ADVERSE FINDINGS	
537c	NO ADVERSE FINDINGS	
538c	NO ADVERSE FINDINGS	
539c	NO ADVERSE FINDINGS	
540d	NO ADVERSE FINDINGS	

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE

DP = DAY POSTPARTUM

- a. Clinical observations were not recorded on day 34 postpartum.
- b. Clinical observations were not recorded on day 33 postpartum.
- c. Clinical observations were not recorded on day 32 postpartum.
- d. Clinical observations were not recorded on day 31 postpartum.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 36 (PAGE 3): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION MALE MICE

MATERNAL DOSAGE GROUP III	MIDDLE DOSAGE	35 MG/KG/DAY
MOUSE #	DESCRIPTION	
541	NO ADVERSE FINDINGS	
542	NO ADVERSE FINDINGS	
543a	NO ADVERSE FINDINGS	
544a	NO ADVERSE FINDINGS	
545a	NO ADVERSE FINDINGS	
546a	NO ADVERSE FINDINGS	
547a	NO ADVERSE FINDINGS	
548a	NO ADVERSE FINDINGS	
549b	NO ADVERSE FINDINGS	
550b	NO ADVERSE FINDINGS	
551b	NO ADVERSE FINDINGS	
552c	NO ADVERSE FINDINGS	
553c	NO ADVERSE FINDINGS	
554c	NO ADVERSE FINDINGS	
555c	NO ADVERSE FINDINGS	
556c	NO ADVERSE FINDINGS	
557c	NO ADVERSE FINDINGS	
558c	NO ADVERSE FINDINGS	
559c	NO ADVERSE FINDINGS	
560d	NO ADVERSE FINDINGS	

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE

DP = DAY POSTPARTUM

- a. Clinical observations were not recorded on day 34 postpartum.
- b. Clinical observations were not recorded on day 33 postpartum.
- c. Clinical observations were not recorded on day 32 postpartum.
- d. Clinical observations were not recorded on day 30 postpartum.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 36 (PAGE 4): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION MALE MICE

MATERNAL DOSAGE GROUP IV		HIGH DOSAGE	175 MG/KG/DAY
MOUSE #		DESCRIPTION	
561		NO ADVERSE FINDINGS	
562		NO ADVERSE FINDINGS	
563a		NO ADVERSE FINDINGS	
564a		NO ADVERSE FINDINGS	
565b		NO ADVERSE FINDINGS	
566b		NO ADVERSE FINDINGS	
567b		NO ADVERSE FINDINGS	
568b		NO ADVERSE FINDINGS	
569b		NO ADVERSE FINDINGS	
570c		NO ADVERSE FINDINGS	
571c		NO ADVERSE FINDINGS	
572c		NO ADVERSE FINDINGS	
573c		NO ADVERSE FINDINGS	
574c		NO ADVERSE FINDINGS	
575c		NO ADVERSE FINDINGS	
576c	DP (38- 40)	PTOSIS	
	DP (38- 41)	LACRIMATION d	
577c		NO ADVERSE FINDINGS	
578c		NO ADVERSE FINDINGS	
579e		NO ADVERSE FINDINGS	
580f		NO ADVERSE FINDINGS	

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE

DP = DAY POSTPARTUM

- Clinical observations were not recorded on day 34 postpartum.
- Clinical observations were not recorded on day 33 postpartum.
- Clinical observations were not recorded on day 32 postpartum.
- Observation confirmed at necropsy.
- Clinical observations were not recorded on day 31 postpartum.
- Clinical observations were not recorded on day 30 postpartum.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 37 (PAGE 1): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION FEMALE MICE

MATERNAL DOSAGE GROUP I	VEHICLE CONTROL	0 (VEHICLE) MG/KG/DAY
MOUSE #	DESCRIPTION	
601	NO ADVERSE FINDINGS	
602a	NO ADVERSE FINDINGS	
603a	NO ADVERSE FINDINGS	
604a	NO ADVERSE FINDINGS	
605a	NO ADVERSE FINDINGS	
606a	NO ADVERSE FINDINGS	
607a	NO ADVERSE FINDINGS	
608a	NO ADVERSE FINDINGS	
609b	NO ADVERSE FINDINGS	
610b	NO ADVERSE FINDINGS	
611b	NO ADVERSE FINDINGS	
612c	NO ADVERSE FINDINGS	
613c	NO ADVERSE FINDINGS	
614c	NO ADVERSE FINDINGS	
615c	NO ADVERSE FINDINGS	
616c	NO ADVERSE FINDINGS	
617c	NO ADVERSE FINDINGS	
618c	NO ADVERSE FINDINGS	
619c	NO ADVERSE FINDINGS	
620d	NO ADVERSE FINDINGS	

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE

DP = DAY POSTPARTUM

- a. Clinical observations were not recorded on day 34 postpartum.
- b. Clinical observations were not recorded on day 33 postpartum.
- c. Clinical observations were not recorded on day 32 postpartum.
- d. Clinical observations were not recorded on day 31 postpartum.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 37 (PAGE 2): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION FEMALE MICE

MATERNAL DOSAGE GROUP II	LOW DOSAGE	7 MG/KG/DAY
MOUSE #	DESCRIPTION	
621a	NO ADVERSE FINDINGS	
622a	NO ADVERSE FINDINGS	
623a	NO ADVERSE FINDINGS	
624a	NO ADVERSE FINDINGS	
625a	NO ADVERSE FINDINGS	
626a	NO ADVERSE FINDINGS	
627a	NO ADVERSE FINDINGS	
628b	NO ADVERSE FINDINGS	
629b	NO ADVERSE FINDINGS	
630b	NO ADVERSE FINDINGS	
631b	NO ADVERSE FINDINGS	
632b	NO ADVERSE FINDINGS	
633b	NO ADVERSE FINDINGS	
634b	NO ADVERSE FINDINGS	
635b	NO ADVERSE FINDINGS	
636c	NO ADVERSE FINDINGS	
637c	NO ADVERSE FINDINGS	
638c	NO ADVERSE FINDINGS	
639c	NO ADVERSE FINDINGS	
640d	NO ADVERSE FINDINGS	

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE

DP = DAY POSTPARTUM

- a. Clinical observations were not recorded on day 34 postpartum.
- b. Clinical observations were not recorded on day 33 postpartum.
- c. Clinical observations were not recorded on day 32 postpartum.
- d. Clinical observations were not recorded on day 31 postpartum.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 37 (PAGE 3): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION FEMALE MICE

MATERNAL DOSAGE GROUP III	MIDDLE DOSAGE	35 MG/KG/DAY
MOUSE #	DESCRIPTION	
641	NO ADVERSE FINDINGS	
642	NO ADVERSE FINDINGS	
643a	NO ADVERSE FINDINGS	
644a	NO ADVERSE FINDINGS	
645a	NO ADVERSE FINDINGS	
646a	NO ADVERSE FINDINGS	
647a	NO ADVERSE FINDINGS	
648a	NO ADVERSE FINDINGS	
649b	NO ADVERSE FINDINGS	
650b	NO ADVERSE FINDINGS	
651b	NO ADVERSE FINDINGS	
652c	NO ADVERSE FINDINGS	
653c	NO ADVERSE FINDINGS	
654c	NO ADVERSE FINDINGS	
655c	NO ADVERSE FINDINGS	
656c	NO ADVERSE FINDINGS	
657c	NO ADVERSE FINDINGS	
658c	NO ADVERSE FINDINGS	
659c	NO ADVERSE FINDINGS	
660d	NO ADVERSE FINDINGS	

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE

DP = DAY POSTPARTUM

- a. Clinical observations were not recorded on day 34 postpartum.
- b. Clinical observations were not recorded on day 33 postpartum.
- c. Clinical observations were not recorded on day 32 postpartum.
- d. Clinical observations were not recorded on day 30 postpartum.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 37 (PAGE 4): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION FEMALE MICE

MATERNAL DOSAGE GROUP IV		HIGH DOSAGE	175 MG/KG/DAY
MOUSE #		DESCRIPTION	
661		NO ADVERSE FINDINGS	
662		NO ADVERSE FINDINGS	
663a		NO ADVERSE FINDINGS	
664a		NO ADVERSE FINDINGS	
665b		NO ADVERSE FINDINGS	
666b		NO ADVERSE FINDINGS	
667b		NO ADVERSE FINDINGS	
668b		NO ADVERSE FINDINGS	
669b		NO ADVERSE FINDINGS	
670c	DP (21- 31)	RIGHT EYE: LENTICULAR OPACITY	
	DP (23- 24)	TAIL: SCAB (1.0 MM IN DIAMETER)	
	DP (33- 41)	RIGHT EYE: LENTICULAR OPACITY d	
671c		NO ADVERSE FINDINGS	
672c		NO ADVERSE FINDINGS	
673c		NO ADVERSE FINDINGS	
674c		NO ADVERSE FINDINGS	
675c		NO ADVERSE FINDINGS	
676c		NO ADVERSE FINDINGS	
677c		NO ADVERSE FINDINGS	
678c		NO ADVERSE FINDINGS	
679e		NO ADVERSE FINDINGS	
680f		NO ADVERSE FINDINGS	

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE

DP = DAY POSTPARTUM

- Clinical observations were not recorded on day 34 postpartum.
- Clinical observations were not recorded on day 33 postpartum.
- Clinical observations were not recorded on day 32 postpartum.
- Observation confirmed at necropsy.
- Clinical observations were not recorded on day 31 postpartum.
- Clinical observations were not recorded on day 30 postpartum.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT
(AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 38 (PAGE 1): BODY WEIGHTS - INDIVIDUAL DATA - F1 GENERATION MALE MICE

MOUSE #	MATERNAL DOSAGE GROUP I				VEHICLE CONTROL 0 (VEHICLE) MG/KG/DAY
	DAY 21	28	35	41	
501	16.2	27.4	31.1	35.2	
502	12.8	21.7	28.9	32.3	
503	12.7	22.1	28.5	31.5	
504	11.7	22.9	30.5	32.4	
505	16.4	27.8	31.0	34.9	
506	12.4	24.0	28.5	30.2	
507	11.3	20.8	27.0	29.8	
508	10.9	21.1	29.0	30.5	
509	10.7	20.0	28.4	32.1	
510	11.9	23.2	31.2	33.9	
511	11.8	23.1	28.9	32.9	
512	10.1	18.7	26.0	30.4	
513	11.3	21.9	28.4	32.1	
514	12.1	22.5	27.5	31.6	
515	11.2	23.0	27.5	30.8	
516	13.2	24.3	30.5	33.9	
517	9.8	20.0	26.5	30.6	
518	10.6	20.4	27.8	31.2	
519	6.9	15.0	23.3	26.7	
520	8.9	19.8	28.2	32.7	

DAY = DAY POSTPARTUM

ALL WEIGHTS WERE RECORDED IN GRAMS (G) .

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 38 (PAGE 2): BODY WEIGHTS - INDIVIDUAL DATA - F1 GENERATION MALE MICE

MOUSE #	MATERNAL DOSAGE GROUP II				LOW DOSAGE 7 MG/KG/DAY
	DAY 21	28	35	41	
521	11.5	21.9	26.9	29.8	
522	13.3	24.0	29.6	34.4	
523	12.9	23.5	28.8	31.3	
524	14.0	25.8	31.2	33.6	
525	11.2	22.7	28.4	32.1	
526	12.0	23.1	29.4	31.8	
527	12.2	22.0	27.1	28.8	
528	12.2	23.9	30.5	32.6	
529	12.6	23.1	29.2	32.2	
530	10.5	20.0	27.7	30.8	
531	10.5	21.2	29.0	32.6	
532	11.0	22.2	30.0	31.8	
533	8.9	19.0	27.0	30.0	
534	11.9	21.7	29.9	32.7	
535	11.6	22.0	29.2	31.5	
536	11.4	20.6	27.0	31.5	
537	10.3	19.5	26.7	31.1	
538	13.6	24.1	30.0	34.0	
539	13.1	25.2	31.4	35.8	
540	13.1	24.7	28.1	30.9	

DAY = DAY POSTPARTUM
ALL WEIGHTS WERE RECORDED IN GRAMS (G) .

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 38 (PAGE 3): BODY WEIGHTS - INDIVIDUAL DATA - F1 GENERATION MALE MICE

MOUSE #	MATERNAL DOSAGE GROUP III			MIDDLE DOSAGE	35 MG/KG/DAY
	DAY 21	28	35	41	
541	12.3	22.1	27.4	30.0	
542	10.0	20.2	25.8	28.7	
543	13.0	22.5	26.9	28.4	
544	13.5	23.4	28.3	30.3	
545	12.3	22.7	30.1	32.6	
546	13.6	24.0	30.5	32.0	
547	12.1	22.7	28.8	31.9	
548	12.2	23.6	29.4	32.5	
549	10.1	19.5	26.4	28.9	
550	11.5	21.9	27.3	29.8	
551	12.0	23.5	31.4	34.0	
552	11.2	21.3	27.4	30.8	
553	15.3	26.7	30.9	34.4	
554	13.8	25.2	32.0	35.6	
555	11.1	21.4	27.4	30.4	
556	12.1	23.7	30.4	34.8	
557	9.3	19.3	26.9	31.0	
558	11.6	21.6	27.1	30.0	
559	11.9	21.4	26.8	29.2	
560	13.9	26.1	31.1	33.0	

DAY = DAY POSTPARTUM
ALL WEIGHTS WERE RECORDED IN GRAMS (G) .

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 38 (PAGE 4): BODY WEIGHTS - INDIVIDUAL DATA - F1 GENERATION MALE MICE

MOUSE #	MATERNAL DOSAGE GROUP IV				HIGH DOSAGE 175 MG/KG/DAY
	DAY 21	28	35	41	
561	12.7	23.1	27.8	30.5	
562	14.2	24.8	29.1	32.2	
563	10.9	21.7	28.6	30.0	
564	11.3	20.2	26.6	28.1	
565	10.5	21.1	28.1	31.5	
566	13.3	24.0	29.9	33.5	
567	9.7	19.3	26.9	29.9	
568	10.9	22.3	28.6	31.4	
569	11.3	21.8	28.1	30.5	
570	10.1	18.1	23.2	26.7	
571	9.8	19.3	25.9	29.2	
572	10.5	20.1	24.3	28.0	
573	11.0	21.7	28.2	32.5	
574	12.0	22.3	28.4	29.5	
575	10.5	21.5	28.8	32.3	
576	14.7	27.2	32.1	36.4	
577	10.7	20.5	26.2	29.5	
578	10.5	21.9	29.6	31.9	
579	13.3	24.9	30.9	34.5	
580	12.0	21.9	28.3	30.2	

DAY = DAY POSTPARTUM
ALL WEIGHTS WERE RECORDED IN GRAMS (G) .

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 39 (PAGE 1): BODY WEIGHTS - INDIVIDUAL DATA - F1 GENERATION FEMALE MICE

MOUSE #	MATERNAL DOSAGE GROUP I				VEHICLE CONTROL	0 (VEHICLE) MG/KG/DAY
	DAY 21	28	35	41		
601	14.6	22.3	25.5	27.0		
602	9.8	15.0	19.9	21.8		
603	12.0	19.9	24.1	26.4		
604	11.6	20.2	23.3	24.9		
605	14.2	21.8	26.4	28.7		
606	13.1	20.3	24.7	23.6		
607	10.1	17.3	22.6	25.0		
608	11.5	19.3	24.3	26.2		
609	9.8	17.5	22.2	23.2		
610	9.9	17.2	20.5	21.0		
611	11.2	20.4	25.4	25.7		
612	9.5	16.8	21.9	23.6		
613	10.5	17.9	21.5	21.7		
614	12.4	21.0	26.3	28.6		
615	9.4	16.0	19.9	22.6		
616	12.1	20.0	22.8	23.6		
617	10.3	18.5	23.2	27.0		
618	10.1	18.7	24.2	28.1		
619	7.9	14.6	20.0	21.6		
620	8.2	16.3	21.2	23.1		

DAY = DAY POSTPARTUM
ALL WEIGHTS WERE RECORDED IN GRAMS (G) .

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 39 (PAGE 2): BODY WEIGHTS - INDIVIDUAL DATA - F1 GENERATION FEMALE MICE

MOUSE #	MATERNAL DOSAGE GROUP II				LOW DOSAGE 7 MG/KG/DAY
	DAY 21	28	35	41	
621	10.0	16.6	21.4	22.1	
622	12.4	20.9	23.7	24.2	
623	11.7	19.9	23.6	25.4	
624	11.0	18.3	22.3	23.3	
625	11.0	20.1	23.2	23.9	
626	11.7	18.9	23.9	24.3	
627	11.1	19.2	23.4	24.3	
628	12.0	19.7	23.2	23.1	
629	9.7	16.0	20.9	21.4	
630	9.7	17.4	21.8	23.7	
631	8.5	14.7	21.1	21.8	
632	10.9	18.9	23.3	25.3	
633	8.6	14.6	20.2	22.9	
634	11.3	19.6	23.5	26.3	
635	11.2	19.1	23.0	25.0	
636	11.3	19.2	23.3	24.6	
637	10.0	17.4	22.5	23.1	
638	12.4	21.1	22.9	23.6	
639	12.6	21.1	22.8	24.5	
640	11.2	18.8	23.2	25.2	

DAY = DAY POSTPARTUM
ALL WEIGHTS WERE RECORDED IN GRAMS (G) .

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 39 (PAGE 3): BODY WEIGHTS - INDIVIDUAL DATA - F1 GENERATION FEMALE MICE

MOUSE #	MATERNAL DOSAGE GROUP III			MIDDLE DOSAGE	35 MG/KG/DAY
	DAY 21	28	35	41	
641	10.6	20.9	24.5	25.7	
642	9.1	16.5	21.4	24.0	
643	12.7	19.4	24.4	24.8	
644	12.2	20.0	24.0	24.9	
645	12.2	20.6	25.0	24.1	
646	11.5	20.0	23.5	23.2	
647	11.9	19.1	23.2	23.6	
648	11.5	20.7	23.1	23.7	
649	11.1	19.1	23.1	23.8	
650	11.6	18.9	21.3	21.2	
651	10.5	19.0	23.3	25.1	
652	10.0	17.6	22.0	24.7	
653	14.5	20.5	25.1	26.6	
654	12.5	19.6	24.0	26.0	
655	11.7	19.5	23.4	23.9	
656	12.6	20.9	23.5	24.7	
657	8.8	17.5	22.0	22.8	
658	11.5	18.7	23.3	24.6	
659	11.4	18.1	23.3	24.9	
660	14.4	20.8	24.3	24.9	

DAY = DAY POSTPARTUM
ALL WEIGHTS WERE RECORDED IN GRAMS (G) .

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT
(AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 39 (PAGE 4): BODY WEIGHTS - INDIVIDUAL DATA - F1 GENERATION FEMALE MICE

MOUSE #	MATERNAL DOSAGE GROUP IV				HIGH DOSAGE 175 MG/KG/DAY
	DAY 21	28	35	41	
661	11.6	18.5	22.6	25.1	
662	13.3	20.4	25.0	26.8	
663	11.1	19.2	24.5	25.4	
664	10.8	18.2	21.2	21.5	
665	9.0	14.8	19.8	22.5	
666	12.2	21.0	24.8	27.0	
667	11.0	17.9	22.8	22.0	
668	10.6	19.7	22.4	23.0	
669	11.5	19.6	23.9	25.2	
670	6.0	11.1	16.1	18.9	
671	10.7	18.1	22.1	21.5	
672	9.6	17.1	22.0	24.2	
673	11.6	19.1	23.3	24.3	
674	11.6	18.7	21.3	21.2	
675	11.4	19.3	22.1	23.2	
676	14.3	23.0	27.0	29.9	
677	11.1	19.9	23.7	25.2	
678	9.8	17.4	23.2	25.4	
679	11.8	19.1	22.5	24.3	
680	11.2	18.5	23.3	23.7	

DAY = DAY POSTPARTUM

ALL WEIGHTS WERE RECORDED IN GRAMS (G) .

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 40 (PAGE 1): SEXUAL MATURATION - INDIVIDUAL DATA - F1 GENERATION MALE MICE

MATERNAL DOSAGE GROUP - MG/KG/DAY											
I 0 (VEHICLE)			II 7			III 35			IV 175		
MOUSE #	PREPUTIAL SEPARATION (DAY)	BODY WEIGHT (G) a	MOUSE #	PREPUTIAL SEPARATION (DAY)	BODY WEIGHT (G) a	MOUSE #	PREPUTIAL SEPARATION (DAY)	BODY WEIGHT (G) a	MOUSE #	PREPUTIAL SEPARATION (DAY)	BODY WEIGHT (G) a
501	29	28.0	521	28	21.9	541	28	22.1	561	28	23.1
502	28	21.7	522	30	26.9	542	28	20.2	562	31	28.1
503	28	22.1	523	30	25.6	543	27	21.6	563	28	21.7
504	28	22.9	524	30	28.4	544	28	23.4	564	28	20.2
505	29	29.5	525	30	25.2	545	29	25.1	565	29	22.7
506	28	24.0	526	30	25.4	546	28	24.0	566	27	22.3
507	29	22.7	527	28	22.0	547	30	25.1	567	29	20.6
508	30	23.5	528	29	25.1	548	28	23.6	568	29	23.6
509	31	24.7	529	28	23.3	549	27	18.1	569	29	23.5
510	30	25.3	530	29	21.4	550	29	23.0	570	30	26.1
511	30	24.7	531	29	22.8	551	29	24.9	571	28	19.3
512	30	22.0	532	30	24.2	552	28	21.3	572	28	20.1
513	29	23.3	533	31	23.7	553	27	25.4	573	28	21.7
514	29	24.0	534	29	23.5	554	29	27.2	574	27	21.7
515	28	23.1	535	27	20.2	555	28	21.4	575	28	21.5
516	27	23.1	536	28	20.6	556	27	22.4	576	28	27.2
517	30	22.9	537	30	23.4	557	29	20.9	577	29	21.8
518	30	23.3	538	29	25.9	558	29	22.8	578	29	23.7
519	30	18.6	539	27	23.8	559	26	18.8	579	27	23.0
520	30	23.3	540	28	24.7	560	27	24.0	580	27	19.9

DAY = DAY POSTPARTUM

a. Body weight on day prepuce was first observed to be separated.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 41 (PAGE 1): SEXUAL MATURATION - INDIVIDUAL DATA - F1 GENERATION FEMALE MICE

MATERNAL DOSAGE GROUP - MG/KG/DAY											
I 0 (VEHICLE)			II 7			III 35			IV 175		
MOUSE #	VAGINAL PATENCY (DAY)	BODY WEIGHT (G) a	MOUSE #	VAGINAL PATENCY (DAY)	BODY WEIGHT (G) a	MOUSE #	VAGINAL PATENCY (DAY)	BODY WEIGHT (G) a	MOUSE #	VAGINAL PATENCY (DAY)	BODY WEIGHT (G) a
601	22	16.0	621	28	16.6	641	26	17.4	661	24	15.0
602	28	15.0	622	21	12.4	642	26	14.3	662	27	19.7
603	27	18.9	623	24	16.0	643	25	17.7	663	24	15.1
604	23	14.0	624	28	18.3	644	26	19.2	664	25	15.6
605	23	17.0	625	25	16.1	645	26	19.0	665	28	15.3
606	24	16.0	626	25	16.0	646	28	20.0	666	24	16.4
607	28	17.3	627	25	15.7	647	27	18.4	667	25	15.7
608	30	21.4	628	25	16.0	648	24	16.1	668	25	16.3
609	30	19.3	629	23	11.5	649	27	17.9	669	26	17.3
610	27	16.0	630	33	21.4	650	25	17.0	670	26	9.6
611	24	15.4	631	24	11.2	651	24	14.3	671	26	15.6
612	23	11.6	632	29	20.1	652	25	14.0	672	28	18.7
613	28	17.9	633	28	15.0	653	22	15.5	673	25	16.7
614	23	15.1	634	25	15.9	654	27	18.8	674	28	18.7
615	26	14.2	635	28	19.7	655	26	17.8	675	23	13.8
616	27	19.3	636	28	19.2	656	24	16.6	676	22	16.1
617	28	18.5	637	28	17.4	657	29	18.6	677	26	17.6
618	32	22.5	638	24	16.2	658	25	16.1	678	24	13.2
619	28	14.6	639	25	18.1	659	27	17.0	679	21	11.8
620	28	16.3	640	21	11.2	660	26	18.3	680	27	16.5

DAY = DAY POSTPARTUM

a. Body weight on day vagina was first observed to be patent.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT
(AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 42 (PAGE 1): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION MALE MICE

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	MOUSE NUMBER	DAY OF NECROPSY	OBSERVATIONS a
I 0 (VEHICLE)	501	DP 41	ALL TISSUES APPEARED NORMAL.
	502	DP 41	ALL TISSUES APPEARED NORMAL.
	503	DP 41	ALL TISSUES APPEARED NORMAL.
	504	DP 41	ALL TISSUES APPEARED NORMAL.
	505	DP 41	ALL TISSUES APPEARED NORMAL.
	506	DP 41	ALL TISSUES APPEARED NORMAL.
	507	DP 41	ALL TISSUES APPEARED NORMAL.
	508	DP 41	ALL TISSUES APPEARED NORMAL.
	509	DP 41	ALL TISSUES APPEARED NORMAL.
	510	DP 41	ALL TISSUES APPEARED NORMAL.
	511	DP 41	ALL TISSUES APPEARED NORMAL.
	512	DP 41	ALL TISSUES APPEARED NORMAL.
	513	DP 41	ALL TISSUES APPEARED NORMAL.
	514	DP 41	ALL TISSUES APPEARED NORMAL.
	515	DP 41	ALL TISSUES APPEARED NORMAL.
	516	DP 41	ALL TISSUES APPEARED NORMAL.
	517	DP 41	ALL TISSUES APPEARED NORMAL.
	518	DP 41	ALL TISSUES APPEARED NORMAL.
	519	DP 41	ALL TISSUES APPEARED NORMAL.
	520	DP 41	ALL TISSUES APPEARED NORMAL.

DP = DAY POSTPARTUM

a. Refer to the individual clinical observations table (Table 36) for external observations confirmed at necropsy.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT
(AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 42 (PAGE 2): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION MALE MICE

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	MOUSE NUMBER	DAY OF NECROPSY	OBSERVATIONS a
II			
7	521	DP 41	ALL TISSUES APPEARED NORMAL.
	522	DP 41	ALL TISSUES APPEARED NORMAL.
	523	DP 41	ALL TISSUES APPEARED NORMAL.
	524	DP 41	ALL TISSUES APPEARED NORMAL.
	525	DP 41	ALL TISSUES APPEARED NORMAL.
	526	DP 41	ALL TISSUES APPEARED NORMAL.
	527	DP 41	ALL TISSUES APPEARED NORMAL.
	528	DP 41	ALL TISSUES APPEARED NORMAL.
	529	DP 41	ALL TISSUES APPEARED NORMAL.
	530	DP 41	ALL TISSUES APPEARED NORMAL.
	531	DP 41	ALL TISSUES APPEARED NORMAL.
	532	DP 41	ALL TISSUES APPEARED NORMAL.
	533	DP 41	ALL TISSUES APPEARED NORMAL.
	534	DP 41	ALL TISSUES APPEARED NORMAL.
	535	DP 41	ALL TISSUES APPEARED NORMAL.
	536	DP 41	ALL TISSUES APPEARED NORMAL.
	537	DP 41	ALL TISSUES APPEARED NORMAL.
	538	DP 41	ALL TISSUES APPEARED NORMAL.
	539	DP 41	ALL TISSUES APPEARED NORMAL.
	540	DP 41	ALL TISSUES APPEARED NORMAL.

DP = DAY POSTPARTUM

a. Refer to the individual clinical observations table (Table 36) for external observations confirmed at necropsy.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 42 (PAGE 3): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION MALE MICE

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	MOUSE NUMBER	DAY OF NECROPSY	OBSERVATIONS a
III			
35	541	DP 41	ALL TISSUES APPEARED NORMAL.
	542	DP 41	ALL TISSUES APPEARED NORMAL.
	543	DP 41	ALL TISSUES APPEARED NORMAL.
	544	DP 41	ALL TISSUES APPEARED NORMAL.
	545	DP 41	ALL TISSUES APPEARED NORMAL.
	546	DP 41	ALL TISSUES APPEARED NORMAL.
	547	DP 41	ALL TISSUES APPEARED NORMAL.
	548	DP 41	ALL TISSUES APPEARED NORMAL.
	549	DP 41	ALL TISSUES APPEARED NORMAL.
	550	DP 41	ALL TISSUES APPEARED NORMAL.
	551	DP 41	ALL TISSUES APPEARED NORMAL.
	552	DP 41	ALL TISSUES APPEARED NORMAL.
	553	DP 41	ALL TISSUES APPEARED NORMAL.
	554	DP 41	ALL TISSUES APPEARED NORMAL.
	555	DP 41	ALL TISSUES APPEARED NORMAL.
	556	DP 41	ALL TISSUES APPEARED NORMAL.
	557	DP 41	ALL TISSUES APPEARED NORMAL.
	558	DP 41	ALL TISSUES APPEARED NORMAL.
	559	DP 41	ALL TISSUES APPEARED NORMAL.
	560	DP 41	ALL TISSUES APPEARED NORMAL.

DP = DAY POSTPARTUM

a. Refer to the individual clinical observations table (Table 36) for external observations confirmed at necropsy.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 42 (PAGE 4): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION MALE MICE

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	MOUSE NUMBER	DAY OF NECROPSY	OBSERVATIONS a
IV 175	561	DP 41	ALL TISSUES APPEARED NORMAL.
	562	DP 41	ALL TISSUES APPEARED NORMAL.
	563	DP 41	ALL TISSUES APPEARED NORMAL.
	564	DP 41	ALL TISSUES APPEARED NORMAL.
	565	DP 41	ALL TISSUES APPEARED NORMAL.
	566	DP 41	ALL TISSUES APPEARED NORMAL.
	567	DP 41	ALL TISSUES APPEARED NORMAL.
	568	DP 41	ALL TISSUES APPEARED NORMAL.
	569	DP 41	LIVER: MEDIAN LOBE, CLEAR FLUID-FILLED CYST (1.0 MM IN DIAMETER). ALL OTHER TISSUES APPEARED NORMAL.
	570	DP 41	ALL TISSUES APPEARED NORMAL.
	571	DP 41	ALL TISSUES APPEARED NORMAL.
	572	DP 41	ALL TISSUES APPEARED NORMAL.
	573	DP 41	ALL TISSUES APPEARED NORMAL.
	574	DP 41	ALL TISSUES APPEARED NORMAL.
	575	DP 41	ALL TISSUES APPEARED NORMAL.
	576	DP 41	ALL TISSUES APPEARED NORMAL.
	577	DP 41	ALL TISSUES APPEARED NORMAL.
	578	DP 41	ALL TISSUES APPEARED NORMAL.
	579	DP 41	ALL TISSUES APPEARED NORMAL.
	580	DP 41	ALL TISSUES APPEARED NORMAL.

DP = DAY POSTPARTUM

a. Refer to the individual clinical observations table (Table 36) for external observations confirmed at necropsy.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT
(AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 43 (PAGE 1): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION FEMALE MICE

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	MOUSE NUMBER	DAY OF NECROPSY	OBSERVATIONS a
I 0 (VEHICLE)	601	DP 41	ALL TISSUES APPEARED NORMAL.
	602	DP 41	ALL TISSUES APPEARED NORMAL.
	603	DP 41	ALL TISSUES APPEARED NORMAL.
	604	DP 41	ALL TISSUES APPEARED NORMAL.
	605	DP 41	ALL TISSUES APPEARED NORMAL.
	606	DP 41	ALL TISSUES APPEARED NORMAL.
	607	DP 41	ALL TISSUES APPEARED NORMAL.
	608	DP 41	ALL TISSUES APPEARED NORMAL.
	609	DP 41	ALL TISSUES APPEARED NORMAL.
	610	DP 41	ALL TISSUES APPEARED NORMAL.
	611	DP 41	ALL TISSUES APPEARED NORMAL.
	612	DP 41	ALL TISSUES APPEARED NORMAL.
	613	DP 41	ALL TISSUES APPEARED NORMAL.
	614	DP 41	ALL TISSUES APPEARED NORMAL.
	615	DP 41	ALL TISSUES APPEARED NORMAL.
	616	DP 41	ALL TISSUES APPEARED NORMAL.
	617	DP 41	ALL TISSUES APPEARED NORMAL.
	618	DP 41	ALL TISSUES APPEARED NORMAL.
	619	DP 41	ALL TISSUES APPEARED NORMAL.
	620	DP 41	ALL TISSUES APPEARED NORMAL.

DP = DAY POSTPARTUM

a. Refer to the individual clinical observations table (Table 37) for external observations confirmed at necropsy.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT
(AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 43 (PAGE 2): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION FEMALE MICE

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	MOUSE NUMBER	DAY OF NECROPSY	OBSERVATIONS a
II			
7	621	DP 41	ALL TISSUES APPEARED NORMAL.
	622	DP 41	ALL TISSUES APPEARED NORMAL.
	623	DP 41	ALL TISSUES APPEARED NORMAL.
	624	DP 41	ALL TISSUES APPEARED NORMAL.
	625	DP 41	ALL TISSUES APPEARED NORMAL.
	626	DP 41	ALL TISSUES APPEARED NORMAL.
	627	DP 41	ALL TISSUES APPEARED NORMAL.
	628	DP 41	ALL TISSUES APPEARED NORMAL.
	629	DP 41	ALL TISSUES APPEARED NORMAL.
	630	DP 41	ALL TISSUES APPEARED NORMAL.
	631	DP 41	ALL TISSUES APPEARED NORMAL.
	632	DP 41	ALL TISSUES APPEARED NORMAL.
	633	DP 41	ALL TISSUES APPEARED NORMAL.
	634	DP 41	ALL TISSUES APPEARED NORMAL.
	635	DP 41	ALL TISSUES APPEARED NORMAL.
	636	DP 41	ALL TISSUES APPEARED NORMAL.
	637	DP 41	ALL TISSUES APPEARED NORMAL.
	638	DP 41	ALL TISSUES APPEARED NORMAL.
	639	DP 41	ALL TISSUES APPEARED NORMAL.
	640	DP 41	ALL TISSUES APPEARED NORMAL.

DP = DAY POSTPARTUM

a. Refer to the individual clinical observations table (Table 37) for external observations confirmed at necropsy.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 43 (PAGE 3): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION FEMALE MICE

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	MOUSE NUMBER	DAY OF NECROPSY	OBSERVATIONS a
III			
35	641	DP 41	ALL TISSUES APPEARED NORMAL.
	642	DP 41	ALL TISSUES APPEARED NORMAL.
	643	DP 41	ALL TISSUES APPEARED NORMAL.
	644	DP 41	ALL TISSUES APPEARED NORMAL.
	645	DP 41	ALL TISSUES APPEARED NORMAL.
	646	DP 41	ALL TISSUES APPEARED NORMAL.
	647	DP 41	ALL TISSUES APPEARED NORMAL.
	648	DP 41	ALL TISSUES APPEARED NORMAL.
	649	DP 41	ALL TISSUES APPEARED NORMAL.
	650	DP 41	ALL TISSUES APPEARED NORMAL.
	651	DP 41	ALL TISSUES APPEARED NORMAL.
	652	DP 41	ALL TISSUES APPEARED NORMAL.
	653	DP 41	ALL TISSUES APPEARED NORMAL.
	654	DP 41	ALL TISSUES APPEARED NORMAL.
	655	DP 41	ALL TISSUES APPEARED NORMAL.
	656	DP 41	ALL TISSUES APPEARED NORMAL.
	657	DP 41	ALL TISSUES APPEARED NORMAL.
	658	DP 41	MESENTERY: DARK RED FLAT MASS (3.0 MM X 3.0 MM X 1.0 MM), CUT SURFACE REVEALED FIRM RED MATERIAL. ALL OTHER TISSUES APPEARED NORMAL.
	659	DP 41	ALL TISSUES APPEARED NORMAL.
	660	DP 41	ALL TISSUES APPEARED NORMAL.

DP = DAY POSTPARTUM

a. Refer to the individual clinical observations table (Table 37) for external observations confirmed at necropsy.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 43 (PAGE 4): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION FEMALE MICE

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	MOUSE NUMBER	DAY OF NECROPSY	OBSERVATIONS a
IV 175	661	DP 41	ALL TISSUES APPEARED NORMAL.
	662	DP 41	ALL TISSUES APPEARED NORMAL.
	663	DP 41	ALL TISSUES APPEARED NORMAL.
	664	DP 41	ALL TISSUES APPEARED NORMAL.
	665	DP 41	ALL TISSUES APPEARED NORMAL.
	666	DP 41	ALL TISSUES APPEARED NORMAL.
	667	DP 41	ALL TISSUES APPEARED NORMAL.
	668	DP 41	ALL TISSUES APPEARED NORMAL.
	669	DP 41	ALL TISSUES APPEARED NORMAL.
	670	DP 41	ALL TISSUES APPEARED NORMAL.
	671	DP 41	ALL TISSUES APPEARED NORMAL.
	672	DP 41	ALL TISSUES APPEARED NORMAL.
	673	DP 41	ALL TISSUES APPEARED NORMAL.
	674	DP 41	ALL TISSUES APPEARED NORMAL.
	675	DP 41	ALL TISSUES APPEARED NORMAL.
	676	DP 41	ALL TISSUES APPEARED NORMAL.
	677	DP 41	ALL TISSUES APPEARED NORMAL.
	678	DP 41	ALL TISSUES APPEARED NORMAL.
	679	DP 41	ALL TISSUES APPEARED NORMAL.
	680	DP 41	ALL TISSUES APPEARED NORMAL.

DP = DAY POSTPARTUM

a. Refer to the individual clinical observations table (Table 37) for external observations confirmed at necropsy.

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 44 (PAGE 1): TERMINAL BODY WEIGHTS, LIVER WEIGHTS AND RATIOS (%) OF LIVER WEIGHT TO TERMINAL BODY WEIGHT - INDIVIDUAL DATA - F1 GENERATION MALE MICE

MOUSE NUMBER	TERMINAL BODY WEIGHT	LIVER	
		ABS. WT.	REL. % TBW
MATERNAL DOSAGE GROUP I		VEHICLE CONTROL	
		0 (VEHICLE) MG/KG/DAY	
507	29.8	1.791	6.01
508	30.5	1.961	6.43
509	32.1	2.399	7.47
510	33.9	2.674	7.89
511	32.9	2.329	7.08
MATERNAL DOSAGE GROUP II		LOW DOSAGE	
		7 MG/KG/DAY	
528	32.6	2.203	6.76
529	32.2	2.408	7.48
530	30.8	2.455	7.97
531	32.6	2.472	7.58
532	31.8	2.288	7.19
MATERNAL DOSAGE GROUP III		MIDDLE DOSAGE	
		35 MG/KG/DAY	
547	31.9	2.053	6.44
548	32.5	2.183	6.72
549	28.9	2.168	7.50
550	29.8	2.046	6.86
551	34.0	2.221	6.53
MATERNAL DOSAGE GROUP IV		HIGH DOSAGE	
		175 MG/KG/DAY	
565	31.5	2.325	7.38
566	33.5	2.419	7.22
567	29.9	2.023	6.76
568	31.4	2.281	7.26
569	30.5	2.183	7.16
ALL WEIGHTS WERE RECORDED IN GRAMS (G). ABS. WT. = ORGAN WEIGHT. REL. % TBW = (ORGAN WEIGHT/TERMINAL BODY WEIGHT) X 100.			

PROTOCOL UZS00010: ORAL (GAVAGE) COMBINED DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFH AMMONIUM SALT (AMMONIUM SALT OF PERFLUORINATED HEXANOIC ACID) IN MICE

TABLE 45 (PAGE 1): TERMINAL BODY WEIGHTS, LIVER WEIGHTS AND RATIOS (%) OF LIVER WEIGHT TO TERMINAL BODY WEIGHT - INDIVIDUAL DATA - F1 GENERATION FEMALE MICE

MOUSE NUMBER	TERMINAL BODY WEIGHT	LIVER	
		ABS. WT.	REL. % TBW
MATERNAL DOSAGE GROUP I		VEHICLE CONTROL	
		0 (VEHICLE) MG/KG/DAY	
606	23.6	1.274	5.40
608	26.2	1.665	6.35
609	23.2	1.488	6.41
610	21.0	1.236	5.88
611	25.7	1.556	6.05
MATERNAL DOSAGE GROUP II		LOW DOSAGE	
		7 MG/KG/DAY	
628	23.1	1.326	5.74
629	21.4	1.292	6.04
630	23.7	1.598	6.74
631	21.8	1.417	6.50
632	25.3	1.764	6.97
MATERNAL DOSAGE GROUP III		MIDDLE DOSAGE	
		35 MG/KG/DAY	
647	23.6	1.441	6.10
648	23.7	1.350	5.70
649	23.8	1.306	5.49
650	21.2	1.203	5.67
651	25.1	1.599	6.37
MATERNAL DOSAGE GROUP IV		HIGH DOSAGE	
		175 MG/KG/DAY	
665	22.5	1.392	6.19
666	27.0	1.715	6.35
667	22.0	1.293	5.88
668	23.0	1.512	6.57
669	25.2	1.602	6.36
ALL WEIGHTS WERE RECORDED IN GRAMS (G). ABS. WT. = ORGAN WEIGHT. REL. % TBW = (ORGAN WEIGHT/TERMINAL BODY WEIGHT) X 100.			

APPENDIX 1 - PROTOCOL



FINAL PROTOCOL

Charles River Laboratories Study No. UZS00010

**Oral (Gavage) Combined Developmental and Perinatal/Postnatal
Reproduction Toxicity Study of PFH Ammonium Salt (Ammonium salt
of Perfluorinated Hexanoic Acid) in Mice**

SPONSOR:

Daikin Industries, LTD
Chemical Division
Umeda Center Building
4-12 Nakazaki-Nishi, 2-chrome
Kita-ku, Osaka 530-8323
JAPAN

PERFORMING LABORATORY:

Charles River Laboratories
Preclinical Services
905 Sheehy Drive, Building A
Horsham, PA 19044
USA

21 December 2009

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1. STUDY NUMBER

UZS00010

2. STUDY TITLE

Oral (Gavage) Combined Developmental and Perinatal/Postnatal Reproduction Toxicity Study of PFH Ammonium Salt (Ammonium salt of Perfluorinated Hexanoic Acid) in Mice

3. PURPOSE

The purpose of this study is to test for toxic effects/disturbances resulting from PFH Ammonium Salt (Ammonium salt of Perfluorinated Hexanoic Acid) treatment of Crl:CD1(ICR) pregnant female mice and development of the embryo and fetus consequent to exposure of the dam from implantation to closure of the hard palate and during lactation. This study evaluates ICH Harmonised Tripartite Guideline stages C through F of the reproductive process and should detect effects on gestation, parturition, lactation and maternal behavior in female mice, and on the development of the offspring of the treated female mice. Because manifestations of effects induced during this period may be delayed in the offspring, observations will be continued through sexual maturity of the F1 generation mice.

4. TESTING FACILITY

Charles River Laboratories
Preclinical Services
905 Sheehy Drive, Building A
Horsham, PA 19044
USA
Main Tel: 215.443.8710
Fax: 215.443.8587

5. STUDY DIRECTOR

, Ph.D., DABT, Fellow ATS (Executive Director, Site Operations
and Toxicology)
Address as cited for Testing Facility

6. SPONSOR

Daikin Industries, LTD
Chemical Division
Umeda Center Building
4-12 Nakazaki-Nishi, 2-chrome
Kita-ku, Osaka 530-8323
JAPAN

7. STUDY MONITOR

Daikin Industries, Ltd.
1-1 Nishi Hitotsuya
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8. PRINCIPAL INVESTIGATOR - DOSE FORMULATION ANALYSIS

Principal Investigator:
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9. PRINCIPAL INVESTIGATOR - BIOANALYSIS

Principal Investigator:
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E-mail:

10. REGULATORY COMPLIANCE

This study will be conducted in compliance with the Good Laboratory Practice (GLP) regulations of the U.S. Environmental Protection Agency¹, the Ministry of Agriculture, Forestry and Fisheries² and the Organisation for Economic Co-operation and Development³ except for the bioanalysis and analytical portion of the study which will be conducted in compliance with the appropriate Organization for Economic Co-operation and Development (OECD) Principles of GLP (ENV/MC/CHEM(98)17).

All changes or revisions of this protocol shall be documented, approved by the Institutional Animal Care and Use Committee, signed by the Study Director, dated and maintained with the protocol.

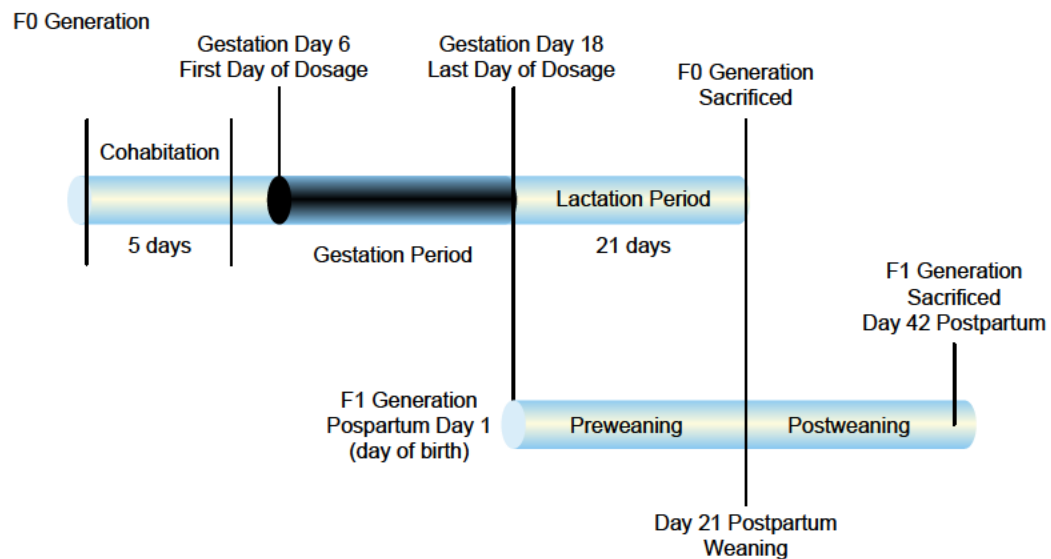
The Testing Facility's Quality Assurance Unit (QAU) will audit the protocol, the raw data and the report, and will inspect critical phases of those portions of the study conducted at the Testing Facility in accordance with the Standard Operating Procedures of the Testing Facility. A process audit, rather than a critical phase inspection, will be performed for analysis of the bulk test substance.

The final report will include a compliance statement signed by the Study Director that the report accurately reflects the raw data obtained during the performance of the study and that all applicable GLP regulations were followed in the conduct of the study. Should deviations from GLP regulations occur, each will be described in detail, together with how the deviation might affect the quality or integrity of the study.

Should any portion of the study be conducted by a subcontractor or by the Sponsor, the Testing Facility management will ensure that a qualified Principal Investigator is identified by the site conducting that portion of the study. All procedures conducted by the Test Site will be specifically defined by the protocol, or will be described in detail in

the Standard Operating Procedures of the Test Site. The QAU for this facility site will conduct critical phase inspections and audit respective results and reports for that study portion according to the SOPs of that site. Such critical phase inspection reports and report audits will be submitted by the site to the Principal Investigator and the Study Director. The dates of the inspections and report submissions will be incorporated into a QAU Statement generated by that site and provided to the Testing Facility for inclusion in the final report. In addition, this site will provide a statement of GLP compliance, as described above, signed by the Principal Investigator for inclusion in the final report. The archival location of any records generated by this site will be identified in the final report.

11. SCHEMATIC OF STUDY DESIGN AND PROPOSED SCHEDULE¹



 Dosage Period

1. For additional details see Attachment 1 and "Tests, Analyses and Measurements" sections of the protocol.

12. TEST SUBSTANCE AND VEHICLE

12.1. Identification

12.1.1. Test Substance

PFH Ammonium Salt (Ammonium salt of Perfluorinated Hexanoic Acid). Ammonium Perfluorohexanoate's CAS number is: 21615-47-4.

The test substance will be supplied as a 50% aqueous solution (lot identification will be documented in the raw data).

The Sponsor will provide to the Testing Facility documentation or certification of the identity, composition, strength and activity/purity of the test substance. This documentation will be included in the final report. The Sponsor's signature and approval of the protocol indicates that appropriate documentation of the method of synthesis, fabrication or derivation of the test substance is on file and that it is available to the appropriate regulatory agencies should it be requested.

12.1.2. Vehicle

Reverse osmosis membrane processed deionized water (R.O. deionized water). There will be no lot number for R.O. deionized water; this material is available from a continuous source at the Testing Facility.

Neither the Sponsor nor the Study Director is aware of any potential contaminants likely to be present in the vehicle that would interfere with the results of this study. Therefore, no analyses other than those mentioned in this protocol will be conducted.

12.2. Safety Precautions

Double nitrile gloves, dust-mist/HEPA-filtered mask, appropriate eye protection, uniform/lab coat and sleeves to be worn during formulation preparation and dosage. The Material Safety Data Sheet (MSDS) is attached to the protocol (Attachment 2).

12.3. Storage

Bulk Test Substance:	Room temperature
Vehicle:	Room temperature
Prepared Formulations:	Room temperature

All test substance shipments should be addressed to the attention of _____), Manager of Formulation Laboratory, at the previously cited Testing Facility address and telephone number.

Shipments should include information concerning storage conditions and shipping cartons should be labeled appropriately. The recipient should be notified in advance of shipment.

13. FORMULATION

13.1. Frequency of Preparation

Formulations (solutions) will be prepared at least once weekly at the Testing Facility. Prepared formulations will be stirred continuously for **24 hours** prior to dosage administration.

Detailed preparation procedures will be attached to this protocol (Attachment 3).

13.2. Adjustment for Activity/Purity

The test substance will be considered 95% by weight of PFH acid for the purpose of dosage calculations.

13.3. Testing Facility Reserve Samples

The Testing Facility will reserve a sample of 5 mL of each lot of bulk test substance and bulk vehicle used during the course of the study. Samples will be stored under the previously cited conditions.

14. ANALYSES

The Sponsor will provide to the Testing Facility documentation or certification of the identity, composition, strength and activity/purity of the test substance. Results of these analyses will be included in the study report.

Samples additional to those described below may be taken if deemed necessary during the course of the study. Additional analyses, if required, will be documented by protocol amendment.

14.1. Acceptance Criteria

Acceptance criteria for analytical results for each group are defined as follows:

1) concentration results will be considered acceptable if the difference between the actual mean value and the targeted concentration is $\pm 10\%$; 2) homogeneity results for a group will be considered acceptable if the relative standard deviation (RSD) for the formulation, calculated as the RSD for the grand mean of the average values for top, middle and bottom locations, is $\leq 5\%$; and 3) results of 10 day stability analysis will be within $\pm 10\%$ of the concentration of the initial stability analysis. Results obtained outside of the criteria will be considered Out of Specification (OOS) and procedures for investigation and notification will be followed in the applicable laboratory Standard Operating Procedure covering OOS results.

14.2. Bulk Test Substance Stability

A sample of approximately 10 mL of the test substance will be taken on the last day of treatment and sent (ambient conditions) for analysis.

Stability will be assessed by normalization purity by HPLC and the value compared to the purity identified on the Certificate of Analysis. A report will be generated for this phase of the study and provided to the Study Director for inclusion in the final report.

14.3. Analyses of Prepared Formulations

Formulation analysis will be performed using Good Laboratory Practice (GLP)-validated HPLC method number (performed as Charles River Laboratories Preclinical Services Montreal Study number 211052). The Test Site Reference number for the work in this current study is 211147. A report will be generated for this phase of the study and provided to the Study Director for inclusion in the final report.

14.3.1. Concentration and Homogeneity

Concentration and homogeneity of the prepared formulations, including vehicle, will be verified during the course of this study. Quadruplicate samples (2 mL each), for analysis of concentration and homogeneity, will be taken from the top, middle and bottom of each concentration 24 hours or more after preparation, and no more than 24 hours before dosing on the first day all concentrations are prepared. Two samples from each quadruplicate set will be shipped (ambient conditions) for analysis; the remaining samples will be retained at the Testing Facility as backup samples and shipped (ambient condition) one week after successful delivery of the initial shipment. Quadruplicate samples, for analysis of concentration, will be taken from the middle of each concentration at the mid-point of the study period and on the last day all concentrations

are prepared 24 hours or more after preparation, and no more than 24 hours before dosing. Two samples from each quadruplicate set will be shipped (ambient conditions) for analysis; the remaining samples will be retained at the Testing Facility as backup samples and shipped (ambient condition) one week after successful delivery of the initial shipment. Backup samples will be stored room temperature until the results of the initial analyses are available, at which time the backup samples may be analyzed or discarded at the Test Site. Samples will be stored at room temperature until analysis.

14.3.2. Stability

Stability of the prepared test substance formulations will be documented during this study in conjunction with a concentration analysis. Stability will be determined for the lowest and highest concentrations after storage at room temperature for 10 days.

14.3.3. Shipping Instructions

Samples to be analyzed will be shipped (ambient conditions) to:

Principal Investigator:
Research Scientist, Analytical Chemistry
Charles River Preclinical Services Montreal
22022 Transcanadienne Senneville
Montreal, Quebec H9X 3R3
CANADA
Tel: +1.514.630.8200 ext 2046
Fax: +1.514.630.8230
E-mail:

15. DISPOSITION

Unused prepared formulations will be discarded at the Testing Facility. Backup samples will be discarded at the Testing Facility following issue of the final report. Disposition of the remaining bulk test substance will be documented in the raw data.

16. TEST SYSTEM

16.1. Species/Strain and Reason for Selection

The Crl:CD1(ICR) mouse was selected as the Test System because: 1) it is one mammalian species accepted and widely used throughout the industry for nonclinical studies of developmental toxicity (embryo-fetal toxicity/teratogenicity); 2) this strain has been demonstrated to be sensitive to developmental toxicants; and 3) historical data and experience exist at the Testing Facility.

16.2. Number

Initial population acclimated: 100 virgin female mice.
Population selected for study: 80 mated female mice (20 per dosage group).

One hundred and sixty F1 generation pups (20 per sex per dosage group) will be selected for continued observations.

16.3. Body Weight and Age

Female mice will be ordered to be approximately 60 days of age at receipt, at which time they will be expected to have body weights of 25 g to 30 g each. Actual body weights will be recorded after receipt and will be documented in the raw data. The weight range will be included in the final report.

16.4. Sex

Female mice will be given the test substance and/or the vehicle. Male mice of the same source and strain will be used only as breeders and are not considered part of the Test System.

16.5. Source

Charles River Laboratories, Inc.

The mice will be shipped in filtered cartons by air freight and/or truck from Charles River Laboratories, Inc., to the Testing Facility.

16.6. Identification

16.6.1. F0 Generation Mice

Mice are permanently identified by tattoo according to the Standard Operating Procedures of the Testing Facility. Male mice are given unique permanent identification numbers upon assignment to the Testing Facility's breeder male mouse population. Female mice are assigned temporary numbers at receipt and given unique permanent identification numbers when assigned to the study on the basis of day 0 of presumed gestation body weights.

16.6.2. F1 Generation Mice

Pups will not be individually identified during lactation; all parameters will be evaluated in terms of the litter. At weaning, each mouse will be identified by tail tattoo.

17. ANIMAL HUSBANDRY

All cage sizes and housing conditions are in compliance with the *Guide for the Care and Use of Laboratory Animals*⁴.

17.1. Housing

17.1.1. F0 Generation Mice/F1 Generation Litters

F0 generation mice will be individually housed in nesting boxes or stainless steel, wire-bottomed cages, except during the cohabitation and postpartum periods. During cohabitation, each pair of mice will be housed in the male mouse's cage. Each dam and delivered litter will be housed in a common nesting box during the postpartum period.

17.1.2. F1 Generation Mice

After weaning, the F1 generation mice will be housed in nesting boxes. Mice will be pair housed until at least PND 28, after which point the mice will be individually housed.

17.2. Nesting Material

Nesting material (bed-o-cobs[®]) will be provided.

Bedding will be changed as often as necessary to keep the animals dry and clean. Bedding changes will be documented in the raw data. Analyses for possible contamination are conducted on each lot of bedding and documented in the raw data.

17.3. Room Air, Temperature and Humidity

The animal room is independently supplied with at least ten changes per hour of 100% fresh air that has been passed through 99.97% HEPA filters. Room temperature will be maintained at 64°F to 79°F (18°C to 26°C) and monitored constantly. Room humidity will also be monitored constantly and maintained at 30% to 70%.

17.4. Light

An automatically controlled 12-hour light:12-hour dark fluorescent light cycle will be maintained. Each dark period will begin at 1900 hours ($\pm$ 30 minutes). The light cycle may be adjusted by the Study Director or designee if deemed necessary to accommodate scheduled laboratory activities. Any such adjustment will be documented in the raw data.

17.5. Feed

Mice will be given Certified Rodent Diet[®] #5002 (PMI[®] Nutrition International) available *ad libitum* from individual feeders.

17.6. Water

Water will be available *ad libitum* from individual bottles attached to the cages and/or from an automatic watering access system. All water will be from a local source and passed through a reverse osmosis membrane before use. Chlorine will be added to the processed water as a bacteriostat; processed water is expected to contain no more than 1.2 ppm chlorine at the time of analysis. Water is analyzed monthly for possible bacterial contamination and twice annually for possible chemical contamination.

17.7. Contaminants

Neither the Sponsor nor the Study Director is aware of any potential contaminants likely to be present in the certified diet, the drinking water or the nesting material at levels that would interfere with the results of this study. Therefore, no analyses other than those routinely performed by the feed supplier or those mentioned in this protocol will be conducted.

18. DAY NUMBERING SYSTEM

Gestation day 0 is defined as the day spermatozoa are observed in a smear of the vaginal contents and/or a copulatory plug observed *in situ*.

The day of birth is designated lactation day 0 (postpartum day 0) in the Health Effects Test Guidelines - Reproduction and Fertility Effects (Office of Prevention, Pesticides and Toxic Substances 870.3800, August, 1998) and in the OECD Guideline for the Testing of Chemicals - Two-Generation Reproduction Toxicity Study (Section 4, No. 416, 22 January 2001). This same day is designated day 1 postpartum (day 1 of lactation) in the Standard Operating Procedures of the Testing Facility. Throughout this protocol, the day of birth will be designated day 1 postpartum (day 1 of lactation) and all subsequent ages of the F1 generation mice and days of the lactation period will be determined and cited accordingly. For the study report, the days will be cited according to the Health Effects Test Guidelines and OECD Guideline for the Testing of Chemicals.

19. RANDOMIZATION AND COHABITATION

Upon arrival, male and female mice will be assigned to individual housing on the basis of computer-generated random units. After acclimation, virgin female mice will be cohabited with breeder male mice, one male mouse per female mouse. The cohabitation period will consist of a maximum of five days. Female mice observed to have a copulatory plug *in situ* will be considered to be at day 0 of presumed gestation and assigned to individual housing.

Healthy mated female mice will be assigned to dosage groups based on computer-generated (weight-ordered) randomization procedures.

Day 1 of lactation (postpartum) is defined as the day of birth and is also the first day on which all pups in a litter are individually weighed (pup body weights will be recorded after all pups in a litter are delivered and groomed by the dam).

Litters will not be culled during the lactation period, because random selection of pups for culling could result in potential biases in pup viabilities and body weight gains during this period.

All F1 generation mice will be weaned at the same age, based on observed growth and viability of the pups, on either day 21 postpartum or, if necessary, on day 28 postpartum. Should it be necessary to extend the lactation period to day 28 postpartum, all affected observational intervals will be adjusted accordingly by protocol amendment.

At weaning, a table of random units will be used to select 20 male and 20 female pups per group, resulting in a total of 160 F1 generation mice (80 per sex) chosen for continued evaluation. At least one male pup and one female pup per litter, when possible, will be selected.

20. ADMINISTRATION

20.1. Route and Reason for Choice

The oral (gavage) route was selected for use because: 1) in comparison with the dietary route, the exact dosage can be accurately administered; and 2) it is one possible route of human exposure.

20.2. Method and Frequency

20.2.1. F0 Generation Mice

Female mice will be given the test substance and/or the vehicle once daily on days 6 through 18 of presumed gestation. Dosages will be adjusted daily for body weight changes and given at approximately the same time each day.

20.2.2. F1 Generation Mice

F1 generation pups will not be directly given the test substance and/or the vehicle, but may be possibly exposed to the test substance or vehicle during maternal gestation (*in utero* exposure) or via maternal milk during the lactation period.

20.3. Rationale for Dosage Selection

Perfluorobutyrate (PFBA) is a perfluoroalkyl acid (PFAA) found in the environment. Previous studies have indicated developmental toxicity of PFAAs (perfluorooctane sulfonate [PFOS] and perfluorooctanoate [PFOA]). PFBA/NH₄⁺ was given to timed-pregnant CD-1 mice by oral gavage daily from gestation day (DG) 1 to 17 at 35, 175 and 350 mg/kg; controls received water. At DG 18, serum levels of PFBA were 3.8, 4.4 and 2.5 µg/mL, respectively, in the three treated groups. PFBA did not significantly affect maternal weight gain, number of implantations, fetal viability, fetus weight, or incidence of fetal malformations. Incidence of full-litter loss was significantly greater in the 350 mg/kg group, and maternal liver weights were significantly increased in the 175 and 350 mg/kg groups. In contrast to PFOA, and PFOS, PFBA exposure during pregnancy did not adversely affect neonatal survival or postnatal growth. Liver enlargement was detected in the PFBA-exposed pups on postnatal (PD) 1, but not by PD 10. Expression of selected hepatic genes in PFBA-exposed pups at PD 1 did not reveal any significant changes from controls. A significant delay in eye-opening in offspring was detected in all three PFBA groups, and slight delays in the onset of puberty were noted in the 175 and 350 mg/kg groups. These data suggest that exposure to PFBA during pregnancy in the mouse did not produce developmental toxicity comparable to that observed with PFOA, in part, due to rapid elimination of the chemical⁽⁵⁾. In the acute pharmacokinetic study (UZS00009), mice were administered a single dose at 35, 175 or 350 mg/kg. All mice survived to scheduled sacrifice, and no adverse clinical signs occurred during this study. Based on these results, dosages of 7, 35 and 175 mg/kg/day were selected for the developmental and perinatal/postnatal reproduction toxicity study.

20.4. Dosage Levels, Concentrations and Dosage Volumes

Dosage Group	Number of Mice Assigned to Study	Dosage (mg/kg/day)	Concentration (mg/mL)	Dosage Volume (mL/kg)	Batch Number
I	20	0	0	5	B-UZS00010-A(Day.Month.Year)
II	20	7	1.4	5	B-UZS00010-B(Day.Month.Year)
III	20	35	7	5	B-UZS00010-C(Day.Month.Year)
IV	20	175	35	5	B-UZS00010-D(Day.Month.Year)

The test substance will be considered 95% by weight of PFH acid for dosage calculations.

21. TESTS, ANALYSES AND MEASUREMENTS - F0 GENERATION^A**21.1. Viability**

All Periods: At least twice daily.

21.2. Clinical Observations and/or General Appearance

Acclimation Period: At least weekly.

Predosage Period: Day 0 of presumed gestation.

Dosage Period: Daily before dosage. Postdosage observations will be recorded between one and two hours after dosage administration. Time intervals for postdosage observations may be adjusted if deemed appropriate by the Study Director or designee during the course of the study. Such adjustments will be documented in the raw data.

Postdosage Period: Once daily.

Maternal Behavior: Days 1, 5, 8, 15 and 21 postpartum. Observed abnormal behavior recorded daily.

Clinical observations may be recorded more frequently than cited above.

A. See APPENDIX 4 for a summarization.

21.3. Body Weights

Acclimation Period:	At least weekly.
Predosage Period:	Day 0 of presumed gestation.
Dosage Period:	Daily.
Postdosage Period:	Daily.

21.4. Mating Performance

Mating will be evaluated daily during the cohabitation period and confirmed by observation of a copulatory plug observed *in situ*.

21.5. Duration of Gestation

The duration of gestation is calculated from day 0 of presumed gestation to the day the first pup is observed.

21.6. Reproductive Parameters

Fertility Index (percentage of matings that result in pregnancies).

Gestation Index (percentage of pregnancies that result in birth of live litters).

Number of offspring per litter (live and dead pups).

Number of implantation sites.

General condition of dam and litter during the postpartum period.

Viability Indices (percentage of pups born that survive 5 and/or 8 days).

Lactation Index (percentage of pups that survive 21 days).

21.7. Natural Delivery

F0 generation female mice will be evaluated for:

Adverse Clinical Signs Observed During Parturition.

Duration of Gestation (day 0 of presumed gestation to the time the first pup is observed).

Litter Size (defined as all pups delivered).

Pup Viability at Birth.

22. METHOD OF SACRIFICE - F0 GENERATION

Mice will be sacrificed by carbon dioxide asphyxiation. Live fetuses will be sacrificed by an intraperitoneal injection of sodium pentobarbital.

23. NECROPSY - F0 GENERATION

Gross lesions will be retained in neutral buffered 10% formalin for possible future evaluation (a table of random units will be used to select one control group mouse from which all tissues examined at necropsy will be retained, in order to provide control tissues for any possible histopathological evaluations of gross lesions). Unless specifically cited below, all other tissues will be discarded.

23.1. Scheduled Sacrifice - Pharmacokinetic Sample Collection

After completion of the 21 day postpartum period, female mice will be sacrificed and a gross necropsy of the thoracic, abdominal and pelvic viscera will be performed. **Five livers per group will be excised, weighed and frozen on dry ice.** Livers will be maintained frozen ($\leq -70^{\circ}\text{C}$) until shipment for analysis as described in section 23.4. The number and distribution of implantation sites will be recorded after staining with 10% ammonium sulfide⁶.

Mice that do not deliver a litter will be sacrificed on day 23 of presumed gestation and examined for gross lesions. Livers will be excised, weighed and frozen on dry ice. Livers will be maintained frozen ($\leq -70^{\circ}\text{C}$) until shipment for analysis as described in section 23.4. Uteri will be stained with 10% ammonium sulfide to confirm the absence of implantation sites⁶.

The liver samples will be analyzed at PCS-MTL (test site reference no. 141663) using a validated LC-MS/MS method (PCS-MTL Study no. 141659). The bioanalytical method will be validated to meet the minimum requirements of the appropriate PCS-MTL Standard Operating Procedures. Remaining unused study samples will be retained at PCS-MTL for approximately 1 year after dispatch of the final report or until authorized to discard by the Study Director. A report will be generated for this phase of the study and provided to the Study Director for inclusion in the final report.

23.2. Dams with No Surviving Pups

Dams with no surviving pups will be sacrificed after the last pup is found dead or missing, presumed cannibalized. A gross necropsy of the thoracic, abdominal and pelvic viscera will be performed and implantation sites will be recorded after staining with 10% ammonium sulfide⁶. Livers will be excised, weighed and frozen on dry ice. Livers will be maintained frozen ($\leq -70^{\circ}\text{C}$) until shipment for analysis as described in section 23.4.

23.3. Mice Found Dead or Unscheduled Sacrifice

Mice that die or are sacrificed before scheduled termination will be examined for the cause of death or condition as soon as possible after the observation is made. The mice will be examined for gross lesions. The lungs, trachea and esophagus will be perfused and saved in neutral buffered 10% formalin for possible future evaluation. When not precluded by autolysis, the heart, kidneys, stomach and spleen will be retained in neutral buffered 10% formalin for possible histological evaluation. When not precluded by autolysis, livers will be excised, weighed and frozen on dry ice. Livers will be maintained frozen ($\leq -70^{\circ}\text{C}$) until shipment for analysis as described in section 23.4. Additional tissues may be retained at the discretion of the Study Director. When not precluded by autolysis, gravid uterine weights will be recorded (if possible). Pregnancy status and uterine contents of female mice will be recorded. Aborted fetuses, conceptuses *in utero* and/or delivered pups will be examined to the extent possible, using the same methods described for term fetuses/pups. Uteri of apparently nonpregnant mice will be stained with 10% ammonium sulfide to confirm the absence of implantation sites⁶. The number and distribution of implantation sites for delivered mice will be recorded after staining with 10% ammonium sulfide⁶.

23.4. Shipping Instructions

Samples to be analyzed will be shipped (on dry ice) to:

Principal Investigator:
ATT:
Charles River Preclinical Services Montreal
22022 Transcanadienne Senneville
Montreal, Quebec H9X 3R3
CANADA
Custom Clearance: H. Kennedy Inc
Tel: +1.514.630.8200 ext 2224
Fax: +1.514.630.8230
E-mail:

Liver and Serum samples will be retained frozen ($\leq -70^{\circ}\text{C}$) until analysis. The recipient will be notified in advance of sample shipment. Copies of blood/liver collection data sheets will be included in the shipment.

24. TESTS, ANALYSES AND MEASUREMENTS - F1 GENERATION

24.1. Viability

Prewaning Period: Litters will be observed for dead pups at least twice daily. The pups in each litter will be counted once daily.

Postweaning Period: Daily.

24.2. Clinical Observations and/or General Appearance

Prewaning Period: Daily.

Postweaning Period: Daily.

Clinical observations may be recorded more frequently than cited above.

24.3. Body Weights

Prewaning Period: Days 1 (birth), 5, 8, 15, 21 postpartum.

Postweaning Period: Weekly.

24.4. Preweaning Developmental Landmark

Eye Opening: From day 11 postpartum.

24.5. Postweaning Developmental Observations

24.5.1. Sexual Maturation

Female mice will be evaluated for the age of vaginal patency, beginning on day 21 postpartum. Male mice will be evaluated for the age of preputial separation, beginning on day 27 postpartum.

25. METHOD OF SACRIFICE - F1 GENERATION MICE

Mice will be sacrificed by carbon dioxide asphyxiation. Pups will be sacrificed by an intraperitoneal injection of sodium pentobarbital (pups ≤ 14 days of age) or by carbon dioxide asphyxiation (pups ≥ 15 days of age).

26. NECROPSY - F1 GENERATION MICE

Gross lesions will be retained in neutral buffered 10% formalin for possible future evaluation (a table of random units will be used to select one control group mouse of each sex from which all tissues examined at necropsy will be retained, in order to provide control tissues for any possible histopathological evaluations of gross lesions). Unless specifically cited below, all other tissues will be discarded.

26.1. Scheduled Sacrifice

Five mice per sex per group (total 40 mice) will be sacrificed on day 42 postpartum for blood sample collection for bioanalysis. Blood samples (as much as possible, but no less than 0.5 mL) and livers (livers will be excised, weighed and frozen on dry ice. Livers will be maintained frozen ($\leq -70^{\circ}\text{C}$) until shipment for analysis as described in section 23.4) will be collected from these mice. Blood samples will be collected via vena cava, after sacrifice. The blood samples will be transferred into uncoated (red top) tubes and spun in a centrifuge. The resulting serum will be transferred into polypropylene tubes labeled at minimum with the protocol number, mouse number, group number, dosage level, day of study, collection interval, date of collection, species, generation and storage conditions. All samples will be frozen on dry ice as soon as possible and maintained frozen ($< -70^{\circ}\text{C}$) until shipment for analysis as described in section 23.4. A gross necropsy of the thoracic, abdominal and pelvic viscera will be performed. The

livers (5 per group per sex) will be excised, weighed and frozen on dry ice. Livers will be maintained frozen ($\leq -70^{\circ}\text{C}$) until shipment for analysis as described in section 23.4.

The remaining mice will be sacrificed by carbon dioxide asphyxiation on day 42 postpartum. A gross necropsy of the thoracic, abdominal and pelvic viscera will be performed.

26.1.1. Bioanalysis

The test substance will be used as reference material for bioanalysis.

The serum samples will be analyzed at PCS-MTL (test site reference no. 141662) using a validated LC-MS/MS method (PCS-MTL Study no. 141837). The bioanalytical method was validated and met the minimum requirements of the appropriate PCS-MTL Standard Operating Procedures. Remaining unused study samples will be retained at PCS-MTL for approximately 1 year after dispatch of the final report or until authorized to discard by the Study Director. A report will be generated for this phase of the study and provided to the Study Director for inclusion in the final report.

26.2. Pups Found Dead on Day 1 Postpartum

Pups that die before examination of the litter for pup viability will be evaluated for vital status at birth. The lungs will be removed and immersed in water. Pups with lungs that sink will be identified as stillborn; pups with lungs that float will be identified as liveborn and to have died shortly after birth. Pups with gross lesions will be preserved in Bouin's solution for possible future evaluation.

26.3. Pups Found Dead or Unscheduled Sacrifice (Prewaning)

Pups that die or are sacrificed before scheduled termination will be examined for gross lesions and the cause of death or condition as soon as possible after the observation is made. Pups found on days 2 to 4 postpartum will be preserved in Bouin's solution for possible future evaluation; pups found on days 5 to 21 postpartum will be preserved in neutral buffered 10% formalin.

26.4. Mice Found Dead or Unscheduled Sacrifice (Postweaning)

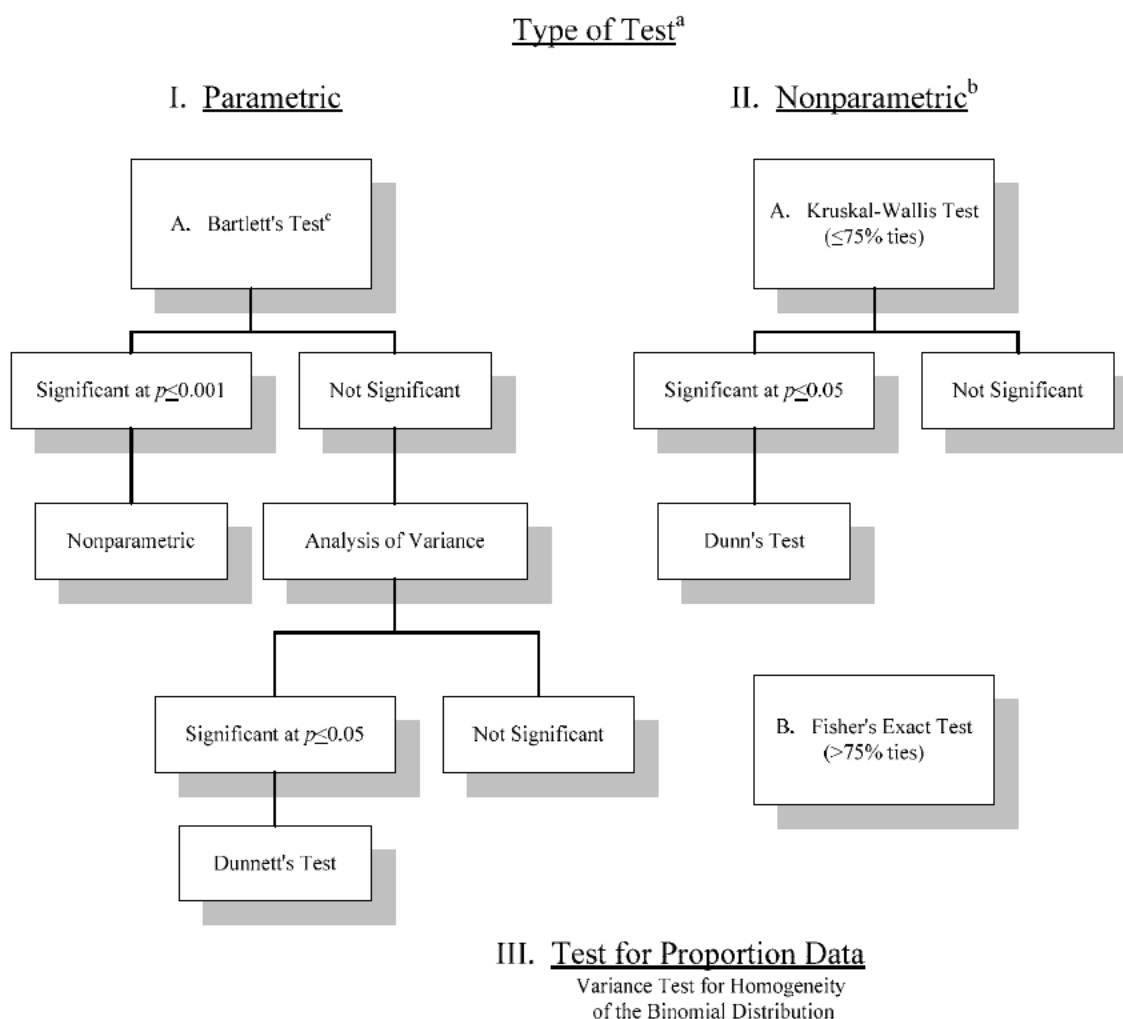
Mice that die or are sacrificed before scheduled termination will be examined for the cause of death or condition as soon as possible after the observation is made. The mice will be examined for gross lesions. When not precluded by autolysis, the heart, kidneys, lungs, stomach and spleen will be retained in neutral buffered 10% formalin for possible histological evaluation. When not precluded by autolysis, livers will be excised, weighed and frozen on dry ice. Livers will be maintained frozen ($\leq -70^{\circ}\text{C}$) until shipment for analysis as described in section 23.4. Additional tissues may be retained at the discretion of the Study Director.

26.5. Pups Not Selected for Continued Observation

All pups culled on day 21 postpartum will be sacrificed and examined for gross lesions; gross lesions will be preserved in neutral buffered 10% formalin. Necropsy will include a single cross-section of the head at the level of the frontal-parietal suture and examination of the cross-sectioned brain for apparent hydrocephaly.

27. PROPOSED STATISTICAL METHODS

Averages and percentages will be calculated. Litter values will be used where appropriate. Additional procedures and/or analyses may be performed, if appropriate.



-
- a. Statistically significant probabilities are reported as either $p \leq 0.05$ or $p \leq 0.01$.
 b. Proportion data are not included in this category.
 c. Test for homogeneity of variance.

Clinical observations and other proportional data will be analyzed using the Variance Test for Homogeneity of the Binomial Distribution⁷.

Continuous data (e.g., maternal body weights, body weight changes, feed consumption values and litter averages for percent male fetuses, percent resorbed conceptuses, fetal body weights and fetal anomaly data) will be analyzed using Bartlett's Test of Homogeneity of Variances⁸ and the Analysis of Variance⁹, when appropriate [i.e., Bartlett's Test is not significant ($p > 0.001$)]. If the Analysis of Variance is significant ($p \leq 0.05$), Dunnett's Test¹⁰ will be used to identify the statistical significance of the individual groups. If the Analysis of Variance is not appropriate [i.e., Bartlett's Test is significant ($p \leq 0.001$)], the Kruskal-Wallis Test¹¹ is used ($\leq 75\%$ ties). In cases where the Kruskal-Wallis Test is statistically significant ($p \leq 0.05$), Dunn's Method of Multiple Comparisons¹² will be used to identify the statistical significance of the individual groups. If there are greater than 75% ties, Fisher's Exact Test¹³ will be used to analyze the data.

Count data will be evaluated using the procedures described above for the Kruskal-Wallis Test¹¹.

28. DATA ACQUISITION, VERIFICATION AND STORAGE

Data generated during the course of this study will be recorded either by hand or using the *Argus Automated Data Collection and Management System*, the *Vivarium Temperature and Relative Humidity Monitoring System* and/or chart recorders. All data will be tabulated, summarized and/or statistically analyzed using the *Argus Automated Data Collection and Management System*, the *Vivarium Temperature and Relative Humidity Monitoring System*, Microsoft[®] Excel (part of Microsoft[®] Office 97/2000/2003/XP), Quattro Pro 8 and/or *The SAS System* (version 6.12). Empower (Waters Corporation) will be used for formulation sample analysis.

Data collection for serum and liver concentration analysis using LC-MS/MS will be performed using Analyst from MDS Sciex. Statistical analysis, including regression analysis, and descriptive statistics such as arithmetic means and standard deviations, accuracy and precision will be performed using Watson laboratory Information Management system (LIMS) and Microsoft Excel. Tables will be prepared from retrospective manual entry on computer (Microsoft Word). All raw data and documents generated at PCS-MTL during this study and the final report will be transferred to the scientific archives of PCS-MTL for a period of approximately 1 year from finalization. Storage details following the 1 year archive period will be documented in the raw data.

Records will be reviewed by the Study Director and/or appropriate management personnel within 21 days after generation. All original records will be stored in the archives at the Testing Facility. All raw data will be bound and indexed. The archived raw data will be scanned and retained on CD-ROM in an Adobe® Acrobat PDF file. A copy of all raw data will be supplied to the Sponsor upon request. Preserved tissues will be stored at the Testing Facility for ten years after mailing of the draft final report, after which time the Sponsor will be contacted to determine the disposition of these materials.

29. RECORDS TO BE MAINTAINED

Protocol and Amendments.
Test Substance, Vehicle and/or Reagent Receipt, Preparation and Use.
Animal Acquisition.
Randomization Schedules.
Mating History.
Supportive Care (if prescribed by Staff Veterinarian).
General Comments.
Clinical Observations and/or General Appearance.
Blood Sample Collection, Processing and Shipment.
Body Weights.
Natural Delivery Observations and Litter Observations
Gross Necropsy Observations.
Organ Weights.
Photographs (if required).
Study Maintenance (room and environmental records).
Feed and Water Analyses.
Packing and/or Shipment Lists.

30. KEY PERSONNEL

Executive Director, Site Operations and Toxicology and Study Director:

Director of Reproductive and Neurobehavioral Toxicology:

Director of Operations:

Associate Director of Regulatory Compliance:

Senior Manager of Study Management:

RQAP-GLP, ALAT

Senior Staff Veterinarian:

Chair, Institutional Animal Care and Use Committee:

Consultant, Veterinary Pathology:

31. FINAL REPORT

The Study Director will provide periodic updates of study progress to the Sponsor. Draft summary tables of unaudited computer-recorded data may accompany these updates. Statistical analyses will not be performed on these interim data.

A comprehensive draft final report will be prepared on completion of the study and will be finalized following consultation with the Sponsor. The report will include the following:

- Summary and Conclusion.

- Experimental Design and Method.

- Evaluation of Test Results.

- Appendices: Figures, Summary and Individual Tables Summarizing the Above Data, Protocol and Associated Amendments and Deviations, Study Director's GLP Compliance Statement, Reports of Supporting Data (if appropriate) and QAU Statement.

32. ANIMAL WELFARE

Animal care and use will be in accordance with the Animal Welfare Act regulations (9 CFR, Parts 1, 2 and 3), the conditions specified in the *Guide for the Care and Use of Laboratory Animals*⁴, the relevant SOPs of the Testing Facility, and the protocol. Anticipated or suspected clinical signs and supportive care agreed upon by the Study Director, veterinary staff and Sponsor should these clinical signs be observed are documented in the IACUC proposal for this study.

Adverse observations will be promptly reported to the Study Director and veterinary staff. The veterinarian may make recommendations regarding care of the animal(s) in addition to those already agreed upon and/or alteration of study procedures to ensure the well-being of the animal(s) should unanticipated responses or circumstances occur. All recommendations shall be discussed with the Study Director and the recommendations and subsequent actions properly documented in the study record. Supportive care of the animal(s) may occur without notification of the Sponsor when such supportive care, as determined by the Study Director, does not adversely affect the study objectives.

If the condition of the animal(s) warrants therapeutic intervention or alterations in study procedures above the previously-agreed-upon conditions, the Sponsor will be contacted, whenever possible, to discuss appropriate action. If the condition of the animal(s) is such that immediate measures must be taken to relieve pain and/or distress, the attending veterinarian will attempt to consult the Study Director prior to initiating medical action,

but the veterinarian has the authority to act immediately at his/her discretion to address the condition under these circumstances. The Sponsor will be informed by the Study Director of any such event as soon as possible.

33. INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE STATEMENT

The procedures described in this protocol have been reviewed by the Testing Facility's Institutional Animal Care and Use Committee. All procedures described in this protocol that involve study animals will be conducted in a manner to avoid or minimize discomfort, distress or pain to the animals.

The signature of the Sponsor's representative below is assurance that the study is not an unnecessary duplication of previous work. Documentation for the necessity of this study may be obtained from the Sponsor. No alternative procedures were available to meet the stated purposes of the study.

34. REFERENCES

- (1) Federal Insecticide, Fungicide and Rodenticide Act/Toxic Substances Control Act (FIFRA/TSCA); Good laboratory practice standards; Final Rule 40 C.F.R Part 160/792; August 17, 1989. U.S. Environmental Protection Agency.
- (2) Good laboratory practice standards for toxicological studies on agricultural chemicals. 59-Nousan-No.3850; August 10, 1984. Repealed as 1 October, 1999. Notification 11-Nousan-No.6283. Japan: Ministry of Agriculture, Forestry and Fisheries, Japan (MAFF).
- (3) OECD Principles of good laboratory practices, [C(97)186/Final] (1998); Environmental Health and Safety Division. OECD Environment Directorate.
- (4) Institute of Laboratory Animal Resources Commission on Life Sciences and the National Research Council. *Guide for the care and use of laboratory animals*. Washington (D.C.): National Academy Press; 1996.
- (5) Das KP, Grey BE, Zehr RD et al. Effects of perfluorobutyrate exposure during pregnancy in the mouse. *Toxicol Sci* 2008;105(1):173-81.
- (6) Salewski E. Färbemethode zum makroskopischen nachweis von implantations stellen am uterus der ratte. G [Staining method for macroscopic demonstration of implantation sites in the rat uterus]. *Arch Pathol Exp Pharmacol* 1964;247:367.

- (7) Snedecor GW, Cochran WG. Variance test for homogeneity of the binomial distribution. *Statistical methods. 6th Ed.* Iowa State University Press, Ames; 1967. p. 240-1.
- (8) Sokal RR, Rohlf FJ. Bartlett' s test of homogeneity of variances. *Biometry: the principles and practice of statistics in biological research.* San Francisco (CA): Freeman & Co; 1969. p. 370-1.
- (9) Snedecor GW, Cochran WG. Analysis of variance. *Statistical methods. 6th Ed.* Iowa State University Press, Ames; 1967. p. 258-98.
- (10) Dunnett CW. A multiple comparison procedure for comparing several treatments with a control. *J Am Stat Assoc* 1955;50:1096-121.
- (11) Sokal RR, Rohlf FJ. Kruskal-Wallis test. *Biometry: the principles and practice of statistics in biological research.* San Francisco (CA): Freeman & Co; 1969. p. 388-91.
- (12) Dunn OJ. Multiple comparisons using rank sums. *Technometrics* 1964;6(3):241-52.
- (13) Siegel S. The Fisher's exact probability test. *Nonparametric statistics for the behavioral sciences.* New York (NY): McGraw-Hill Co; 1956. p. 96-105.

35. PROTOCOL APPROVAL

35.1. Testing Facility Management

Corporate Vice President
Toxicology and Pathology
Global Preclinical Services

-- 18-Dec-2009
Date

35.1.1. Study Director

Executive Director, Site Operations
and Toxicology
Study Director

21-Dec-09
Date

35.2. For The Sponsor^a

Toxicologist
Study Monitor

22 - Dec - 09
Date

a. Date of Sponsor Approval: 14 December 2009

**ATTACHMENT 1 -
PROPOSED STUDY SCHEDULE**

PROPOSED SCHEDULE^{a,b}

15 DEC 2009	Animal Receipt and Experimental Start Date - Acclimation Begins (F0 generation mice).
23 DEC 2009 PM - 28 DEC 2009 AM	Cohabitation Period.
24 DEC 2009	First Possible Day 0 of Presumed Gestation.
28 DEC 2009	Last Possible Day 0 of Presumed Gestation.
30 DEC 2009 - 15 JAN 2010	Dosage Period - Days 6 through 18 of presumed gestation.
11 JAN 2010	First Possible Delivery (Day 18 of presumed gestation).
20 JAN 2010	Last Possible Delivery (Day 23 of presumed gestation).
16 JAN 2010	First Possible Day 23 of Presumed Gestation Female Sacrifice.
20 JAN 2010	Last Possible Day 23 of Presumed Gestation Female Sacrifice.
21 JAN 2010	Earliest Possible F1 Generation Prewaning Observation - Eye Opening Begins

- a. The study initiation date is the date the Study Director signs the protocol.
- b. Throughout this schedule, the day of birth is designated day 1 postpartum (day 1 of lactation) and all subsequent ages of the F1 generation mice and days of the lactation period will be determined and cited accordingly, as described above the protocol section, "Day Numbering System."

31 JAN 2010	First Possible Day 21 Weaning (Dams and F1 generation pups not selected for continued observation sacrificed).
09 FEB 2010	Last Possible Day 21 Weaning.
31 JAN 2010	Earliest Possible F1 Generation Postweaning Observation - Sexual Maturation
21 FEB 2010 - 02 MAR 2010	F1 Generation Mice Scheduled Sacrificed and Blood Sample Collection.
21 MAY 2010	Audited Draft Report - Submission Date.
23 JUN 2010	Experimental Termination Date.

**ATTACHMENT 2 -
MATERIAL SAFETY DATA SHEET**



Safety Data Sheet
according to 1907/2006/EC, Article 31

Page 1/5

Printing date 28.11.2007

Revision: 30.11.2005

1 Identification of the substance/preparation and of the company/undertaking

· **Product details**

· **Trade name:** PFH Ammonium Salt
(C-1500N)

· **Application of the substance / the preparation** Emulsifier

· **Manufacturer/Supplier:**

DAIKIN INDUSTRIES, LTD. CHEMICAL DIVISION:
Umeda Center Bldg., 4-12, Nakazaki-Nishi2-chome, Kita-Ku, Osaka, JAPAN
Phone: (+81) 6-6373-4349 Fax: (+81) 6-6373-4389

· **Further information obtainable from:** <http://www.daikin.co.jp/chm/en/index.html>

· **Information in case of emergency:** +81-6-6349-7521, +49-211-179 225, 1-256-306-5000

2 Hazards identification

· **Hazard description:**



Xi Irritant

· **Information concerning particular hazards for human and environment:**

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

R 41 Risk of serious damage to eyes.

· **Classification system:**

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

3 Composition/information on ingredients

· **Chemical characterization**

· **Description:** liquid solution, water 50%

· **Dangerous components:**

21615-47-4 Ammonium Perfluorohexanoate

Xi; R 41 50.0%

· **Additional information:** For the wording of the listed risk phrases refer to section 16.

4 First-aid measures

· **After inhalation:** Supply fresh air; consult doctor in case of complaints.

· **After skin contact:** Generally the product does not irritate the skin.

· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

· **After swallowing:** If symptoms persist consult doctor.

5 Fire-fighting measures

· **Suitable extinguishing agents:**

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **Special hazards caused by the substance, its products of combustion or resulting gases:**

Hydrogen fluoride (HF)

Formation of toxic gases is possible during heating or in case of fire.

· **Protective equipment:** Wear fully protective suit.

GB
(Contd. on page 2)

Safety Data Sheet
according to 1907/2006/EC, Article 31

Printing date 28.11.2007

Revision: 30.11.2005

Trade name: PFH Ammonium Salt
(C-1500N)

(Contd. of page 1)

6 Accidental release measures

- **Person-related safety precautions:**
There is no acute toxic risk known to be associated with this substance. Use self-contained respiratory protective device and non-permeable gloves are recommended against inhalation and transdermal uptake (see attached ppt file)
- **Measures for environmental protection:**
*Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.*
- **Measures for cleaning/collecting:**
*Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.*

7 Handling and storage

- **Handling:**
- **Information for safe handling:**
*Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
See attached ppt file.*
- **Information about fire - and explosion protection:** *No special measures required.*
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** *No special requirements.*
- **Information about storage in one common storage facility:** *Not required.*
- **Further information about storage conditions:** *None.*

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** *No further data; see item 7.*
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** *The lists valid during the making were used as basis.*
- **Personal protective equipment:**
- **General protective and hygienic measures:**
*Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes.*
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**
*The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation*
- **Material of gloves**
Double glove, supported nitrile or neoprene over latex under-glove, recommended for extended use. Gloves should be discarded at end of use if soiled.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 3)

GB

Safety Data Sheet
according to 1907/2006/EC, Article 31

Printing date 28.11.2007

Revision: 30.11.2005

Trade name: PFH Ammonium Salt
(C-1500N)

(Contd. of page 2)

· **Eye protection:**

Tightly sealed goggles

· **Body protection:** Protective work clothing**9 Physical and chemical properties**· **General Information**

Form:	Solution
Colour:	Colourless
Odour:	Aromatic

· **Change in condition**

Melting point/Melting range: Undetermined.
Boiling point/Boiling range: 100°C

· **Flash point:** Not applicable.· **Self-igniting:** Product is not selfigniting.· **Danger of explosion:** Product does not present an explosion hazard.· **Vapour pressure at 20°C:** 23.0 hPa· **Density:** Not determined.· **Solubility in / Miscibility with water:** Fully miscible.· **pH-value at 20°C:** 7.0· **Solvent content:**

Organic solvents:	0.0 %
Water:	50.0 %

· **Solids content:** 50.0 %**10 Stability and reactivity**· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.· **Dangerous reactions** No dangerous reactions known.· **Dangerous decomposition products:**

Hydrogen fluoride

Fluorophosgene on contact with naked flame or red hot objects.

11 Toxicological information· **Acute toxicity:**· **LD/LC50 values relevant for classification:****21615-47-4 Ammonium Perfluorohexanoate**

Oral LD50 >2000 mg/kg (rat)

Dermal LD50 >2000 mg/kg (rat)

· **Primary irritant effect:**· **on the skin:** No irritant effect.· **on the eye:** Strong irritant with the danger of severe eye injury.

(Contd. on page 4)

GB

Safety Data Sheet
according to 1907/2006/EC, Article 31

Printing date 28.11.2007

Revision: 30.11.2005

Trade name: PFH Ammonium Salt
(C-1500N)

(Contd. of page 3)

- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant
- **Toxicokinetics, metabolism and distribution**
ADME
Rat : Male : T_{1/2} = 1.0 hr, Female : T_{1/2} = 0.42 hr
Monkey : Male : T_{1/2} = 5.3 hr, Female : T_{1/2} = 2.4 hr
- **Repeated dose toxicity**
90-day oral toxicity in rodents
Male NOEL = 10 mg/kg/day (body weight loss at >50 mg/kg, lower Cholesterol and Ca)
Female NOEL = 50 mg/kg/day (lower globulin at 200 mg/kg)
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
Combined repeated dose toxicity with the reproduction/development toxicity screening test
Reproductive (OECD TG 422)
Male & Female NOAEL = 300,450 mg/kg/day (F1: no reproductive changes)

12 Ecological information

- **Information about elimination (persistence and degradability):**
- **Other information:** The product is difficultly biodegradable.
- **Ecotoxicological effects:**
- **Aquatic toxicity:**
Acute toxicity to *Daphnia magna*
24 hr EC₅₀ = >100 mg/L
48 hr EC₅₀ = >100 mg/L
NOEC = >100 mg/L

Acute toxicity to Fish
96 hr LC₅₀ = >100 mg/L
NOEC = >100 mg/L

Algal inhibition test
72 hr EbC₅₀ = 90 mg/L
0-72 hr ErC₅₀ = 86 mg/L
NOEC = 50 mg/L
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13 Disposal considerations

- **Product:**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

(Contd. on page 5)

Safety Data Sheet
according to 1907/2006/EC, Article 31

Printing date 28.11.2007

Revision: 30.11.2005

Trade name: PFH Ammonium Salt
(C-1500N)

(Contd. of page 4)

14 Transport information

- Land transport ADR/RID (cross-border)
- ADR/RID class: -

- Maritime transport IMDG:
- IMDG Class: -
- Marine pollutant: No

- Air transport ICAO-TI and IATA-DGR:
- ICAO/IATA Class: -

15 Regulatory information

- Labelling according to EU guidelines:
Observe the general safety regulations when handling chemicals.
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.

- Code letter and hazard designation of product:
Xi Irritant

- Risk phrases:
41 Risk of serious damage to eyes.

- Safety phrases:
23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).
26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
39 Wear eye/face protection.
60 This material and its container must be disposed of as hazardous waste.

- National regulations:

- Waterhazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Relevant R-phrases
41 Risk of serious damage to eyes.

- Department issuing MSDS: Toxicology and Product Regulatory
- Contact: www.daikin.co.jp/chm/

GB

**ATTACHMENT 3 -
TEST SUBSTANCE PREPARATION PROCEDURE**

ATTACHMENT 3

TEST SUBSTANCE PREPARATION PROCEDURES

Test Substance: PFH Ammonium Salt (Ammonium salt of Perfluorinated Hexanoic Acid); supplied as a 50% aqueous solution

Vehicle: R.O. deionized water

A. Purpose:

The purpose of this procedure is to provide a method for the preparation of the dosage solutions of the test substance for oral (gavage) administration to mice on Study No. UZS00010.

B. General Information:

1. All solution containers will be labeled and color-coded. Each label will specify the study number, vehicle or test substance identification, batch number, concentration, dosage level, dosage group, preparation date, expiration date, and storage conditions, as applicable.
2. Formulations (solutions) of the test substance will be prepared at least once weekly at the Testing Facility by direct dilution of the Sponsor-supplied stock test substance solution with the vehicle; the formulations are stable for at least 10 days. Prepared formulations will be stirred continuously for at least 24 hours prior to dosage administration.
3. Formulations (solutions) will be administered at a final dosage volume of 5 mL/kg.
4. Safety:

- ☒ Double nitrile gloves, uniform/lab coat, goggles or safety glasses with side shields
- ☒ Dust mist/HEPA-filtered Mask
- ☐ Half-Face Respirator
- ☐ Full-Face Respirator/Positive Pressure Hood
- ☒ Tyvek[®] Sleeves

5. The test substance will be considered 95% by weight of PFH acid for the purpose of dosage calculations.
6. Sampling requirements: Cited in protocol
7. Storage: Cited in protocol

C. Preparation of the Dosage Solution for Dosage Group I (0 mg/mL):

NOTE: The dosage formulation for Dosage Group I, which contains the vehicle only, will be prepared, sampled and aliquotted prior to the handling of the test substance.

1. Add the required amount of vehicle to an appropriately sized and labeled container (See TA/S DILUTION CALCULATION SHEET).
2. Add a magnetic stir bar to the container. Place the container on a magnetic stir plate and mix continuously prior to sampling and/or aliquotting.
3. Aliquot the vehicle into an appropriate number of appropriately sized and labeled containers. Aliquots will be stored at room temperature.
5. On the day prior of dosage administration, remove the required number of aliquots from storage. Add a magnetic stir bar to the container. Place the container on a magnetic stir plate and stir continuously at ambient temperature for prior to dosage administration. Continue to mix the vehicle during dosage administration. Any vehicle remaining after being used for dosage administration will be discarded at the Testing Facility.

D. Preparation of the Test Substance Dosage Solutions for Dosage Groups II through IV:

1. Add the required amount of vehicle to an appropriately sized and labeled container (See TA/S DILUTION CALCULATION SHEET).
2. Add the required amount of the Sponsor-supplied stock test substance solution to the container (See TA/S DILUTION CALCULATION SHEET).

3. Add a magnetic stir bar to the container. Place the container on a magnetic stir plate and mix continuously for at least 24 hours prior to sampling and/or aliquotting.
4. Aliquot the formulation into an appropriate number of appropriately sized and labeled containers. Aliquots will be stored at room temperature and used within 10 days after the date of preparation.
5. On the day prior to dosage administration, remove the required number of aliquots from storage. Add a magnetic stir bar to the container. Place the container on a magnetic stir plate and stir continuously at ambient temperature for **at least 24 hours** prior to dosage administration. Continue to mix the formulation during dosage administration. Any formulation remaining after being used for dosage administration will be discarded at the Testing Facility.
6. Repeat steps D1 through D5 for each concentration.

Version: UZS00010(08.DEC.2009) # of pages: 3

**ATTACHMENT 4 -
TESTS, ANALYSES AND MEASUREMENTS**

Clinical Observations

Viability	Twice daily
Acclimation Period	Weekly
Predosage Period	DG 0
Dosage Period	Daily. Before dosage and within 1 and 2 hours postdosage
Postdosage Period	Once daily
Maternal Behavior	Days 1, 5, 8 15 and 21 postpartum. Observed abnormal behavior recorded daily

Body Weights

Acclimation Period	Weekly
Predosage Period	DG 0
Dosage Period	Daily
Postdosage Period	Daily

Mating Performance

Cohabitation Period	Daily, confirmed by copulatory plug
---------------------	-------------------------------------

Natural Delivery Parameters

Natural Delivery	DG 17 + (exact date to be recorded)
Fertility Index	% of matings that result in pregnancies
Gestation Index	% of pregnancies that result in birth of live litters
Number of offspring per litter	Live or dead
Number of Implantation sites	
General Condition of dam and litter during postpartum period	
Viability Indices	% of pups born that survive 5 and/or 8 days
Lactation Index	% of pups that survive 21 days
Adverse Clinical Signs	During parturition
Duration of Gestation	
Litter size	All pups delivered
Pup Viability at Birth	



Protocol Amendment No. 1

**Oral (Gavage) Combined Developmental and Perinatal/Postnatal
Reproduction Toxicity Study of PFH Ammonium Salt (Ammonium salt of
Perfluorinated Hexanoic Acid) in Mice**

Testing Facility Study No. UZS00010

1. Attachment 3 - Test Substance Preparation Procedure

The test substance preparation procedure attached to the protocol [UZS00010 (08.DEC.2009)] is being replaced with the attached test substance preparation procedure [UZS00010 (23.DEC.2009)].

Justification:

The new preparation procedure corrects the procedure from a weight/volume (mg/ml) procedure to a weight/weight (mg/g) procedure.

Protocol Amendment No. 1

Page 2

Testing Facility Study No. UZS00010

Amendment Approval:

28 Dec 09

Date

Executive Director, Site Operations and Toxicology
Study Director

ATTACHMENT 3**TEST SUBSTANCE PREPARATION PROCEDURES**

Test Substance: PFH Ammonium Salt (Ammonium salt of Perfluorinated Hexanoic Acid);
supplied as a 50% aqueous solution

Vehicle: R.O. deionized water

A. Purpose:

The purpose of this procedure is to provide a method for the preparation of the dosage solutions of the test substance for oral (gavage) administration to mice on Study No. UZS00010.

B. General Information:

1. All solution containers will be labeled and color-coded. Each label will specify the study number, vehicle or test substance identification, batch number, concentration, dosage level, dosage group, preparation date, expiration date, and storage conditions, as applicable.
2. Formulations (solutions) of the test substance will be prepared at least once weekly at the Testing Facility by direct dilution of the Sponsor-supplied stock test substance solution with the vehicle; the formulations are stable for at least 10 days. Prepared formulations will be stirred continuously for at least 24 hours prior to dosage administration.
3. Formulations (solutions) will be administered at a final dosage volume of 5 mL/kg.

4. Safety:

- ☒ Double nitrile gloves, uniform/lab coat, goggles or safety glasses with side shields
- ☒ Dust mist/HEPA-filtered Mask
- ☐ Half-Face Respirator
- ☐ Full-Face Respirator/Positive Pressure Hood
- ☒ Tyvek[®] Sleeves

5. The test substance will be considered 95% by weight of PFH acid for the purpose of dosage calculations.

6. Sampling requirements: Cited in protocol
7. Storage: Cited in protocol

C. Preparation of the Dosage Solution for Dosage Group I (0 mg/mL):

NOTE: The dosage formulation for Dosage Group I, which contains the vehicle only, will be prepared, sampled and aliquotted prior to the handling of the test substance.

1. Add the required amount of vehicle to an appropriately sized and labeled container (See TA/S DILUTION CALCULATION SHEET).
2. Add a magnetic stir bar to the container. Place the container on a magnetic stir plate and mix continuously prior to sampling and/or aliquotting.
3. Aliquot the vehicle into an appropriate number of appropriately sized and labeled containers. Aliquots will be stored at room temperature.
5. On the day prior to dosage administration, remove the required number of aliquots from storage. Add a magnetic stir bar to the container. Place the container on a magnetic stir plate and stir continuously at ambient temperature for prior to dosage administration. Continue to mix the vehicle during dosage administration. Any vehicle remaining after being used for dosage administration will be discarded at the Testing Facility.

D. Preparation of the Test Substance Dosage Solutions for Dosage Groups II through IV:

1. Weigh the required amount of the Sponsor-supplied stock test substance solution (in grams) in an appropriately sized volumetric flask (See TA/S DILUTION CALCULATION SHEET).
2. QS to the final required volume with vehicle (See TA/S DILUTION CALCULATION SHEET).
3. Add a magnetic stir bar to the flask. Place the flask on a magnetic stir plate and mix continuously for at least 24 hours prior to and during sampling and/or aliquotting.
4. Aliquot the formulation into an appropriate number of appropriately sized and labeled containers. Aliquots will be stored at room temperature and used within 10 days after the date of preparation.

5. On the day prior to dosage administration, remove the required number of aliquots from storage. Add a magnetic stir bar to the container. Place the container on a magnetic stir plate and stir continuously at ambient temperature for **at least 24 hours** prior to dosage administration. Continue to mix the formulation during dosage administration. Any formulation remaining after being used for dosage administration will be discarded at the Testing Facility.
6. Repeat steps D1 through D5 for each concentration.

Version: UZS00010(23.DEC.2009) # of pages: 3



Protocol Amendment No. 2

Oral (Gavage) Combined Developmental and Perinatal/Postnatal Reproduction Toxicity Study of PFH Ammonium Salt (Ammonium salt of Perfluorinated Hexanoic Acid) in Mice

Testing Facility Study No. UZS00010

1. Section 14.1. Acceptance Criteria

Acceptance criteria for analytical results for each group are defined as follows: 1) concentration results will be considered acceptable if the difference between the actual mean value and the targeted concentration is $\pm 10\%$; 2) homogeneity results for a group will be considered acceptable if the relative standard deviation (RSD) for the formulation, calculated as the RSD for the grand mean of the average values for top, middle and bottom locations, is $\leq 5\%$; ~~and 3) results of 10 day stability analysis will be within $\pm 10\%$ of the concentration of the initial stability analysis. Results obtained outside of the criteria will be considered Out of Specification (OOS) and procedures for investigation and notification will be followed in the applicable laboratory Standard Operating Procedure covering OOS results.~~

Justification:

This change is being made because stability will be determined under a validation study (211052) rather than in conjunction with a concentration analysis.

2. Section 14.3.2. Stability

Stability of the prepared test substance formulations will **not** be documented during this study in conjunction with a concentration analysis. **Stability will be assessed under Charles River Laboratories Preclinical Services Montreal Study Number 211052.**

Justification:

This change is being made to indicate that stability will be assessed under the validation study rather than in conjunction with a concentration analysis.

Protocol Amendment No. 2

Page 2

Testing Facility Study No. UZS00010

Amendment Approval:

Date: 6 APR 2010

Executive Director, Site Operations and Toxicology
Study Director

**APPENDIX 2 - DEVIATIONS FROM THE PROTOCOL AND THE STANDARD
OPERATING PROCEDURES OF THE TESTING FACILITY**

DEVIATIONS

All deviations that occurred during the study have been authorized/acknowledged by the Study Director, assessed for impact, and documented in the study records. All protocol deviations and all SOP and GLP deviations that could have impacted the quality or integrity of the study are listed below. Minor SOP deviations that did not impact the quality or integrity of the study have been included at the discretion of the Study Director.

None of the deviations were considered to have impacted the overall integrity of the study or the interpretation of the study results and conclusions.

DL - Day of lactation

In-life Observations, Measurements and Evaluations

- On 19 January 2010, the daily clinical observations were not recorded for the pups of dam 478 (Group IV) on DL 5. Additionally, clinical observations were not recorded for F1 generation male and female rats on postpartum days 32 through 35 (15 February 2010). These deviations did not adversely affect the outcome or interpretation of the study because it was a single event and/or sufficient data were collected on other days.
- On 19 January 2010, maternal behavior was not recorded for dam 422 (Group II) on DL 7. This deviation did not adversely affect the outcome or interpretation of the study because sufficient data were collected on other days and other rats.

Postmortem

- On 23 February 2010, the liver from F1 generation male mouse 569 (Group IV) containing a gross lesion was retained frozen rather than in neutral buffered 10% formalin. This deviation did not adversely affect the outcome or interpretation of the study because the liver was needed for analysis and no treatment related lesions were occurring.

APPENDIX 3 - CERTIFICATE OF ANALYSIS



Certificate of Analysis

Daikin Industries, LTD.

Name of Sample *PFH Ammonium Salt (C-1500N)*
Lot. *7005*
Date of Analysis *May 14, 2009*
Purify *47.4% (Effective component in Water)*
 **50.8*0.934%=47.4%*

COMPOSITION

identity		Conc.
#1	Ammonium Perfluorohexanoate CAS RN. 21615-47-4	93.4%
#2	Unknown	6.6%
<i>Total</i>		<i>100%</i>

Analysis system (HPLC)

Equipment : *Waters Alliance2695*
Detector : *Waters 2487UV*
Detection wavelength : *210nm*

Analysis condition

Column : *TOSOH TSKGel ODS120T 4.6mm×150mm*
Temp. : *40 °C*
Mobile phase : *A=acetonitrile , B=Solution of 0.6% perchloric acid in water*
Gradient : *A:B=50:50(mass%) (0-10min.) → 90:10(mass%) (15-20min.)*
Injection volume : *20μL*
Injection Concentration : *1% (dilute 50times with water)*

Chemical R&D Center
Unidyne Group
Senior Researcher

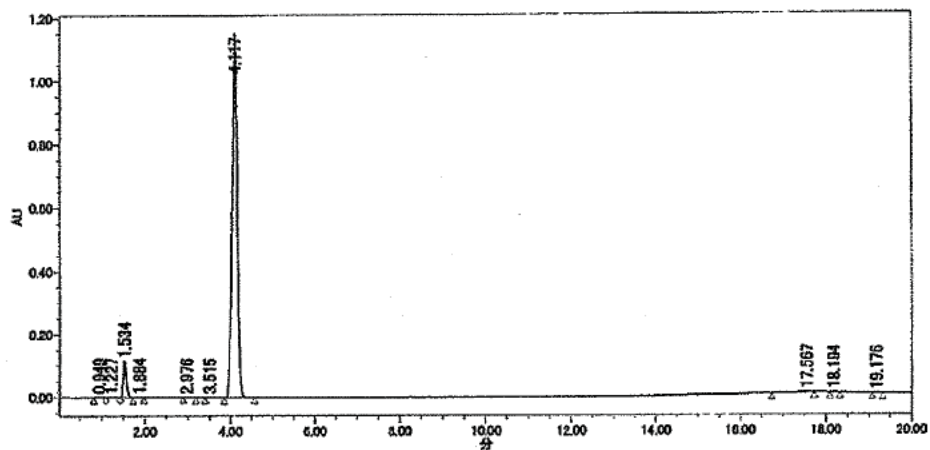
SIGNATURE

DATE : May 18, 2009

Analysis

サンプル名: C1500N
 サンプルの種類: 未知試料
 バイアル: 82
 注入#: 1
 注入量: 20.00 μ l
 分析時間: 20.00 分
 サンプルセット名:

分析担当者: System
 分析日: 2009/05/14 11:49:44
 取り込みメソッドセット: 090514S
 解析日: 2009/05/14 13:55:17
 解析メソッド: C1500N
 チャンネル名: 2487チャンネル 1
 解析チャンネルの説明:



	成分名	Retention Time(min.)	Area (μ Vsec.)	Area (%)	Height (μ V)		
1		0.949	17634	0.18	2554		
2		1.227	20551	0.20	1927		
3		1.534	574660	5.71	116134		
4		1.884	5543	0.06	710		
5		2.976	2424	0.02	414		
6		3.515	4940	0.05	361		
7		4.117	9390042	93.38	1144218		
8		17.567	29475	0.29	984		
9		18.194	6956	0.07	1098		
10		19.176	3881	0.04	592		



Amended expire date

Test Substance : PFH Ammonium Salt (Ammonium salt of Perfluorinated
Hexanoic Acid). Ammonium Perfluorohexanoate's
CAS number : 21615-47-4.
Name of test substance : C1500N
Lot No. : 7005

EXPIRY DATE : 31 July 2012

Sep 16, 2010
.....
Date

Daikin Industries, LTD
Chemical Division

APPENDIX 4 - ANALYTICAL REPORT



FINAL REPORT

**Test Site Ref. No. 211147
Testing Facility Study No. UZS00010**

**Analysis of Dose Formulation Samples and Bulk Material Purity and Stability
from Study Titled: “Oral (Gavage) Combined Developmental and
Perinatal/Postnatal Reproduction Toxicity Study of PFH Ammonium Salt
(Ammonium Salt of Perfluorinated Hexanoic Acid) in Mice” by High
Performance Liquid Chromatography**

TEST SITE:

**Charles River Laboratories Preclinical Services Montreal
2202 Transcanadienne
Senneville, Quebec
Canada H9X 3R3**

TESTING FACILITY:

**Charles River Laboratories Preclinical Services
905 Sheehy Drive, Building A
Horsham, PA 19044
USA**

SPONSOR:

**Daikin Industries, LTD
Chemical Division
Umeda Center Building
4-12 Nakazaki-Nishi, 2-chrome
Kita-ku, Osaka 530-8323
Japan**

23 June 2011

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Appendix 1 Certificate of Analysis25

Testing Facility Study No. UZS00010

Test Site Ref. No. 211147

1. COMPLIANCE STATEMENT

This portion of the study, conducted at Charles River Laboratories Preclinical Services Montreal (PCS-MTL), 22022 Transcanadienne, Senneville, Quebec, Canada, H9X 3R3, complied with the Good Laboratory Practice (GLP) Regulations of the United States Food and Drug Administration and the appropriate GLP principles of the Organization for Economic Co-operation and Development (OECD), (ENV/MC/CHEM(98)17.

_____ 23 Jun 2011
Date

Principal Investigator
Research Scientist, Analytical Chemistry
Laboratory Sciences
Charles River Laboratories

Testing Facility Study No. UZS00010

Page 7
Test Site Ref. No. 211147**2. QUALITY ASSURANCE STATEMENT**

In compliance with the Good Laboratory Practice Regulations, Reference No. 211147 has been audited. The data presented in the final report accurately represent the data collected during the conduct of the study.

Phase or Segment Audited	Date of Inspection	Dates of Reports to Test Site Management and Principal Investigator	Dates of Reports to Testing Facility Management/ Study Director & Lead QA
Protocol Review	02 December 2009	07 December 2009	12 May 2010
SOP Review - In-life	23 February 2010	23 February 2010	12 May 2010
Protocol Amendment Review	26 April 2010	27 April 2010	12 May 2010
Protocol Amendment Review	26 April 2010	27 April 2010	12 May 2010
Anchem Dose Data Anchem Dose Report - Report Review Anchem Dose Report Tabulation	26 April 2010 to 04 May 2010	04 May 2010	12 May 2010
Final Report Review	08 June 2011 to 13 June 2011	13 June 2011	16 June 2011

In addition to the above-mentioned inspections, process based and/or routine facility inspections were also conducted during the course of this study. Any findings specific to this study from these inspections are reported with this QA Statement. All other observations and the dates of reports to PCS-MTL Management are retained on file according to PCS-MTL Quality Assurance Standard Operating Procedures.

Inspector
Quality Assurance
Charles River Laboratories

23 Jun 2011
Date

Testing Facility Study No. UZS00010

Test Site Ref. No. 211147

3. SUMMARY

The purpose of this phase of the study was to determine the concentration and the purity and stability of the bulk drug substance of Perfluorohexanoic acid (PFH) ammonium salt in dose formulations from Charles River Laboratories Study No. UZS00010 titled “Oral (Gavage) Combined Developmental and Perinatal/Postnatal Reproduction Toxicity Study of PFH Ammonium Salt (Ammonium salt of Perfluorinated Hexanoic Acid) in Mice” by high performance liquid chromatography (HPLC).

The method of analysis, documented in Analytical Procedure AP.211147.SL.03 for concentration determination was previously validated under Study No. 211052. The method documented in Analytical Procedure AP.211147.PU.02, for bulk material purity and stability analysis was provided by the Sponsor.

The study samples analyzed were within the acceptance criteria of $\pm 10\%$ of their nominal concentrations, with the exception of the Group 2 samples prepared on 28 December 2009, 04 and 11 January 2010. For homogeneity, the relative standard deviation (RSD) for the formulation for the grand mean of the average value for the top, middle and bottom formulations for each group was $\leq 5\%$.

The bulk material was analyzed for purity and stability, and the result was compared to the purity value stated on the Certificate of Analysis (CoA) and was deemed acceptable since the purity value was within $\pm 10\%$ of the value indicated in the Certificate of Analysis.

Testing Facility Study No. UZS00010

Test Site Ref. No. 211147

4. INTRODUCTION

A high performance liquid chromatographic (HPLC) method was used to determine the concentration of test article in dose formulations and the purity and stability of the bulk drug substance from Study No. UZS00010 titled “Oral (Gavage) Combined Developmental and Perinatal/Postnatal Reproduction Toxicity Study of PFH Ammonium Salt (Ammonium salt of Perfluorinated Hexanoic Acid) in Mice”.

The method of analysis, documented in Analytical Procedure AP.211147.SL.03 for concentration determination was previously validated under Study No. 211052. The method documented in Analytical Procedure AP.211147.PU.02, for bulk material purity and stability analysis was provided by the Sponsor.

For the work detailed in this report, the study initiation date was 21 December 2009 (the signature date of the protocol) and the completion date is the signature date of the final report. The experimental start date was 27 January 2010 and the experimental end date was 16 February 2010.

5. REFERENCE STANDARD AND VEHICLE

5.1. Reference Standard (Bulk Substance)

Identity:	PFH Ammonium Salt (C-1500N)
Lot number:	7005
Purity:	47.4% (total purity)
Expiry date:	31 July 2010
Description:	Clear colourless liquid
Storage conditions:	Room temperature, light
Handling precautions:	As per the material safety data sheets
Supplier:	Charles River Pennsylvania

The reference standard characterization is the responsibility of the Sponsor who provided a Certificate of Analysis ([Appendix 1](#)) for inclusion in this study report. The expiry date was provided by the Sponsor in a written correspondence.

Details of identity, purity, storage conditions and handling precautions were supplied by the Sponsor. Remaining reference standard was used on subsequent studies for the Sponsor.

Testing Facility Study No. UZS00010

Test Site Ref. No. 211147

5.2. Vehicle

Identity: Reverse osmosis deionized water

Storage conditions: Room temperature

6. EXPERIMENTAL PROCEDURES

6.1. Standard Stock Solutions

Standard stock solutions of reference standard were prepared in diluent (acetonitrile:methanol:water (10:10:80, v/v/v) containing 0.1% (v/v) phosphoric acid) at a nominal concentration of 2.37 mg/mL.

6.2. Standard Solutions

Standard solutions of reference standard were prepared in diluent covering the nominal concentration range of 23.7 to 237 µg/mL.

6.3. Spiked Samples

Spiked samples were prepared in vehicle at nominal concentrations of 0.500 and 90.0 mg/mL. Each was diluted with diluent to give nominal concentrations of 40.0 and 180 µg/mL, respectively.

6.4. Study Samples

Formulation samples (top, middle and bottom) from Study No. UZS00010 prepared on 28 December 2009 and sampled on 29 December 2009 were received at ambient temperature on 30 December 2009 for concentration and homogeneity determination. Furthermore, formulation samples (middle) prepared on the 04 and 11 January 2010 were received at ambient temperature on the 06 and 13 January 2010 for concentration analysis. The samples prepared on the 28 December 2009, 04 and 11 January 2010 were stored at room temperature for approximately 39, 32 and 25 days until analysis. The samples at nominal concentrations of 1.4, 7 and 35 mg/mL were diluted with diluent to give injected concentrations within the range of the calibration curve.

For concentration analysis, the results were considered acceptable if the difference between the actual mean value and the targeted concentration was within $\pm 10\%$. For homogeneity, the results were considered acceptable if the relative standard deviation (RSD) for the formulation calculated as the RSD for the grand mean of the average values for the top, middle and bottom locations was $\leq 5\%$.

Testing Facility Study No. UZS00010

Test Site Ref. No. 211147

6.5. Bulk Test Substance Stability

A 10 mL sample of the test substance (50% w/w) was received from study UZS00010 for stability assessment. The sample was shipped at ambient temperature on 19 January 2010 and received at PCS-MTL on 21 January 2010. The sample was stored at room temperature and analyzed on 28 January 2010. The bulk substance was diluted 50 times with diluent (ultra pure water) to give a target concentration of 1% test substance. Stability was assessed by HPLC purity normalization and the result obtained was compared against the purity value stated in the Certificate of Analysis.

6.6. Analysis

The standard, blank, spiked sample and study sample solutions were analyzed for concentration by HPLC using the following conditions:

HPLC system: Agilent Technologies 1100 series
Data capture system: Waters Corporation Empower 2 (Build 2154 FR2 SPB),
Column: Zorbax Eclipse Plus C-18, 3.5 μ m (100 x 2.1 mm id)
Column temperature: Set at 35°C
Mobile phase gradient elution: Eluant A: 20 mM sodium phosphate in water
Eluant B: 10 mM sodium perchlorate in acetonitrile

Time (min)	%B
0	10
8	70
8.1	10
15	10

Flow-rate: 0.350 mL/min
Ultra-violet detection wavelength: 210 nm (response time: 0.5 s)
Injection volume: 25 μ L
Sample tray temperature: Set at 20°C
Reference standard retention time: ~7.0 min

The blank and bulk substance solutions were analyzed for purity and stability using the following conditions:

HPLC system: Agilent Technologies 1100 series
Data capture system: Waters Corporation Empower 2 (Build 2154 FR2 SPB)
Column: TOSOH TSKGel ODS120T, (150 x 4.6 mm id)
Column temperature: Set at 40°C

Testing Facility Study No. UZS00010

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Mobile phase gradient elution: Eluant A: acetonitrile
Eluant B: 0.6% perchloric acid in water

Time (min)	%B
0	50
10	50
15	10
20	10
20.1	50
25	50

Flow-rate: 1.00 mL/min
Ultra-violet detection wavelength: 210 nm
Injection volume: 20 µL
Sample tray temperature: Set at 20°C
Reference standard retention time: ~3.9 min

6.7. System Suitability

For concentration determination, the reproducibility of the chromatographic system was determined by injecting a calibration standard solution, at a nominal concentration of 190 µg/mL in triplicate, at the beginning, throughout and at the end of the chromatographic run.

For bulk substance stability, the reproducibility of the chromatographic system was determined by injecting a 1% test sample solution, in triplicate, at the beginning and at the end of the chromatographic run.

A coefficient of variation (CV) of $\leq 3\%$ in peak area and a difference of $\pm 10\%$ between the average response for the standards (test sample solution) injected at the end and throughout the run, compared with those injected at the beginning were considered acceptable.

6.8. Data Collection and Statistical Methods

Data collection was performed using Empower 2 (Build 2154 FR2 SPB), from Waters Corporation.

Statistical analyses included linear regression with no weighting factor, using Empower 2 and descriptive statistics such as arithmetic means and standard deviations, using Microsoft Excel (Version 2000/2003).

Tables were prepared from retrospective manual entry on computer (Microsoft Word, Version 2000/2003). The data presented in the tables were calculated from non-rounded values and may not be accurately reproduced from the individual data presented.

6.9. Quality Assurance

The Quality Assurance department of PCS-MTL undertook and documented inspections and process audits of the analytical laboratory during the study conduct, and audited the study report as well as the raw data. The Quality Assurance Statement is presented on [Page 7](#).

6.10. Archives

All raw data and documents generated at PCS-MTL during this study, and the final report will be transferred to the scientific archives of PCS-MTL for a period of approximately one year from finalization. Storage details following the one year archive period will be documented in the raw data as per study protocol.

7. RESULTS AND DISCUSSION

Representative chromatograms are presented in [Figure 1](#), [Figure 2](#), [Figure 3](#), [Figure 4](#), [Figure 5](#) and [Figure 6](#).

7.1. System Suitability

The CV for the calibration standards was $\leq 3\%$, and the difference between the average response for the standards injected at the end and throughout the run, compared with those injected at the beginning was within $\pm 10\%$. Acceptance criteria with respect to system suitability were met.

For bulk substance stability, the CV for 1% test sample solution was $\leq 3\%$, and the difference between the average responses for the test sample solutions injected at the end, compared with those injected at the beginning was within $\pm 10\%$.

7.2. Study Samples

All study samples analyzed for concentration were within the acceptance criteria of $\pm 10\%$ of their target values, with the exception of the Group 2 samples prepared on 28 December 2009 and on 04 and 11 January 2010 (mean recoveries of 123, 114 and 111%, respectively); therefore, as part of the investigation, the back-up samples were analyzed and the results confirmed the initial results (mean recoveries of 123, 115 and 111%, respectively). The investigation demonstrated that the Group 2 samples prepared on 28 December 2009, 04 and 11 January 2010 were out of specification. For homogeneity, the relative standard deviation of the grand mean for all locations was $\leq 5\%$ for all groups.

Results are presented in [Table 1](#) and [Table 2](#).

7.3. Bulk Test Substance Stability

Stability of the bulk substance was assessed and the purity was determined to be 100%. The difference between the purity value obtained, when compared with the purity value indicated on the Certificate of Analysis was 7.1%. Results are presented in [Table 3](#).

8. CONCLUSION

Overall, the dose formulations were within specification, with the exception of the Group 2 samples prepared on 28 December 2009 and on the 04 and 11 January 2010. Homogeneity results show that the formulation technique used produces homogenous preparations.

In addition, purity and stability of the bulk reference material was assessed following 13 days of storage at room temperature and results were deemed acceptable.

Table 1 Study Samples - Concentration and Homogeneity

Preparation date	Group	Nominal concentration (mg/mL)	Sampling location	Measured concentration (mg/mL)	(Percent of nominal)	Homogeneity (RSD)
28 Dec 2009	1	0	Top	< LLOQ	-	-
				< LLOQ	-	
			Middle	< LLOQ	-	
				< LLOQ	-	
			Bottom	< LLOQ	-	
				< LLOQ	-	
			Mean	< LLOQ	-	
	2	1.4	Top	1.72	123*	0.3
				1.74	124*	
			Middle	1.74	124*	
				1.70	122*	
			Bottom	1.72	123*	
				1.73	124*	
			Mean	1.73	123*	
	2 (back-up)	1.4	Top	1.72	123*	0.4
				1.71	122*	
			Middle	1.72	123*	
				1.73	123*	
			Bottom	1.71	123*	
				1.74	125*	
			Mean	1.72	123*	

LLOQ - lower limit of quantitation (0.500 mg/mL)

* results out of acceptance criteria

Table 1 Study Samples - Concentration and Homogeneity (Cont'd)

Preparation date	Group	Nominal concentration (mg/mL)	Sampling location	Measured concentration (mg/mL)	(Percent of nominal)	Homogeneity (RSD)
28 Dec 2009	3	7	Top	7.50	107	0.3
				7.48	107	
			Middle	7.52	108	
				7.54	108	
			Bottom	7.52	108	
				7.49	107	
			Mean	7.51	107	
	4	35	Top	35.9	103	0.6
				35.6	102	
			Middle	36.6	104	
				35.7	102	
			Bottom	35.8	102	
				35.7	102	
			Mean	35.9	103	

LLOQ - lower limit of quantitation (0.500 mg/mL)

Table 2 Study Samples - Concentration

Preparation date	Group identification/level	Nominal concentration (mg/mL)	Measured concentration (mg/mL)	Mean measured concentration (mg/mL)	Percent of nominal	Mean percent of nominal
04 Jan 2010	1/ Mid	0	< LLOQ	< LLOQ	-	-
			< LLOQ		-	
	2/ Mid	1.4	1.61	1.60	115*	114*
			1.58		113*	
	2/ Mid (back-up)	1.4	1.60	1.61	115*	115*
			1.61		115*	
	3/ Mid	7	7.20	7.14	103	102
			7.08		101	
	4/ Mid	35	34.8	35.0	99.4	100
			35.1		100	
11 Jan 2010	1/ Mid	0	< LLOQ	< LLOQ	-	-
			< LLOQ		-	
	2/ Mid	1.4	1.54	1.56	110	111*
			1.57		112*	
	2/ Mid (back-up)	1.4	1.55	1.55	111*	111*
			1.55		111*	
	3/ Mid	7	7.07	7.07	101	101
			7.07		101	
	4/ Mid	35	35.3	35.3	101	101
			35.4		101	

* results out of acceptance criteria

LLOQ - lower limit of quantitation (0.500 mg/mL)

Testing Facility Study No. UZS00010

Test Site Ref. No. 211147

Table 3 Bulk Substance Stability (13 Days Storage at Room Temperature)

Bulk substance assessed purity (%)	Bulk substance impurity (%)	Bulk material CoA purity (%)	Bulk material CoA total impurity (%)	Percent difference^a
100	0.0	93.4	6.6	7.1

a assessed purity is compared with the purity stated on the C of A

Figure 1 **Representative Standard Chromatogram**
(Nominal Concentration: 190 µg/mL)

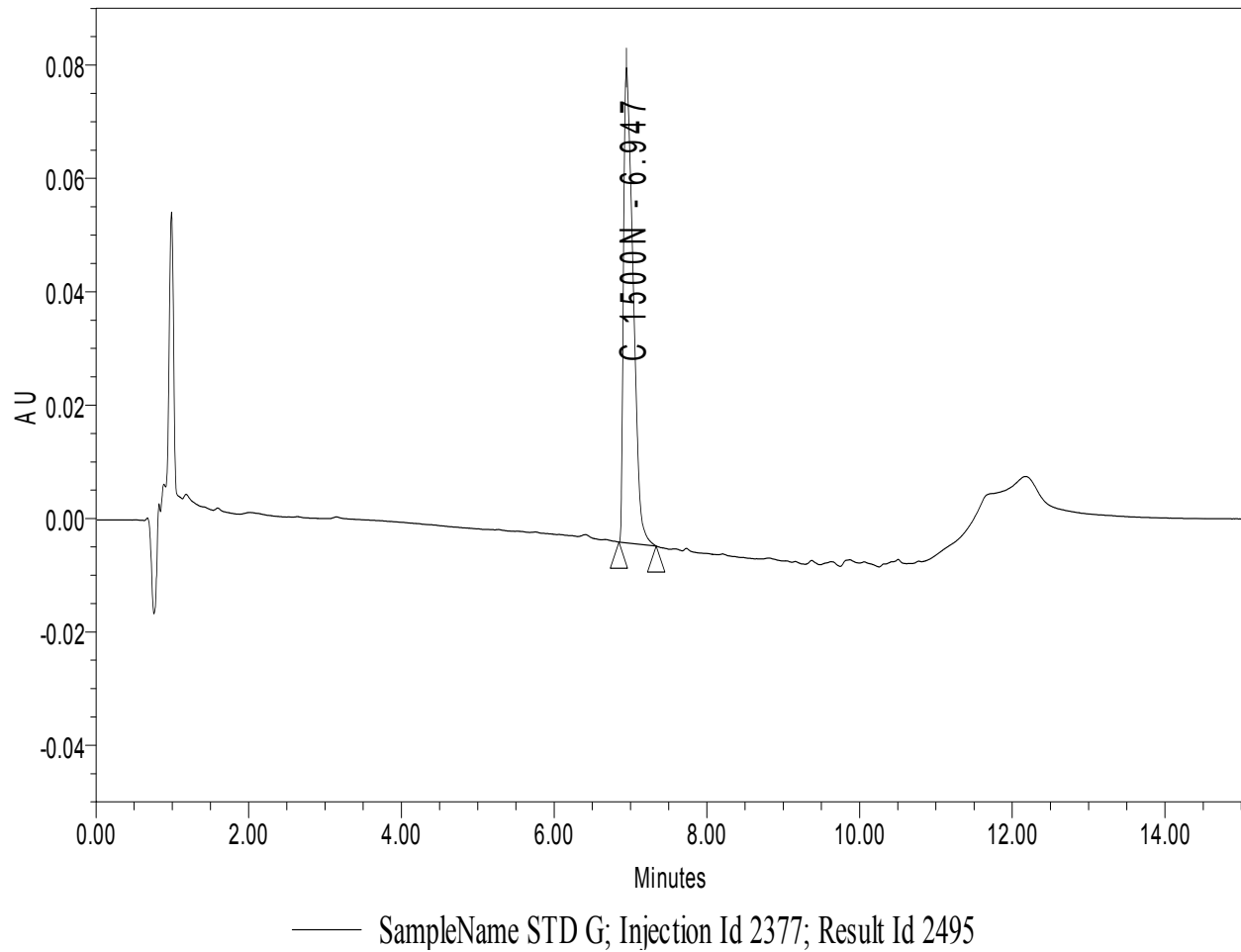
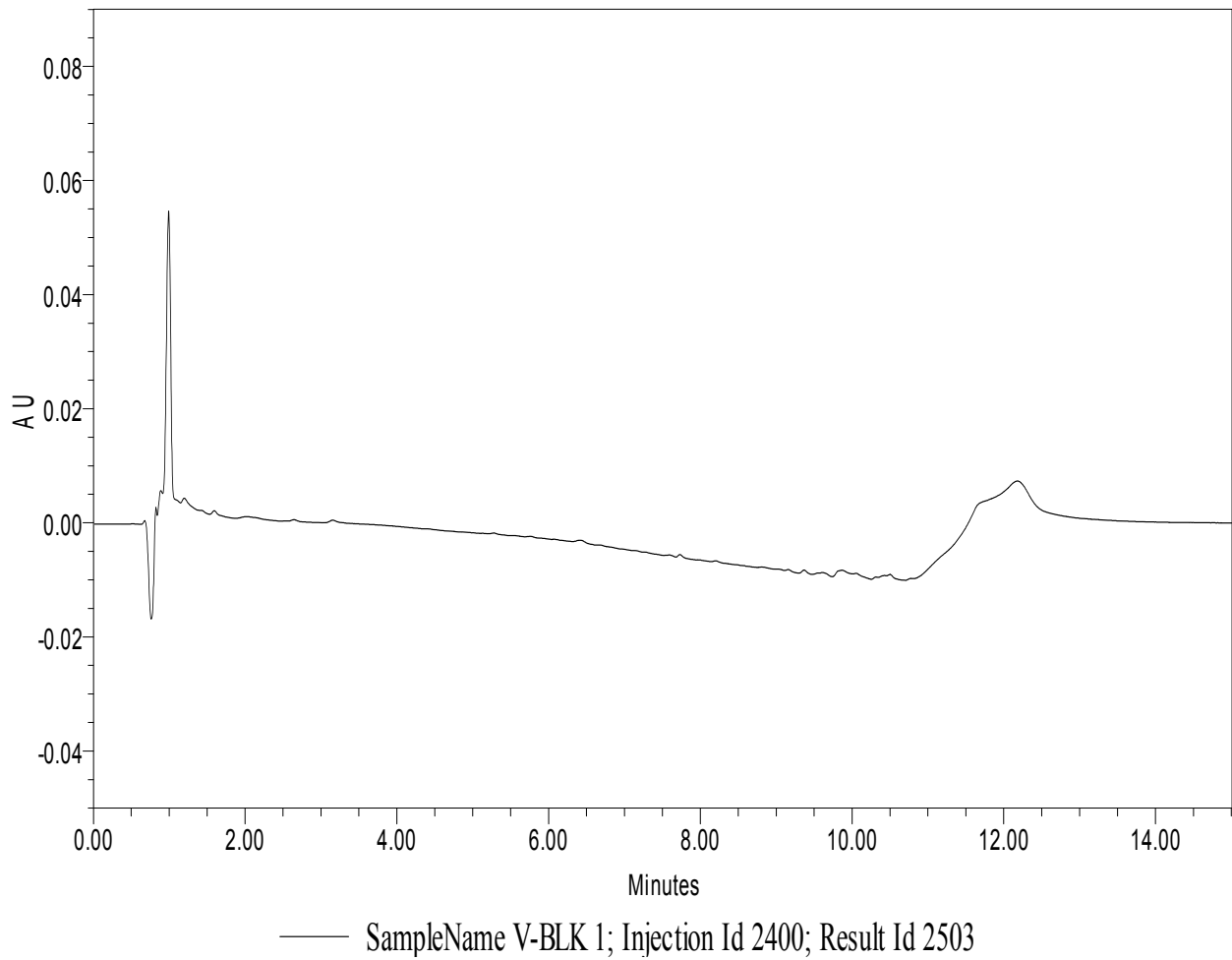


Figure 2 **Representative Blank Vehicle**



Testing Facility Study No. UZS00010

Test Site Ref. No. 211147

Figure 3

Representative Study Sample Chromatogram
(Group 3, Mid, Sampling Date: 29 December 2009, Nominal
Concentration: 7.00 mg/mL; Nominal Injected
Concentration: 112 µg/mL)

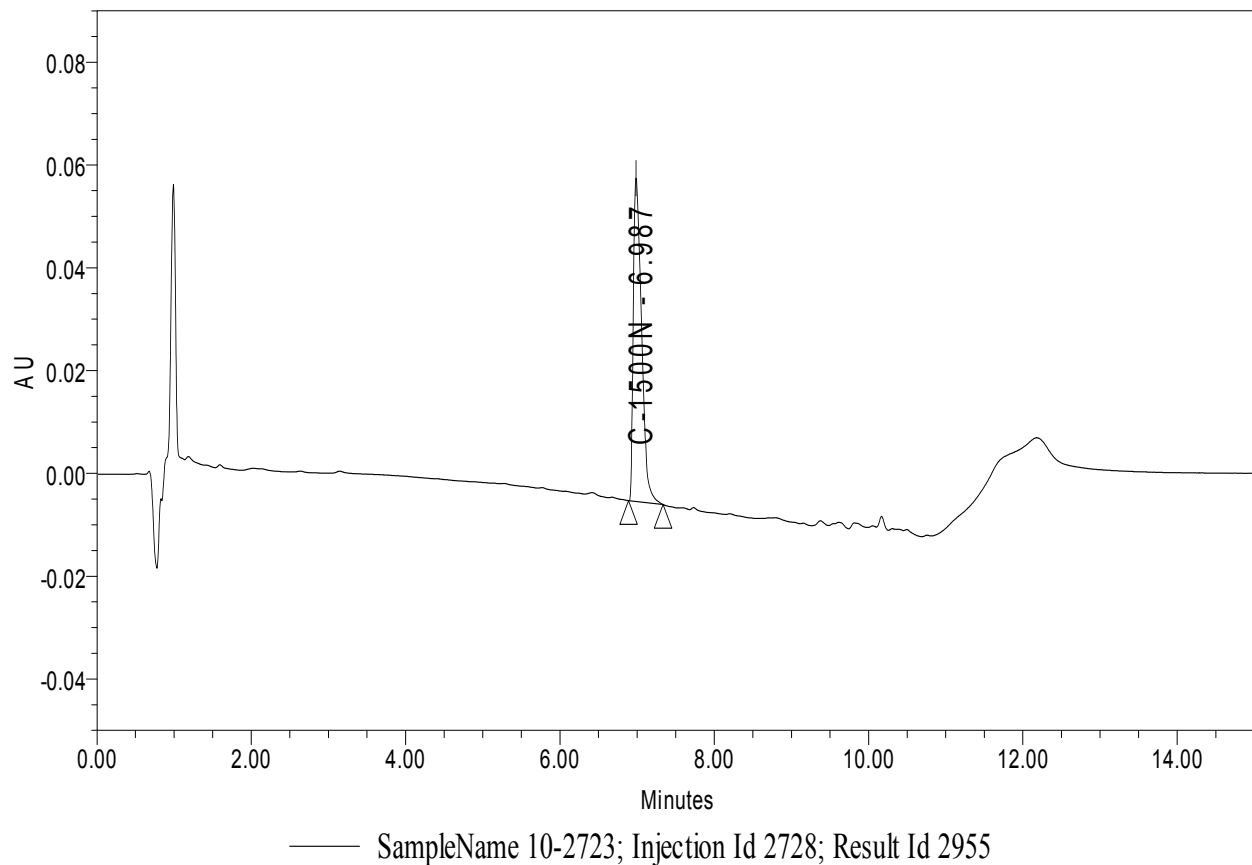
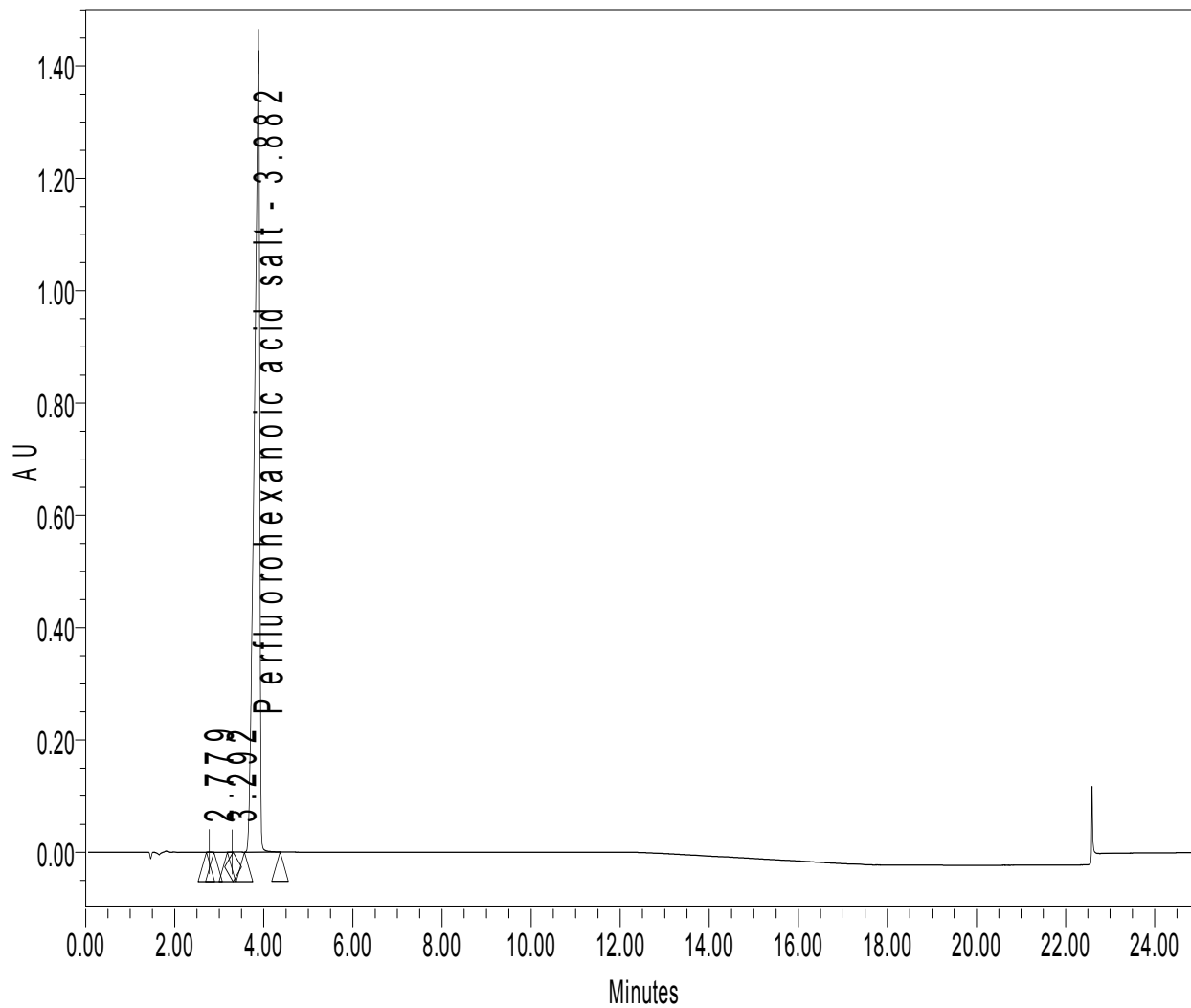
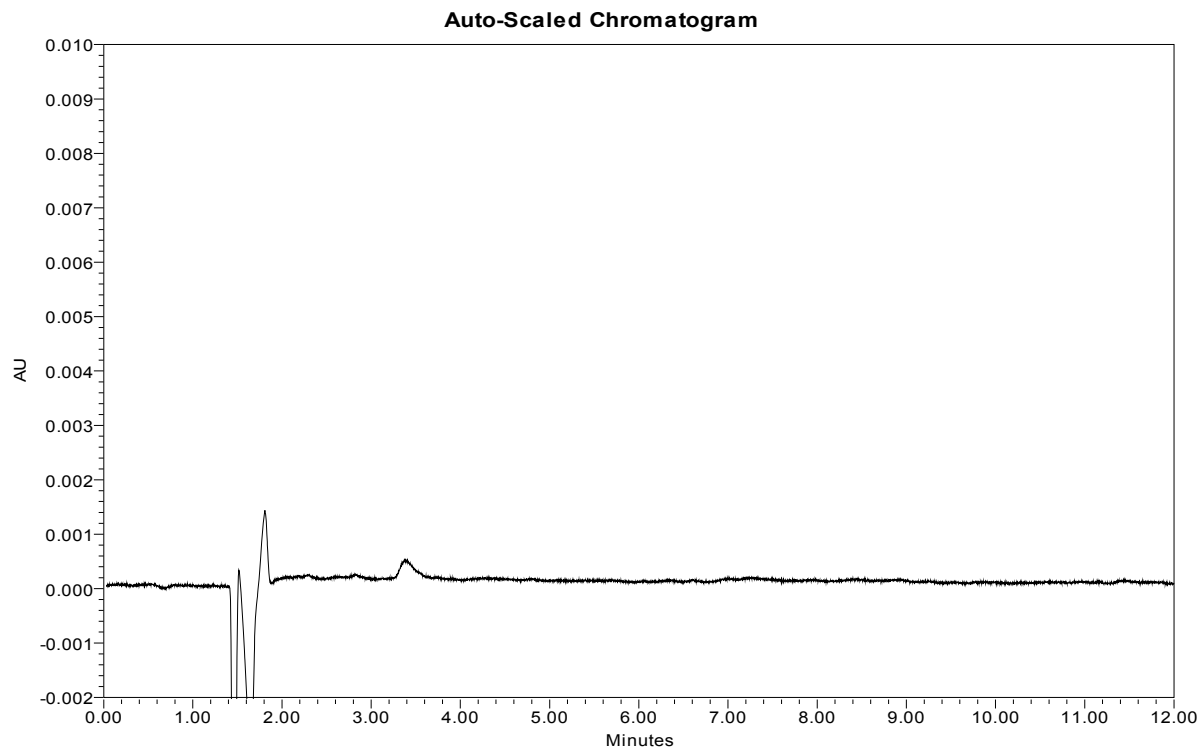


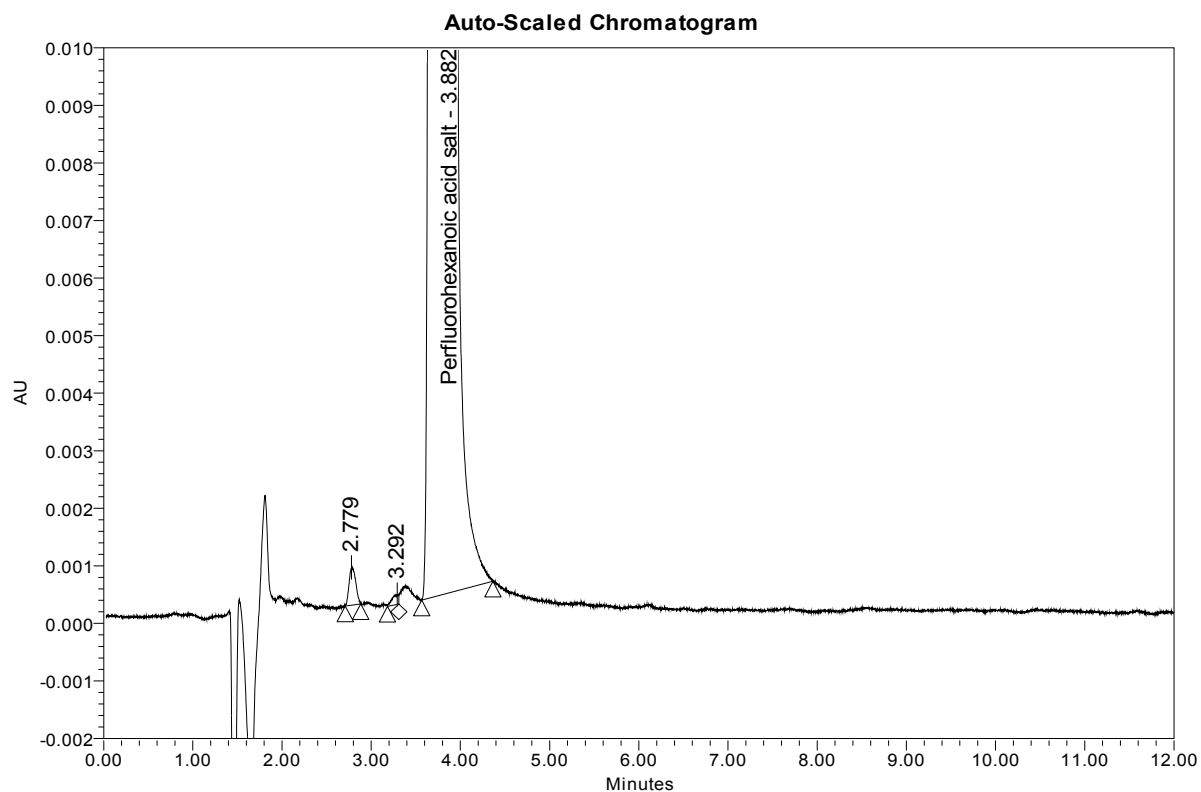
Figure 4 **Representative Bulk Substance Sample (Full Scale)**



— SampleName SS1; Injection Id 1205; Result Id 1252

Figure 5 **Representative Blank Sample (Auto-scaled)****Peak Results**

	Name	SMP_Name	Injection Id	Result Id	% Area	Area	RT
1	Perfluorohexanoic acid salt	BLK	1185	1255			3.873

Figure 6 **Representative Bulk Substance Sample (Auto-scaled)****Peak Results**

	Name	SMP_Name	Injection Id	Result Id	% Area	Area	RT
1		SS1	1205	1252	0.03	3401	2.779
2		SS1	1205	1252	0.01	866	3.292
3	Perfluorohexanoic acid salt	SS1	1205	1252	99.96	11840218	3.882

Appendix 1

Certificate of Analysis

Testing Facility Study No. UZS00010

Test Site Ref. No. 211147

DAIKIN**Certificate of Analysis****Daikin Industries,LTD.**

Name of Sample *PFH Ammonium Salt (C-1500N)*
Lot. *7005*
Date of Analysis *May 14, 2009*
Purify *47.4% (Effective component in Water)*
 **50.8*0.934%=47.4%*

COMPOSITION

identity		Conc.
#1	Ammonium Perfluorohexanoate CAS RN. 21615-47-4	93.4%
#2	Unknown	6.6%
Total		100%

Analysis system (HPLC)

Equipment : *Waters Alliance2695*
Detector : *Waters 2487UV*
Detection wavelength : *210nm*

Analysis condition

Column : *TOSOH TSKGel ODS120T 4.6mm×150mm*
Temp. : *40 °C*
Mobile phase : *A=acetonitrile 、 B=Solution of 0.6% perchloric acid in water*
Gradient : *A:B=50:50(mass%) (0-10min.) → 90:10(mass%) (15-20min.)*
Injection volume : *20μL*
Injection Concentration : *1% (dilute 50times with water)*

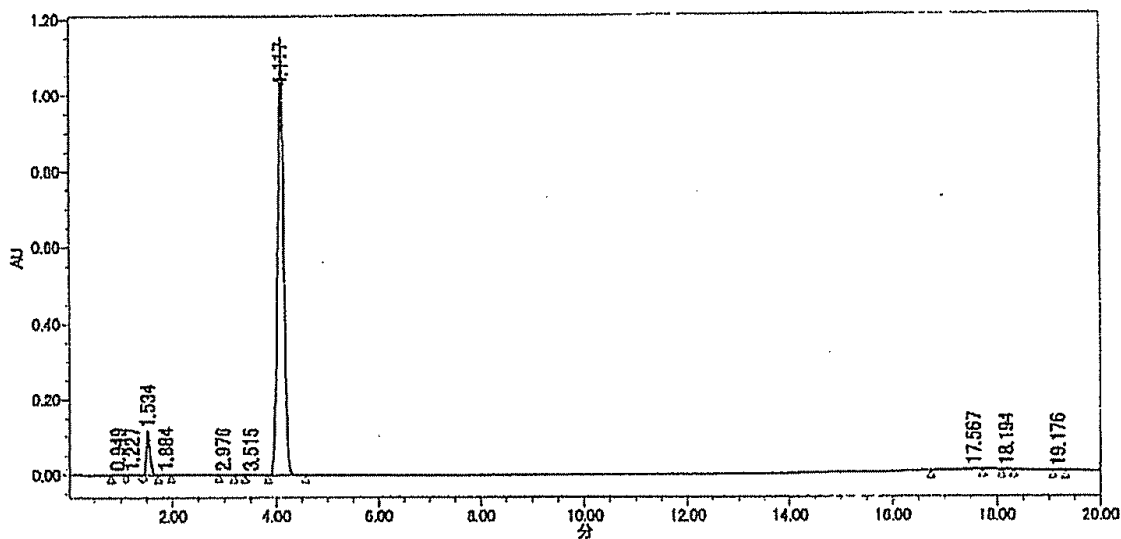
Chemical R&D Center
Unidyne Group
Senior Researcher

SIGNATURE**DATE : May 18, 2009**

Analysis

サンプル名: Q1500N
 サンプルの種類: 未知試料
 バイアル: 82
 注入#: 1
 注入量: 20.00 μ l
 分析時間: 20.00 分
 サンプルセット名:

分析担当者: System
 分析日: 2009/05/14 11:40:44
 取り込みメソッドセット: 090514S
 解析日: 2009/05/14 13:55:17
 解析メソッド: C1500N
 チャンネル名: 2487チャンネル 1
 解析チャンネルの説明:



	成分名	Retention Time(min.)	Area (μ Vsec.)	Area (%)	Height (μ V)		
1		0.949	17034	0.18	2554		
2		1.227	20551	0.20	1027		
3		1.534	574660	5.71	116134		
4		1.884	5543	0.06	710		
5		2.976	2424	0.02	414		
6		3.515	4940	0.05	361		
7		4.117	9390042	93.38	1144218		
8		17.567	29475	0.29	984		
9		18.194	6956	0.07	1098		
10		19.176	3881	0.04	592		

APPENDIX 5 - PHARMACOKINETIC REPORTS



FINAL REPORT

**Test Site Ref. No. 141662
Testing Facility Study No. UZS00010**

**Determination of Perfluorohexanoic Acid (PFHxA) in Mouse Serum by
Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS) in
Support of Study No. UZS00010**

**TEST SITE:
Charles River Laboratories Preclinical Services Montreal
22022 Transcanadienne
Senneville, Quebec
Canada H9X 3R3**

**TESTING FACILITY:
Charles River Laboratories
Preclinical Services
905 Sheehy Drive, Building A
Horsham, PA 19044
USA**

**SPONSOR:
Daikin Industries, LTD
Chemical Division
Umeda Center Building
4-12 Nakazaki-Nishi, 2-chrome
Kita-ku, Osaka 530-8323
Japan**

20 June 2011

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Testing Facility Study No. UZS00010

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Test Site Ref. No. 141662

1. COMPLIANCE STATEMENT

This phase of the study, conducted at Charles River Laboratories Preclinical Services Montreal (PCS-MTL), 22022 Transcanadienne, Senneville, Quebec, Canada, H9X 3R3, complied with the appropriate Organization for Economic Co-operation and Development (OECD) Principles of GLP (ENV/MC/CHEM(98)17).

Date

20 Jun 2011

Bioanalytical Principal Investigator
Research Scientist, Bioanalysis
Laboratory Sciences
Charles River Laboratories

Testing Facility Study No. UZS00010

Test Site Ref. No. 141662

2. QUALITY ASSURANCE STATEMENT

In compliance with the appropriate Good Laboratory Practice Regulations, Reference No. 141662 has been audited. The data presented in the final report accurately represent the data collected during the conduct of the study.

Phase or Segment Audited	Date of Inspection	Dates of Reports to Test Site Management and Principal Investigator	Dates of Reports to Testing Facility Management/ Study Director & Lead QA
Protocol Review	02 December 2009	07 December 2009	11 May 2010
SOP Review - In-life	09 March 2010	09 March 2010	11 May 2010
Bioanalysis Data Sample Management/Shipping Records - Data Review Bioanalysis Report Tabulation Bioanalysis Matrix Report	04 May 2010 to 07 May 2010	07 May 2010	11 May 2010
Final Report Review	10 June 2011	10 June 2011	16 June 2011

In addition to the above-mentioned inspections, process based and/or routine facility inspections were also conducted during the course of this study. Any findings specific to this study from these inspections are reported with this QA Statement. All other observations and the dates of reports to PCS-MTL Management are retained on file according to PCS-MTL Quality Assurance Standard Operating Procedures.

20 Jun 2011
Date

Inspector
Quality Assurance
Charles River Laboratories

3. SUMMARY

The concentrations of perfluorohexanoic acid (PFHxA) in mouse serum samples in support of Testing Facility Study No. UZS00010, entitled “Oral (Gavage) Combined Developmental and Perinatal/Postnatal Reproduction Toxicity Study of PFH Ammonium Salt (Ammonium Salt of Perfluorinated Hexanoic Acid) in Mice”, were determined using a previously validated liquid chromatography-tandem mass spectrometry (LC-MS/MS) method. Results for all samples analyzed are presented in this report.

Note: In this bioanalytical portion study, the reference standard is identified as perfluorohexanoic acid (PFHxA) which is equivalent to PFH ammonium salt (ammonium salt of perfluorinated Hexanoic Acid).

Testing Facility Study No. UZS00010

Test Site Ref. No. 141662

4. INTRODUCTION

The concentrations of perfluorohexanoic acid in mouse serum samples were determined by a liquid chromatography-tandem mass spectrometry (LC-MS/MS) method. The method of analysis, documented in PCS-MTL analytical procedure AP.141662.SE.01, was previously validated (Study No. 141837).

For the work detailed in this report, the experimental start date was 09 March 2010 and the experimental end date was 09 March 2010. The completion date is the signature date of the final report.

5. REFERENCE STANDARD, INTERNAL STANDARD AND BLANK MATRIX

5.1. Reference Standard

Identity:	PFH ammonium salt (50% aqueous solution: 474 mg/mL) (also known as perfluorohexanoic acid or PFHxA)
Lot number:	7005
Purity:	93.4% (correction factor: 0.474, corrected for effective component in solution)
Expiry date:	31 July 2010
Storage conditions:	In a controlled temperature area set at 21°C

5.2. Internal Standard

Identity:	Perfluoro-n-[1, 2- ¹³ C ₂] hexanoic acid (also known as PFHxA-1, 2- ¹³ C ₂)
Lot number:	MPFHxA0809
Purity:	> 98% (50 µg/mL certified solution)
Expiry date:	19 August 2012
Storage condition:	In a refrigerator set at 4°C, dark

The reference standard characterization was the responsibility of the Sponsor who provided a Certificate of Analysis ([Appendix 1](#)) for inclusion in this study report.

Details of identity, purity, storage conditions and handling precautions were supplied by the Sponsor. Remaining reference standard was stored at PCS-MTL for use on subsequent studies for the Sponsor.

Testing Facility Study No. UZS00010

Test Site Ref. No. 141662

5.3. Blank Matrix

Identity: Female mouse serum
Species: *Mus musculus*
Strain: CD1

6. EXPERIMENTAL PROCEDURES

6.1. Calibration Standards

Calibration standards of reference standard were prepared in blank female mouse serum covering the theoretical concentration range of 1.00 to 1000 µg/mL. Calibration standards consisted of blank female mouse serum (250 µL) spiked with appropriate standard working solution (methanol; 5 µL).

6.2. Quality Control Samples

Quality control (QC) samples of reference standard were prepared in blank female mouse serum at theoretical concentrations of 3.00, 60.0 and 700 µg/mL. QC samples consisted of blank female mouse serum (250 µL) spiked with appropriate QC working solution (methanol; 5 µL).

6.3. Study Samples

Study samples were received from Charles River Laboratories Preclinical Services (Pennsylvania) and stored frozen in the freezer set to maintain at -80°C prior to analysis.

Remaining unused study samples will be retained at PCS-MTL for approximately 1 year after dispatch of the final report or until authorized to discard by the Study Director.

6.4. Analysis

Single and double blank samples consisted of blank female mouse serum (250 µL) plus methanol (5 µL). To each standard, QC, single and double blank sample and study samples (10 µL), acetonitrile (100 µL) was added and the mixtures vortexed (~30 seconds) and centrifuged (~14000 rpm, ~10 minutes, set at 4°C). An aliquot (10 µL) of the supernatant was transferred to an appropriately labelled tube containing internal standard (100 ng/mL; 1.0 mL) or for double blank sample an aliquot (10 µL) of the supernatant was transferred to an appropriately labelled tube containing a solution of water:methanol (30:70, v/v; 1.0 mL) and the mixture vortexed. An aliquot (100 µL) of the mixture was transferred to a 96-well collection plate containing a solution of water:methanol (30:70, v/v; 900 µL) and the extracts vortexed (~30 seconds).

Testing Facility Study No. UZS00010

Test Site Ref. No. 141662

The standard, QC, blank and study sample extracts were analyzed by LC-MS/MS using the following conditions:

6.4.1. Liquid Chromatography

HPLC system:	Agilent Technologies 1100 series binary pump and degasser, and Shimadzu SIL-HTC autosampler						
Column:	Waters XBridge Shield RP18, 3.5 μ m (50 x 4.6 mm id)						
Column temperature:	Set at 50°C						
Mobile phase gradient elution:	Eluent A: 2mM ammonium acetate, pH 4.0 Eluent B: methanol:2mM ammonium acetate (pH 4.0); 80:20, v/v						
<table border="1"> <thead> <tr> <th>Time (min)</th><th>%B</th></tr> </thead> <tbody> <tr> <td>0.0</td><td>70</td></tr> <tr> <td>3.5</td><td>70</td></tr> </tbody> </table>		Time (min)	%B	0.0	70	3.5	70
Time (min)	%B						
0.0	70						
3.5	70						
Flow rate:	1.0 mL/min						
Injection volume:	5 μ L						
Autosampler tray temperature:	Set at 4°C						
Autosampler needle wash:	Water:methanol:acetic acid; 20:80:1, v/v/v						

6.4.2. MS/MS Conditions

MS system:	MDS Sciex API 4000
Data capture system:	MDS Sciex Analyst, Version 1.4.1
Ionization mode:	Negative electrospray ionization (ESI)
Scan type:	Multiple reaction monitoring (MRM)
Resolution:	Unit/unit
Ion spray voltage:	-4500 V
Ion source gas 1 (zero air):	60 psi
Ion source gas 2 (zero air):	60 psi
Curtain gas:	30 psi
Collision activated dissociation gas (CAD):	6 dacs
Temperature:	600°C

Monitoring ions and respective parameters:

Name	Q1 Mass	Q3 Mass	Retention Time (min)	Scan Time (msec)	DP (V)	EP (V)	CE (eV)	CXP (V)
Perfluorohexanoic acid	313.0	268.8	~2.6	200	-40	-5	-13	-15
PFHxA-1,2- ¹³ C2	315.0	270.0	~2.6	100	-40	-5	-13	-15

Some conditions may vary

6.5. System Suitability

The reproducibility of the chromatographic system was determined by injecting an extracted calibration standard, at least in triplicate, at the beginning of the chromatographic run. To assess system stability, QC samples were injected at the end of each run.

A coefficient of variation (CV) of $\leq 5\%$ with respect to peak area ratio for an extracted calibration standard injected at the beginning of the run, and QC samples injected at the end of each run meeting acceptance criteria, were considered acceptable

6.6. Data Collection and Statistical Methods

Data collection was performed using Analyst, Version 1.4.1, from MDS Sciex.

Statistical analyses included quadratic regression with $1/\text{concentration}^2$ weighting and descriptive statistics such as arithmetic means and standard deviations, accuracy and precision using Watson Laboratory Information Management System (LIMS) (Version 7.2.0.02) and Microsoft Excel (Version 2000/2003).

Tables were prepared from retrospective manual entry on computer (Microsoft Word, Version 2000/2003).

6.7. Method Validation

The analytical method was previously validated (Study No. 141837) with respect to selectivity, linearity, lower limit of quantitation (LLOQ), carry-over, intra- and inter-assay precision and accuracy, stock solution stability, injection medium integrity, short-term matrix stability, freeze-thaw matrix stability, long-term matrix stability and dilution integrity.

6.8. Quality Assurance

The Quality Assurance department of PCS-MTL undertook and documented inspections and process audits of the laboratories in which this study was performed at PCS-MTL, and audited the study report as well as the raw data. The Quality Assurance Statement is presented on [page 7](#).

6.9. Archives

All raw data and documents generated at PCS-MTL during this study, together with the final report will be retained in the scientific archives of PCS-MTL for approximately one year after dispatch of the final report. Subsequent storage details will be documented in the raw data.

7. RESULTS AND DISCUSSION

A representative calibration line is presented in [Figure 1](#), and representative chromatograms are presented in [Figure 2](#), [Figure 3](#), [Figure 4](#), [Figure 5](#), [Figure 6](#), [Figure 7](#) and [Figure 8](#).

7.1. System Suitability

Acceptance criteria with respect to system suitability were met on all occasions.

7.2. Study Samples

Results for the study samples are presented in [Table 1](#). The calibration standard and quality control sample statistics are presented in [Table 2](#) and [Table 3](#), respectively.

Table 1 Serum Concentrations of Pefluorohexanoic Acid (PFHxA)

Subject	Gender	Dosage Group	Study Day	Nominal Time	Concentration (µg/mL)
507	Male	1	42	PND 42 Terminal	< LLOQ
508	Male	1	42	PND 42 Terminal	< LLOQ
509	Male	1	42	PND 42 Terminal	< LLOQ
510	Male	1	42	PND 42 Terminal	< LLOQ
511	Male	1	42	PND 42 Terminal	< LLOQ
528	Male	2	42	PND 42 Terminal	< LLOQ
529	Male	2	42	PND 42 Terminal	< LLOQ
530	Male	2	42	PND 42 Terminal	< LLOQ
531	Male	2	42	PND 42 Terminal	< LLOQ
532	Male	2	42	PND 42 Terminal	< LLOQ
547	Male	3	42	PND 42 Terminal	< LLOQ
548	Male	3	42	PND 42 Terminal	< LLOQ
549	Male	3	42	PND 42 Terminal	< LLOQ
550	Male	3	42	PND 42 Terminal	< LLOQ
551	Male	3	42	PND 42 Terminal	< LLOQ
565	Male	4	42	PND 42 Terminal	< LLOQ
566	Male	4	42	PND 42 Terminal	< LLOQ
567	Male	4	42	PND 42 Terminal	< LLOQ
568	Male	4	42	PND 42 Terminal	< LLOQ
569	Male	4	42	PND 42 Terminal	< LLOQ
606	Female	1	42	PND 42 Terminal	< LLOQ
608	Female	1	42	PND 42 Terminal	< LLOQ
609	Female	1	42	PND 42 Terminal	< LLOQ
610	Female	1	42	PND 42 Terminal	< LLOQ
611	Female	1	42	PND 42 Terminal	< LLOQ
628	Female	2	42	PND 42 Terminal	< LLOQ
629	Female	2	42	PND 42 Terminal	< LLOQ
630	Female	2	42	PND 42 Terminal	< LLOQ
631	Female	2	42	PND 42 Terminal	< LLOQ
632	Female	2	42	PND 42 Terminal	< LLOQ
647	Female	3	42	PND 42 Terminal	< LLOQ
648	Female	3	42	PND 42 Terminal	< LLOQ
649	Female	3	42	PND 42 Terminal	< LLOQ
650	Female	3	42	PND 42 Terminal	< LLOQ
651	Female	3	42	PND 42 Terminal	< LLOQ

Table 1 **Serum Concentrations of Pefluorohexanoic Acid (PFHxA) (Cont'd)**

Subject	Gender	Dosage Group	Study Day	Nominal Time	Concentration (µg/mL)
665	Female	4	42	PND 42 Terminal	< LLOQ
666	Female	4	42	PND 42 Terminal	< LLOQ
667	Female	4	42	PND 42 Terminal	< LLOQ
668	Female	4	42	PND 42 Terminal	< LLOQ
669	Female	4	42	PND 42 Terminal	< LLOQ

LLOQ = Lower limit of detection (theoretical concentration 1.00 µg/mL)

Table 2 Calibration Standard Statistics

Analytical Run	Concentration (µg/mL)									
	1.00	2.00	5.00	25.0	50.0	100	200	400	800	1000
1	1.04	1.87	4.84	25.5	50.4	101	202	415	779	1003
Mean	1.04	1.87	4.84	25.5	50.4	101	202	415	779	1003
S.D.	nc	nc	nc	nc	nc	nc	nc	nc	nc	nc
%CV	nc	nc	nc	nc	nc	nc	nc	nc	nc	nc
% Bias	3.8	-6.5	-3.2	1.9	0.8	0.9	0.9	3.7	-2.6	0.3
n	1	1	1	1	1	1	1	1	1	1

nc - Not calculated for data sample set (n < 3)

Table 3 **Quality Control Sample Statistics**

Analytical Run	Concentration (µg/mL)		
	3.00	60.0	760
1			
	2.83	63.4	756
	2.95	64.5	701
	2.82	63.2	738
	2.91	694 ^a	58.1 ^a
Mean	2.879	63.68	731.6
S.D.	0.0626	0.701	27.93
%CV	2.2	1.1	3.8
% bias	-4.0	6.1	4.5
n	4	3	3

a = Outside of acceptance criteria; not included in the statistical calculations

Testing Facility Study No. UZS00010

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Figure 1 **Representative Calibration Line (Theoretical Concentration 1.00 to 1000 µg/mL)**

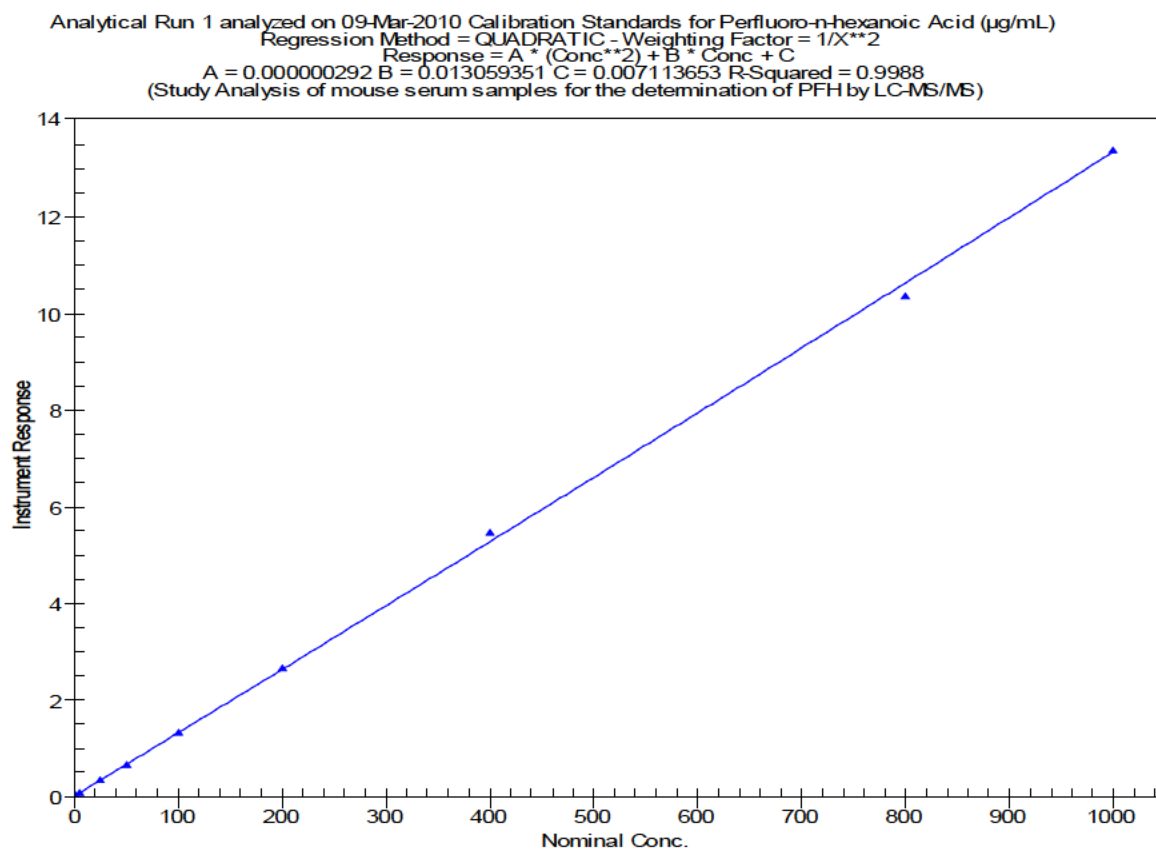


Figure 2 **Representative LLOQ Standard Chromatogram**
(Theoretical Concentration 1.00 µg/mL)

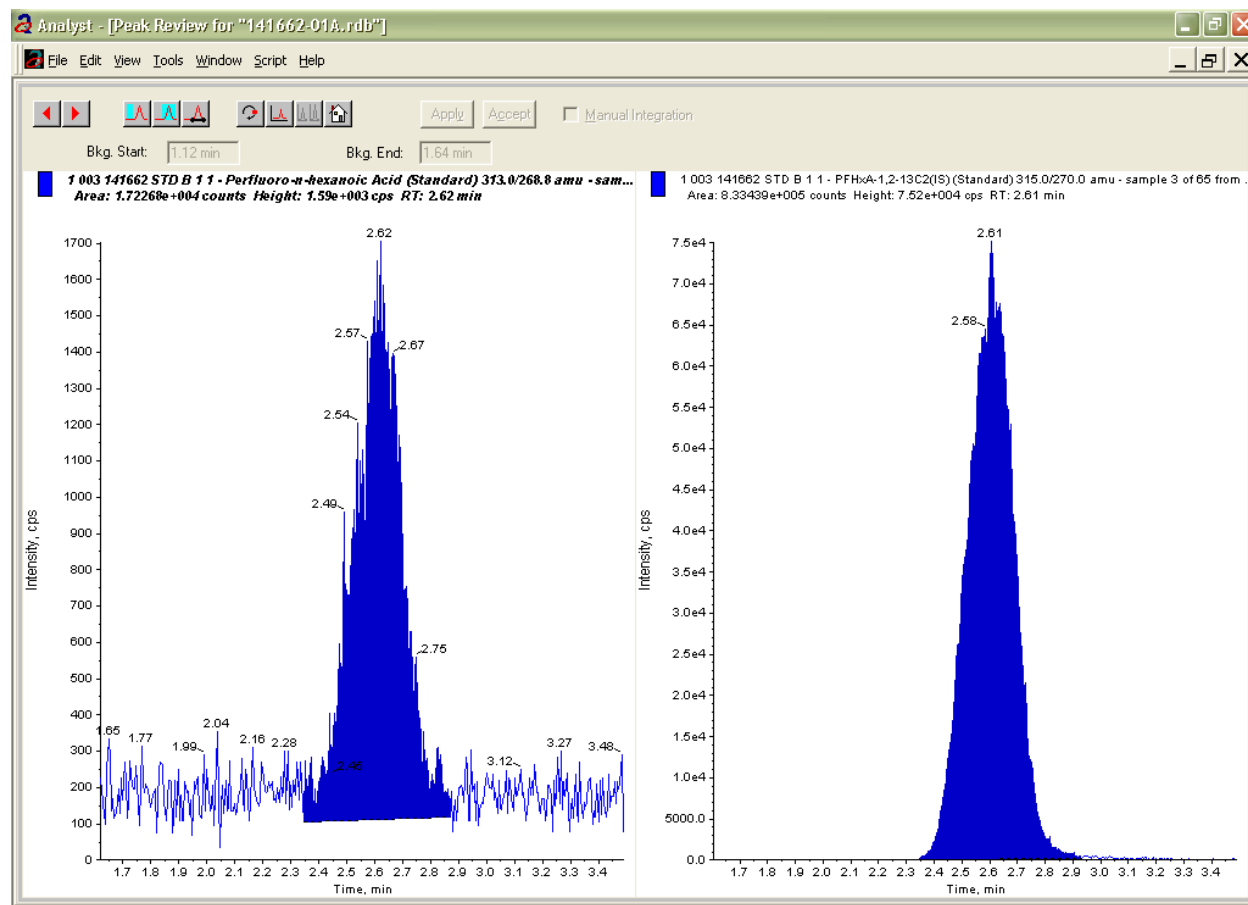


Figure 3 **Representative ULOQ Standard Chromatogram**
(Theoretical Concentration 1000 µg/mL)

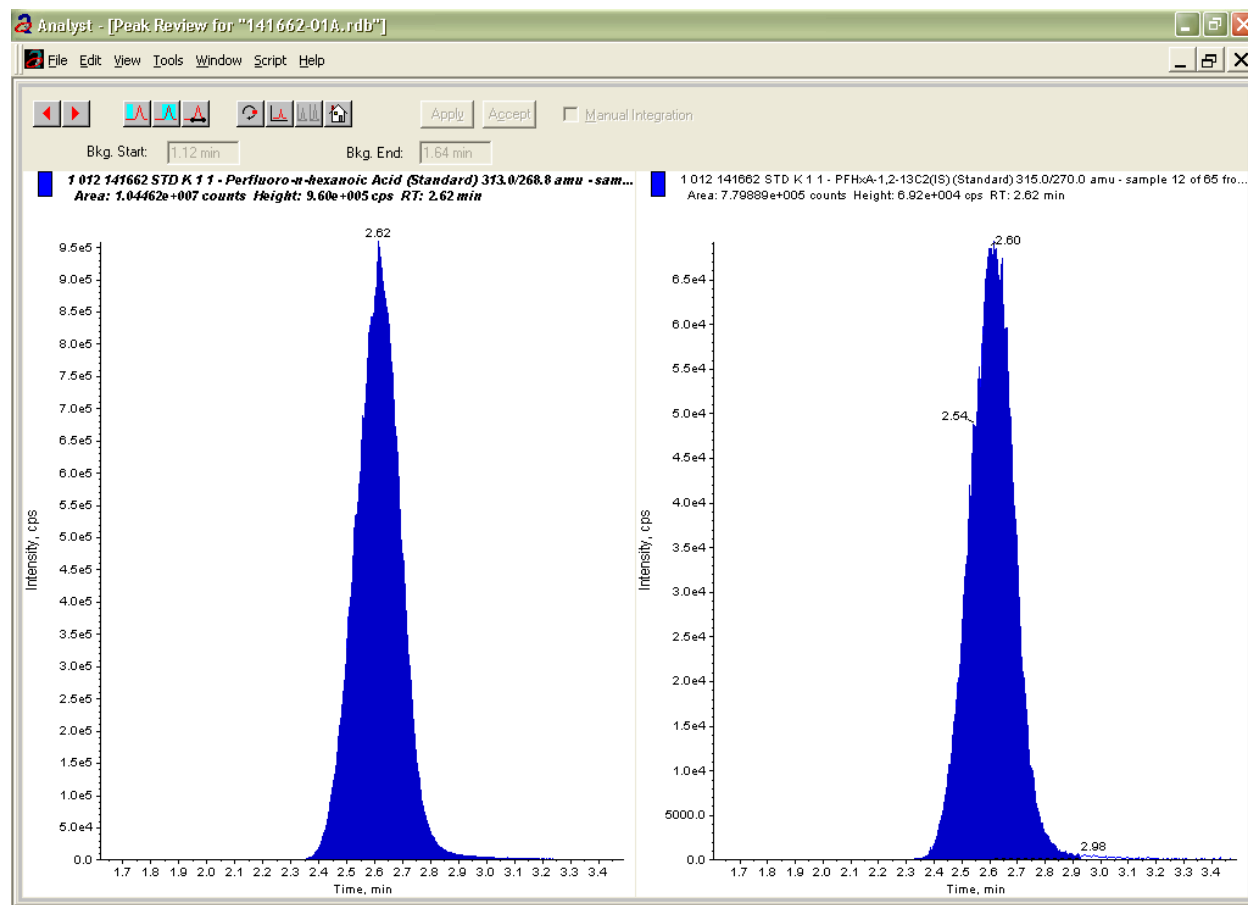


Figure 4 **Representative Double Blank Chromatogram**

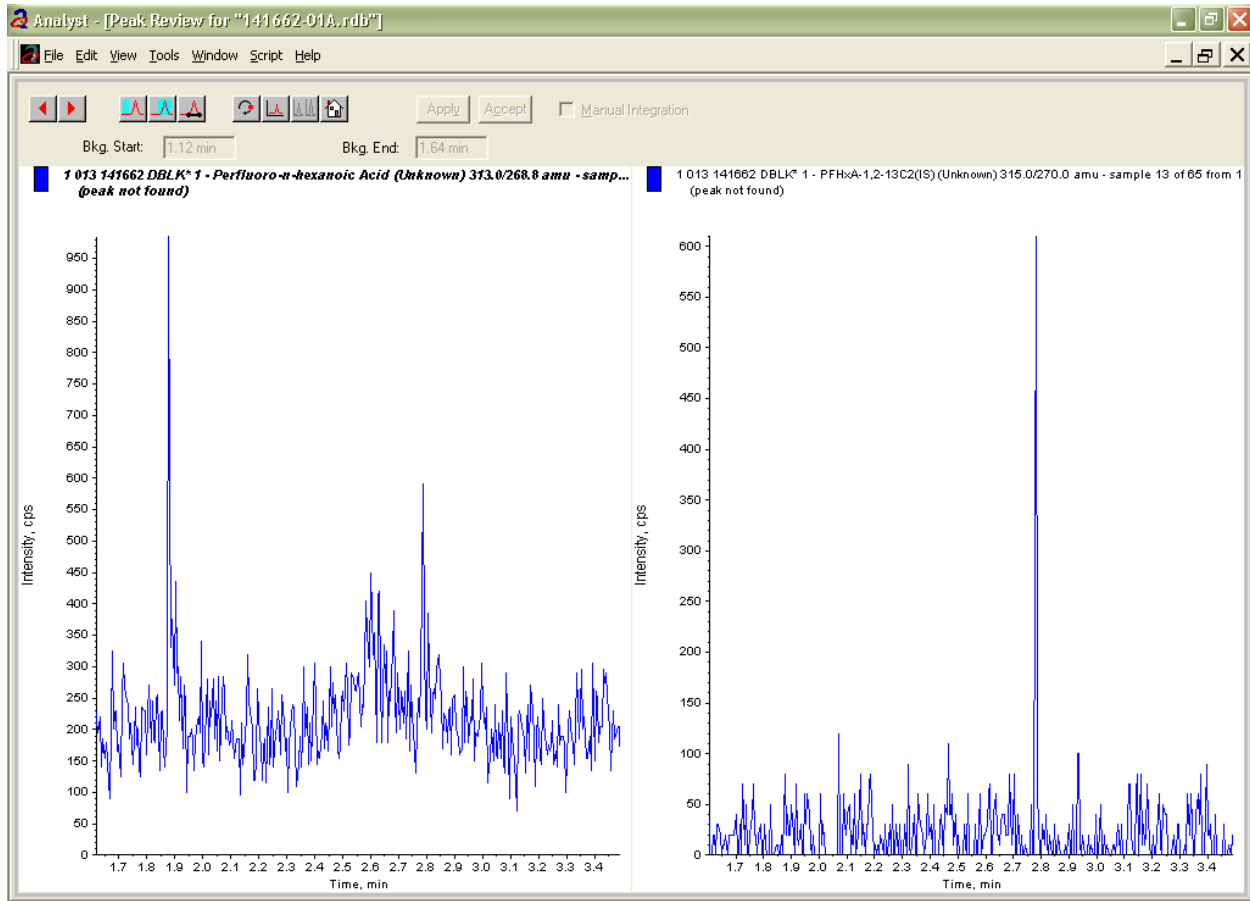


Figure 5 **Representative Sample Chromatogram (Group 1, Animal 507, PND42, Terminal)**

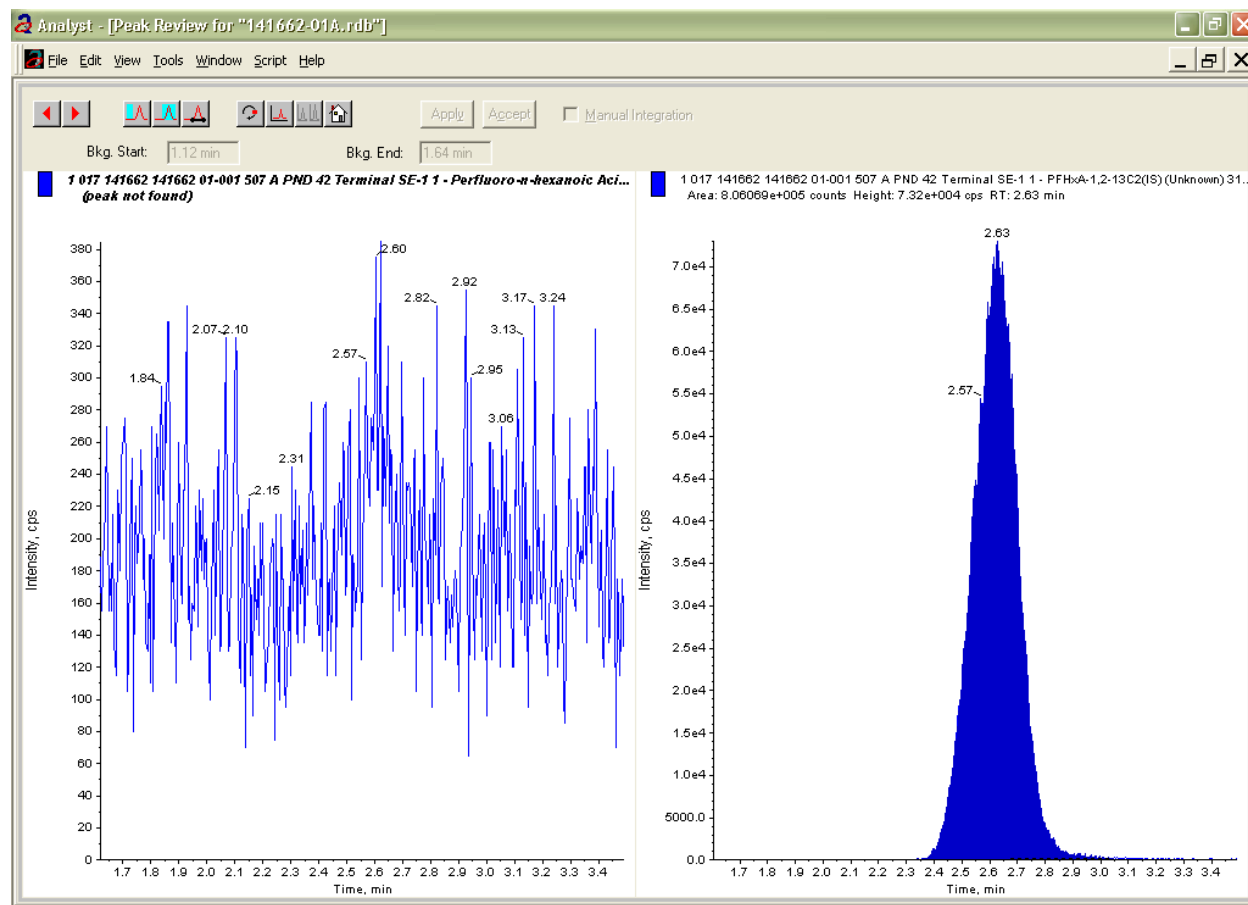


Figure 6 **Representative Sample Chromatogram (Group 2, Animal 528, PND42, Terminal)**

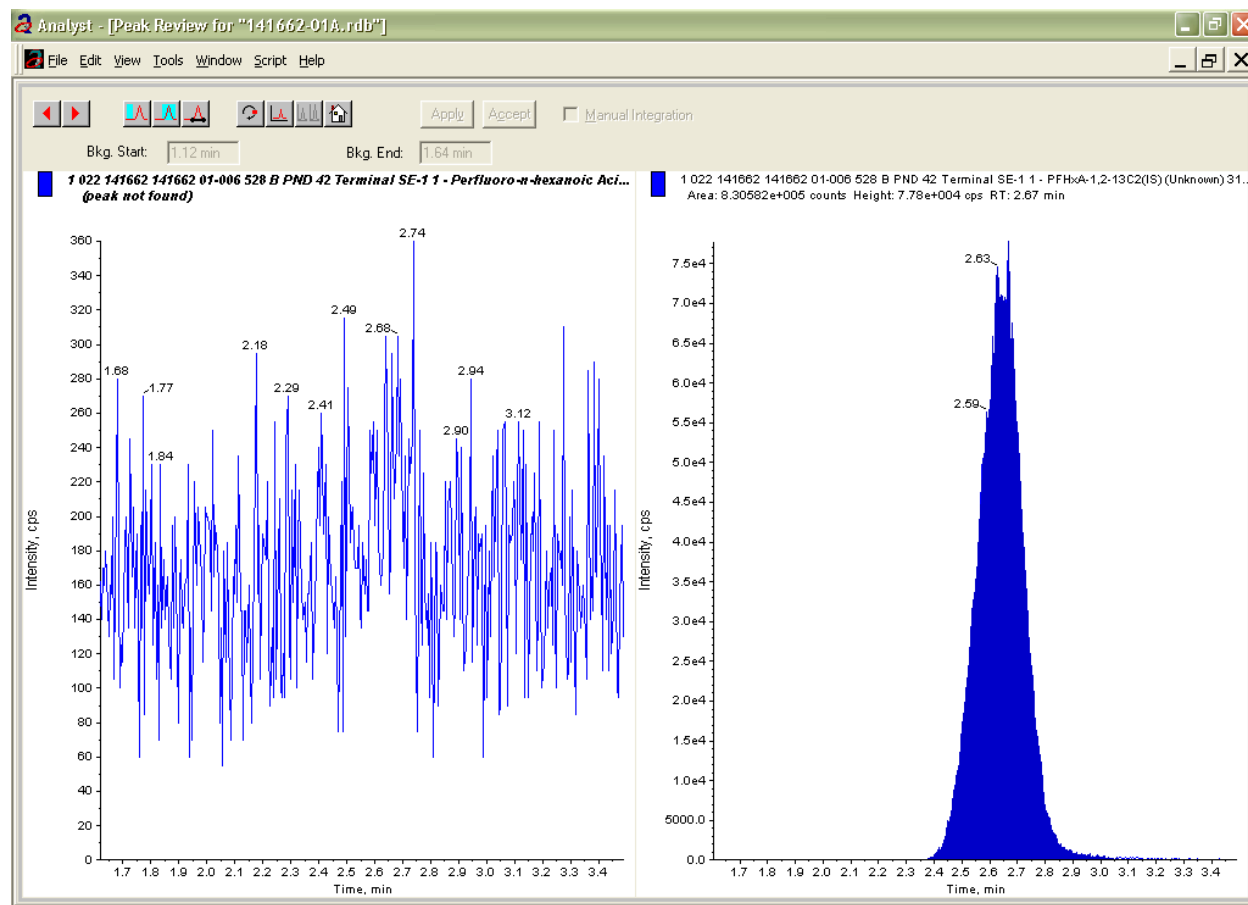


Figure 7 **Representative Sample Chromatogram (Group 3, Animal 547, PND42, Terminal)**

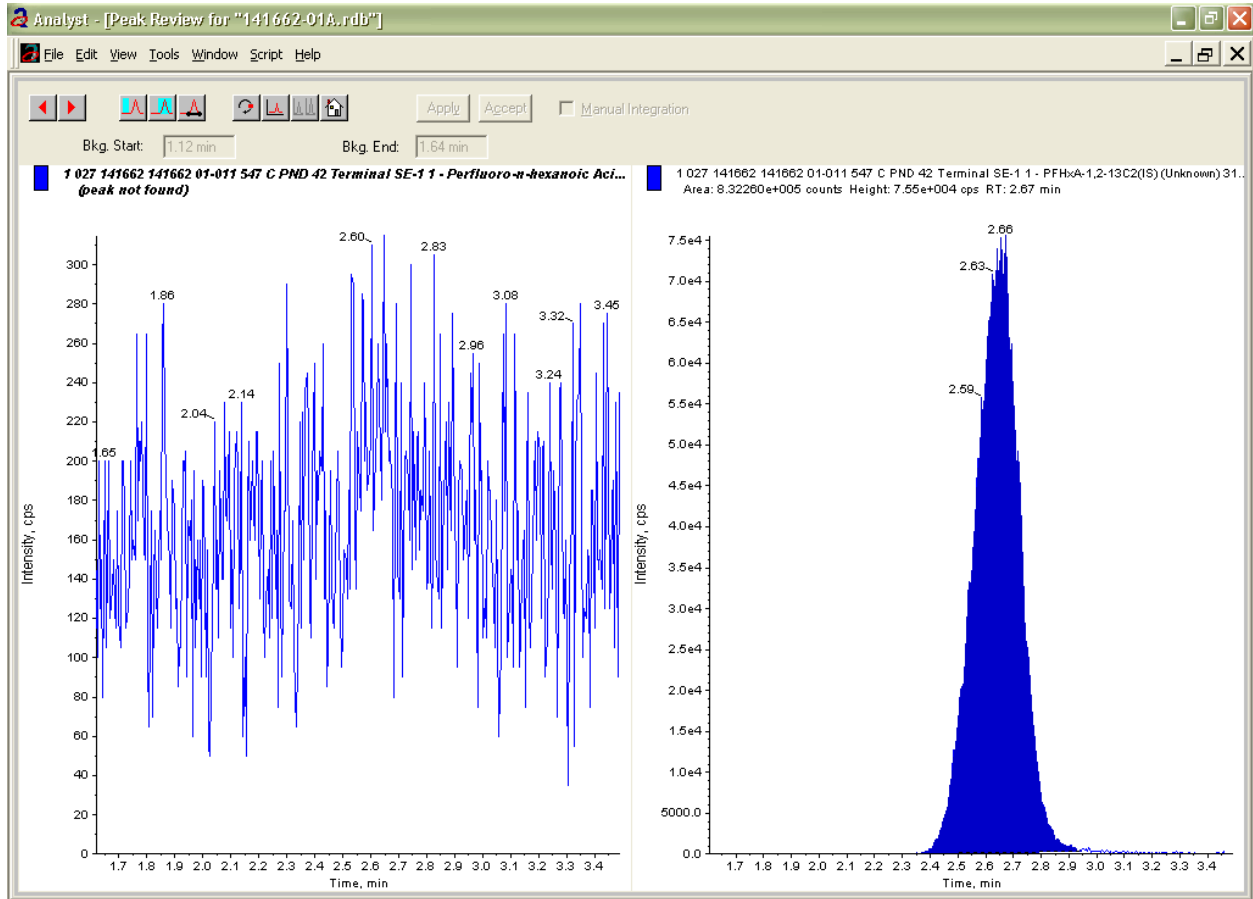
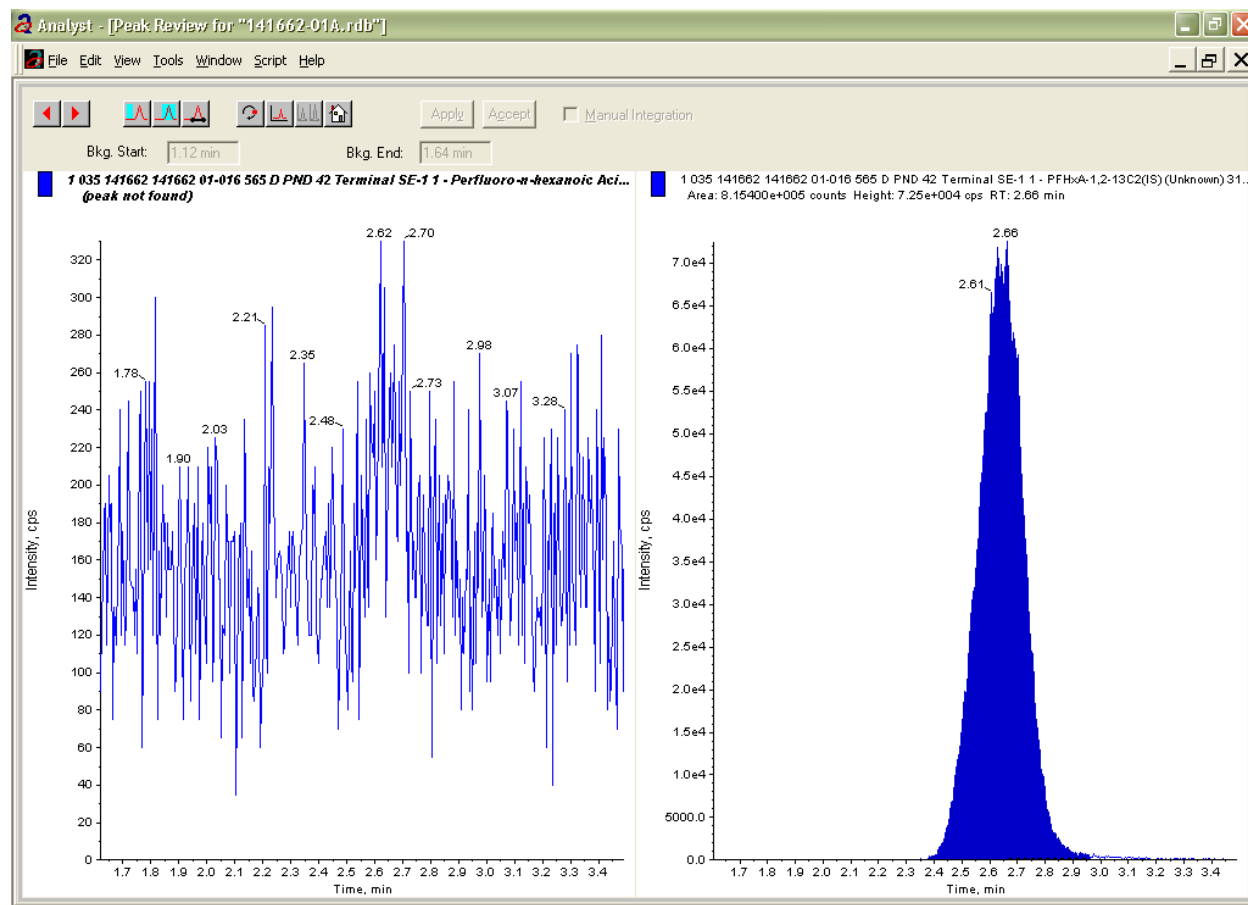


Figure 8 **Representative Sample Chromatogram (Group 4, Animal 565, PND42, Terminal)**



Appendix 1

Certificate of Analysis

**Certificate of Analysis***Daikin Industries, LTD.*

Name of Sample *PFH Ammonium Salt (C-1500N)*
Lot. *7005*
Date of Analysis *May 14, 2009*
Purity *47.4% (Effective component in Water)*
**50.8*0.934%=47.4%*

COMPOSITION

identity		Conc.
#1	Ammonium Perfluorohexanoate CAS RN. 21615-47-4	93.4%
#2	Unknown	6.6%
Total		100%

Analysis system (HPLC)

Equipment : *Waters Alliance2695*
Detector : *Waters 2487UV*
Detection wavelength : *210nm*

Analysis condition

Column : *TOSOH TSKGel ODS120T 4.6mm×150mm*
Temp. : *40 °C*
Mobile phase : *A=acetonitrile, B=Solution of 0.6% perchloric acid in water*
Gradient : *A:B=50:50(mass%) (0-10min.) →90:10(mass%) (15-20min.)*
Injection volume : *20μL*
Injection Concentration : *1% (dilute 50times with water)*

Chemical R&D Center
Unidyne Group
Souley Ranaochar

SIGNATURE
DATE : May 18, 2009

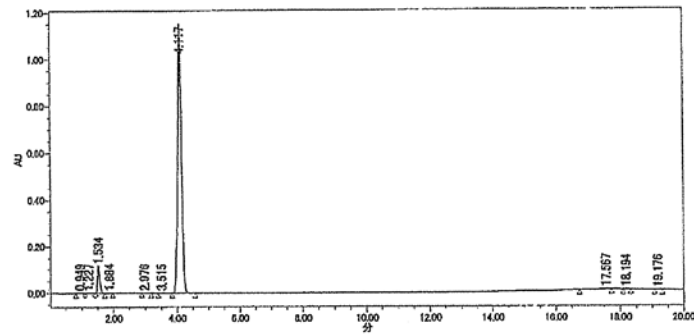
Testing Facility Study No. UZS00010

Test Site Ref. No. 141662

Analysis

サンプル名: C1500N
サンプルの種類: 未知試料
バイアル: 82
注入#: 1
注入量: 20.00 μ l
分析時間: 20.00 分
サンプルセット名:

分析担当: System
分析日: 2008/05/14 11:40:44
取り込みメソッドセット: 090514S
解析日: 2008/05/14 13:55:17
解析メソッド: C1500N
チャンネル名: 2487チャンネル 1
解析チャンネルの説明:



成分名	Retention Time(min)	Area (μ Vsec)	Area (%)	Height (μ V)		
1	0.949	17634	0.18	2554		
2	1.227	20551	0.20	1827		
3	1.534	574690	5.71	110134		
4	1.804	5543	0.05	710		
5	2.976	2424	0.02	414		
6	3.515	4940	0.05	381		
7	4.117	9390042	93.38	1144210		
8	17.567	29475	0.29	604		
9	18.194	9550	0.07	1098		
10	19.176	3881	0.04	592		



FINAL REPORT

Test Site Ref. No. 141663
Testing Facility Study No. UZS00010

**Determination of Perfluorohexanoic Acid (PFHxA) in Mouse Liver
Homogenate by Liquid Chromatography-tandem Mass Spectrometry
(LC-MS/MS) in Support of Study No. UZS00010**

TEST SITE:
Charles River Laboratories Preclinical Services Montreal
22022 Transcanadienne
Senneville, Quebec
Canada H9X 3R3

TESTING FACILITY:
Charles River Laboratories
Preclinical Services
905 Sheehy Drive, Building A
Horsham, PA 19044
USA

SPONSOR:
Daikin Industries, LTD
Chemical Division
Umeda Center Building
4-12 Nakazaki-Nishi, 2-chrome
Kita-ku, Osaka 530-8323
Japan

20 June 2011

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1. COMPLIANCE STATEMENT

This phase of the study, conducted at Charles River Laboratories Preclinical Services Montreal (PCS-MTL), 22022 Transcanadienne, Senneville, Quebec, Canada, H9X 3R3, complied the appropriate Organization for Economic Co-operation and Development (OECD) Principles of GLP (ENV/MC/CHEM(98)17).

Date

20 Jun 2011

Bioanalytical Principal Investigator
Research Scientist, Bioanalysis
Laboratory Sciences
Charles River Laboratories

Testing Facility Study No. UZS00010

Page 7
Test Site Ref. No. 141663**2. QUALITY ASSURANCE STATEMENT**

In compliance with the appropriate Good Laboratory Practice Regulations, Reference No. 141663 has been audited. The data presented in the final report accurately represent the data collected during the conduct of the study.

Phase or Segment Audited	Date of Inspection	Dates of Reports to Test Site Management and Principal Investigator	Dates of Reports to Testing Facility Management/ Study Director & Lead QA
Protocol Review	02 December 2009	07 December 2009	20 May 2010
SOP Review - In-life	22 February 2010	22 February 2010	20 May 2010
Bioanalysis - Process Audits	22 February 2010	24 February 2010	20 May 2010
Bioanalysis Data	28 April 2010 to	11 May 2010	20 May 2010
Protocol Amendment Review	28 April 2010	11 May 2010	20 May 2010
Sample Management/Shipping Records - Data Review	29 April 2010 to	11 May 2010	20 May 2010
Bioanalysis Matrix Report	11 May 2010		
Bioanalysis Report Tabulation			
Final Report Review	10 June 2011	10 June 2011	16 June 2011

In addition to the above-mentioned inspections, process based and/or routine facility inspections were also conducted during the course of this study. Any findings specific to this study from these inspections are reported with this QA Statement. All other observations and the dates of reports to PCS-MTL Management are retained on file according to PCS-MTL Quality Assurance Standard Operating Procedures.

20/ Jun / 2011
Date

Inspector
Quality Assurance
Charles River Laboratories

3. SUMMARY

The concentrations of perfluorohexanoic acid (PFHxA) in mouse liver homogenate samples in support of Testing Facility Study No. UZS00010, entitled “Oral (Gavage) Combined Developmental and Perinatal/Postnatal Reproduction Toxicity Study of PFH Ammonium Salt (Ammonium Salt of Perfluorinated Hexanoic Acid) in Mice”, were determined using a previously validated liquid chromatography-tandem mass spectrometry (LC-MS/MS) method. Results for all samples analyzed are presented in this report.

Note: In this bioanalytical portion of the study, the reference standard is identified as perfluorohexanoic acid (PFHxA) which is equivalent to PFH ammonium salt (ammonium salt of perfluorinated Hexanoic Acid).

Testing Facility Study No. UZS00010

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4. INTRODUCTION

The concentrations of perfluorohexanoic acid (PFHxA) in mouse liver homogenate samples were determined by a liquid chromatography-tandem mass spectrometry (LC-MS/MS) method. The method of analysis, documented in PCS-MTL analytical procedure AP.141663.LI.03, was previously validated (Study No. 141659).

For the work detailed in this report, the experimental start date was 22 February 2010 and the completion date is the signature date of the final report.

5. REFERENCE STANDARD, INTERNAL STANDARD AND BLANK MATRIX

5.1. Reference Standard

Identity:	PFH ammonium salt (50% aqueous solution: 474 mg/mL) (also known as perfluorohexanoic acid or PFHxA)
Lot number:	7005
Purity:	93.4% (correction factor: 0.474, corrected for effective component in solution)
Expiry date:	31 July 2010
Storage conditions:	In a controlled temperature area set at 21°C

5.2. Internal Standard

Identity:	Perfluoro-n-[1, 2- ¹³ C ₂] hexanoic acid (also known as PFHxA-1, 2- ¹³ C ₂)
Lot number:	MPFHxA0809
Purity:	> 98% (50 µg/mL certified solution)
Expiry date:	19 August 2012
Storage condition:	In a refrigerator set at 4°C, dark

The reference standard characterization was the responsibility of the Sponsor who provided a Certificate of Analysis ([Appendix 1](#)) for inclusion in this study report.

Details of identity, purity, storage conditions and handling precautions were supplied by the Sponsor. Remaining reference standard was stored at PCS-MTL for use on subsequent studies for the Sponsor.

Testing Facility Study No. UZS00010

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5.3. Blank Matrix

Identity: Female mouse liver Homogenate
Species: *Mus musculus*
Strain: CD1

6. EXPERIMENTAL PROCEDURES

6.1. Blank Liver Homogenate

Blank female mouse liver homogenate was prepared by homogenizing blank female mouse liver tissue in 0.5 M tetrabutyl ammonium hydrogen sulphate, pH 10.0 with a ratio of 50.0 mg liver tissue to 500 µL of buffer solution.

6.2. Calibration Standards

Calibration standards of reference standard were prepared in blank female mouse liver homogenate covering the theoretical concentration range of 0.0200 to 10.0 µg/mL. Calibration standards consisted of blank female mouse liver homogenate (500 µL) spiked with appropriate standard working solution (methanol; 5 µL).

6.3. Quality Control Samples

Quality control (QC) samples of reference standard were prepared in blank female mouse liver homogenate at theoretical concentrations of 0.0600, 1.50 and 8.00 µg/mL. QC samples consisted of blank female mouse liver homogenate (500 µL) spiked with appropriate QC working solution (methanol; 5 µL).

6.4. Study Samples

Study liver samples were received from Charles River Laboratories Preclinical Services (Pennsylvania) and stored frozen in the freezer set to maintain at -80°C until sample homogenization. Once homogenized, study liver sample homogenates were stored frozen in the freezer set to maintain at -80°C prior to analysis.

Remaining unused study sample homogenates will be retained at PCS-MTL for approximately 1 year after dispatch of the final report or until authorized to discard by the Study Director.

6.5. Analysis

Single and double blank samples consisted of blank female mouse liver homogenate (500 μL) plus methanol (5 μL). To each standard, QC, single blank and study sample homogenate (505 μL), internal standard (50.0 $\mu\text{g/mL}$; 10 μL) was added, or for double blanks (505 μL), methanol (10 μL) was added, and the mixtures vortexed (~ 60 seconds) and centrifuged (~ 14000 rpm; $\sim 0^\circ\text{C}$, ~ 10 minutes). The samples were stored for ~ 1 hour ($\sim 4^\circ\text{C}$) and then centrifuged (~ 14000 rpm; $\sim 0^\circ\text{C}$, ~ 10 minutes). An aliquot (~ 400 μL) of the supernatant was loaded, by gravity, onto a 96-well SLE extraction plate (Biotage, 400 mg) and let soaked in the sorbent (~ 10 minutes). The samples were eluted, by gravity, twice with methyl tertiary butyl ether (850 μL), evaporated (N_2 , top and bottom temperature set at 45°C) and reconstituted (methanol:water; 50:50, v/v; 100 μL). An aliquot (20 μL) of the extracts was diluted (methanol:water; 50:50, v/v; 780 μL) and stored ($\sim 4^\circ\text{C}$) until injection.

The standard, QC, blank and sample extracts were analyzed by LC-MS/MS using the following conditions:

6.5.1. Liquid Chromatography

HPLC system:

Agilent Technologies 1100 series binary pump and degasser, and Shimadzu SIL-HTC autosampler

Column:

Thermo[®] Aquasil C18, 5 μm (50 x 2.1 mm id)

Column temperature:

Set at 50°C

Mobile phase gradient elution:

Eluent A: 2mM ammonium acetate, pH 4.0

Eluent B: methanol:2mM ammonium acetate, pH 4.0 (80:20, v/v)

Time (minutes)	Flow Rate (mL/min)	%B
0.00	0.5	20
15.0	0.5	100
15.1	1.0	100
18.1	1.0	100
18.2	1.0	20
21.0	1.0	20
21.1	0.5	20
23.0	0.5	20

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Injection volume: 5 µL
 Autosampler tray temperature: Set at 4°C
 Autosampler needle wash: Water:methanol:acetic acid (20:80:1, v/v/v)
 Valco valve:

Time (minutes)	HPLC Column Flow
0.0	Waste
3.0	Mass spectrometer
11.0	Waste

Divert pump mobile phase: Water:methanol:acetic acid (20:80:1, v/v/v)
 Divert pump flow rate: 0.5 mL/min

6.5.2. MS/MS Conditions

MS system: MDS Sciex API 4000
 Data capture system: MDS Sciex Analyst, version 1.4.1
 Ionization mode: Negative electrospray ionization (ESI)
 Scan type: Multiple reaction monitoring (MRM)
 Resolution: Unit/unit
 Ion spray voltage: -2500V
 Ion source gas 1 (zero air): 60 psi
 Ion source gas 2 (zero air): 60 psi
 Curtain gas: 30 psi
 Collision activated dissociation gas (CAD): 6 dacs
 Temperature: 600°C

Monitoring ions and respective parameters:

Name	Q1 Mass	Q3 Mass	Retention Time (min)	Scan Time (msec)	DP (V)	EP (V)	CE (eV)	CXP (V)
PFH	313.0	268.8	~6.0	200	-40	-5	-13	-15
PFHxA-1,2- ¹³ C ₂	315.0	270.0	~6.0	100	-40	-5	-13	-15

Some conditions may vary and are documented in the raw data

6.6. System Suitability

The reproducibility of the chromatographic system was determined by injecting an extracted calibration standard, at least in triplicate, at the beginning of the chromatographic run. To assess system stability, QC samples were injected at the end of each run.

A coefficient of variation (CV) of $\leq 5\%$ with respect to peak area ratio for an extracted calibration standard injected at the beginning of the run, and QC samples injected at the end of each run meeting acceptance criteria, were considered acceptable.

6.7. Data Collection and Statistical Methods

Data collection was performed using Analyst, version 1.4.1, from MDS Sciex.

Statistical analyses included quadratic regression with $1/\text{concentration}^2$ weighting and descriptive statistics such as arithmetic means and standard deviations, accuracy and precision using Watson Laboratory Information Management System (LIMS) (version 7.2.0.02) and Microsoft Excel (version 2000/2003).

Tables were prepared from retrospective manual entry on computer (Microsoft Word, version 2000/2003).

6.8. Method Validation

The analytical method was previously validated (Study No. 141659) with respect to selectivity, linearity, lower limit of quantitation (LLOQ), carry-over, intra- and inter-assay precision and accuracy, stock solution stability, injection medium integrity, short-term matrix stability, freeze-thaw matrix stability, long-term matrix stability and dilution integrity.

6.9. Quality Assurance

The Quality Assurance department of PCS-MTL undertook and documented inspections and process audits of the laboratories in which this study was performed at PCS-MTL, and audited the study report as well as the raw data. The Quality Assurance Statement is presented on [page 7](#).

6.10. Archives

All raw data and documents generated at PCS-MTL during this study and the final report will be retained in the scientific archives of PCS-MTL for approximately one year after dispatch of the final report. Subsequent storage details will be documented in the raw data.

7. RESULTS AND DISCUSSION

A representative calibration line is presented in [Figure 1](#), and representative chromatograms are presented in [Figure 2](#) to [Figure 12](#).

7.1. System Suitability

Acceptance criteria with respect to system suitability were met on all occasions.

7.2. Study Samples

Results for the study samples are presented in [Table 1](#). The calibration standard and quality control sample statistics are presented in [Table 2](#) and [Table 3](#), respectively.

Table 1 **Liver Homogenate Concentration of Perfluorohexanoic Acid (PFHxA)**

Subject	Gender	Subject Group	Study Day	Nominal Time	Concentration (µg/mL)
401	Female	1	21	Liver	< LLOQ
402	Female	1	21	Liver	< LLOQ
403	Female	1	21	Liver	< LLOQ
406	Female	1	21	Liver	< LLOQ
409	Female	1	21	Liver	< LLOQ
507	Male	1	42	PND 42 Liver	< LLOQ
508	Male	1	42	PND 42 Liver	< LLOQ
509	Male	1	42	PND 42 Liver	< LLOQ
510	Male	1	42	PND 42 Liver	< LLOQ
511	Male	1	42	PND 42 Liver	< LLOQ
606	Female	1	42	PND 42 Liver	< LLOQ
608	Female	1	42	PND 42 Liver	< LLOQ
609	Female	1	42	PND 42 Liver	< LLOQ
610	Female	1	42	PND 42 Liver	< LLOQ
611	Female	1	42	PND 42 Liver	< LLOQ
421	Female	2	21	Liver	< LLOQ
422	Female	2	21	Liver	< LLOQ
424	Female	2	21	Liver	< LLOQ
425	Female	2	21	Liver	< LLOQ
426	Female	2	21	Liver	< LLOQ
428	Female	2	21	Liver	< LLOQ
430	Female	2	21	Liver	< LLOQ
431	Female	2	21	Liver	< LLOQ
432	Female	2	21	Liver	< LLOQ
528	Male	2	42	PND 42 Liver	< LLOQ
529	Male	2	42	PND 42 Liver	< LLOQ
530	Male	2	42	PND 42 Liver	< LLOQ
531	Male	2	42	PND 42 Liver	< LLOQ
532	Male	2	42	PND 42 Liver	< LLOQ
628	Female	2	42	PND 42 Liver	< LLOQ
629	Female	2	42	PND 42 Liver	< LLOQ
630	Female	2	42	PND 42 Liver	< LLOQ
631	Female	2	42	PND 42 Liver	< LLOQ
632	Female	2	42	PND 42 Liver	< LLOQ

Table 1 **Liver Homogenate Concentration of Perfluorohexanoic Acid (PFHxA) (Cont'd)**

Subject	Gender	Subject Group	Study Day	Nominal Time	Concentration (µg/mL)
441	Female	3	21	Liver	< LLOQ
443	Female	3	21	Liver	< LLOQ
444	Female	3	21	Liver	< LLOQ
447	Female	3	21	Liver	< LLOQ
448	Female	3	21	Liver	< LLOQ
449	Female	3	21	Liver	< LLOQ
547	Male	3	42	PND 42 Liver	< LLOQ
548	Male	3	42	PND 42 Liver	< LLOQ
549	Male	3	42	PND 42 Liver	< LLOQ
550	Male	3	42	PND 42 Liver	< LLOQ
551	Male	3	42	PND 42 Liver	< LLOQ
647	Female	3	42	PND 42 Liver	< LLOQ
648	Female	3	42	PND 42 Liver	< LLOQ
649	Female	3	42	PND 42 Liver	< LLOQ
650	Female	3	42	PND 42 Liver	< LLOQ
651	Female	3	42	PND 42 Liver	< LLOQ
463	Female	4	21	Liver	< LLOQ
465	Female	4	21	Liver	< LLOQ
466	Female	4	21	Liver	< LLOQ
467	Female	4	21	Liver	< LLOQ
468	Female	4	21	Liver	< LLOQ
565	Male	4	42	PND 42 Liver	< LLOQ
566	Male	4	42	PND 42 Liver	< LLOQ
567	Male	4	42	PND 42 Liver	< LLOQ
568	Male	4	42	PND 42 Liver	< LLOQ
569	Male	4	42	PND 42 Liver	< LLOQ
665	Female	4	42	PND 42 Liver	< LLOQ
666	Female	4	42	PND 42 Liver	< LLOQ
667	Female	4	42	PND 42 Liver	< LLOQ
668	Female	4	42	PND 42 Liver	< LLOQ
669	Female	4	42	PND 42 Liver	< LLOQ

LLOQ - Lower limit of quantitation (theoretical concentration 0.0200 µg/mL)

Table 2 Calibration Standard Statistics

Analytical Run	Concentration (µg/mL)									
	0.0200	0.0400	0.100	0.250	1.00	2.50	4.50	6.50	8.50	10.0
1	0.0199	0.0401	0.0999	0.257	1.01	2.43	4.35	6.58	8.68	9.95
2	0.0198	0.0404	0.101	0.263	1.03	2.27	4.31	6.42	8.52	10.6
Mean	0.01986	0.04026	0.10038	0.2598	1.021	2.348	4.332	6.498	8.603	10.257
S.D.	nc	nc	nc	nc	nc	nc	nc	nc	nc	nc
%CV	nc	nc	nc	nc	nc	nc	nc	nc	nc	nc
% Bias	-0.7	0.7	0.4	3.9	2.1	-6.1	-3.7	0.0	1.2	2.6
n	2	2	2	2	2	2	2	2	2	2

nc - Not calculated for data sample set (n < 3)

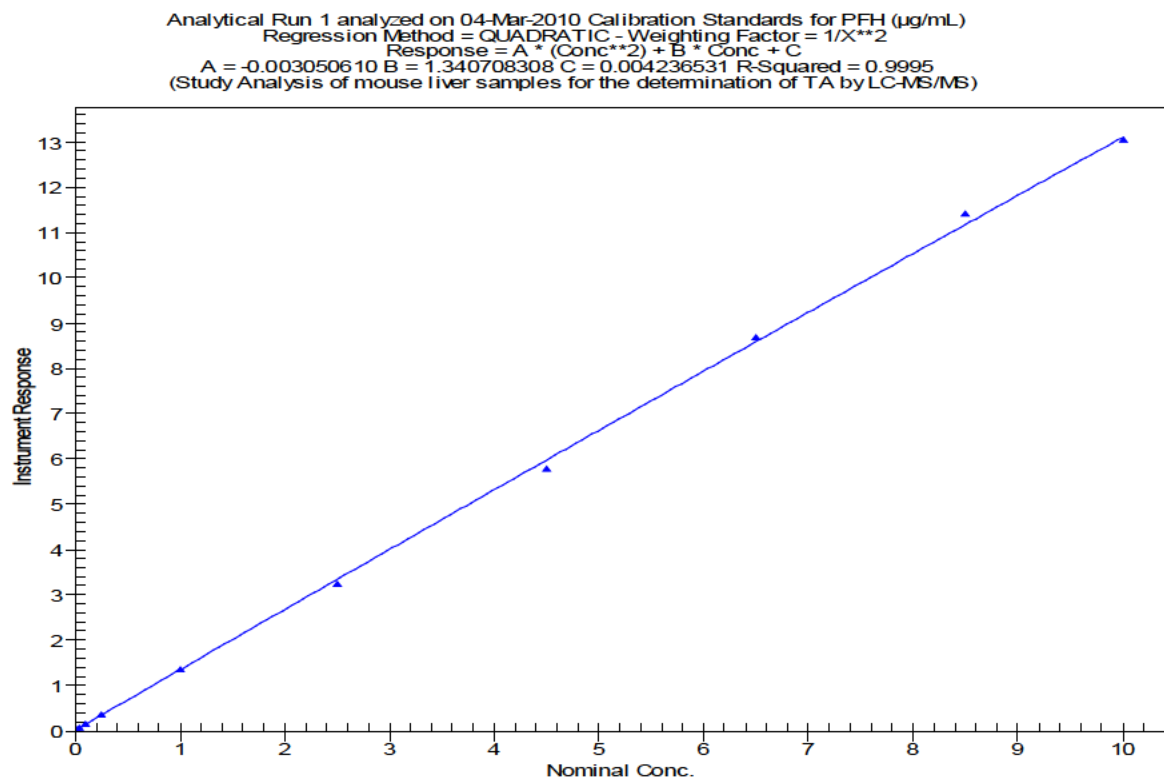
Table 3 **Quality Control Sample Statistics**

Analytical Run	Concentration (µg/mL)		
	0.0600	1.50	8.00
1	0.0600	1.66	8.55
	0.0600	1.60	8.63
	0.0611	1.66	8.69
2	0.0643	1.66	8.28
	0.0652	1.62	8.76
	0.0645	1.62	8.52
	0.0633	1.61	8.46
	0.0613	1.60	8.82
Mean	0.06246	1.629	8.589
S.D.	0.00210	0.0238	0.1749
%CV	3.4	1.5	2.0
% bias	4.1	8.6	7.4
n	8	8	8

Testing Facility Study No. UZS00010

Test Site Ref. No. 141663

Figure 1 **Representative Calibration Line (Theoretical Concentration
0.0200 to 10.0 µg/mL)**



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Figure 2 **Representative LLOQ Standard Chromatogram (Theoretical
Concentration 0.02000 µg/mL)**

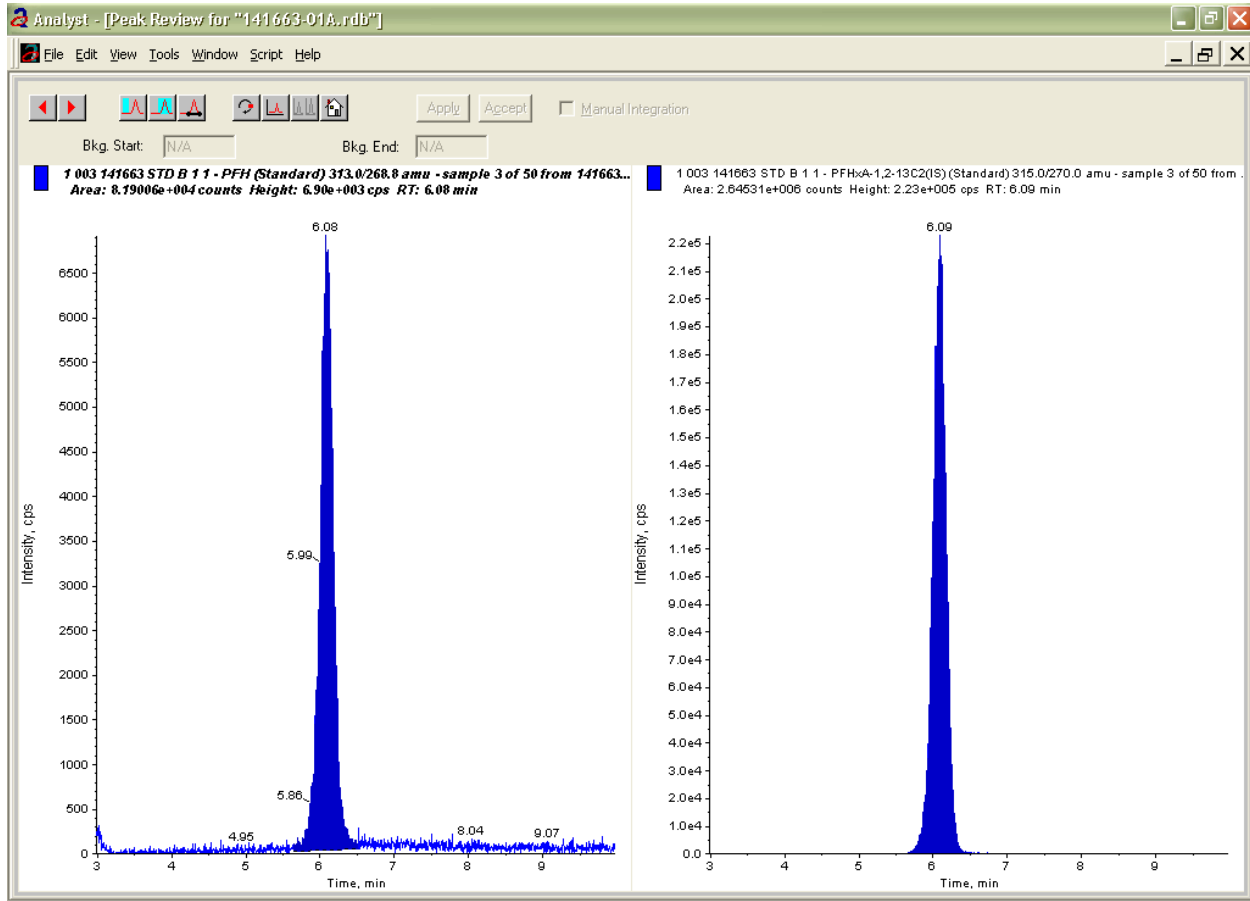


Figure 3 **Representative ULOQ Standard Chromatogram (Theoretical Concentration 10.0 µg/mL)**

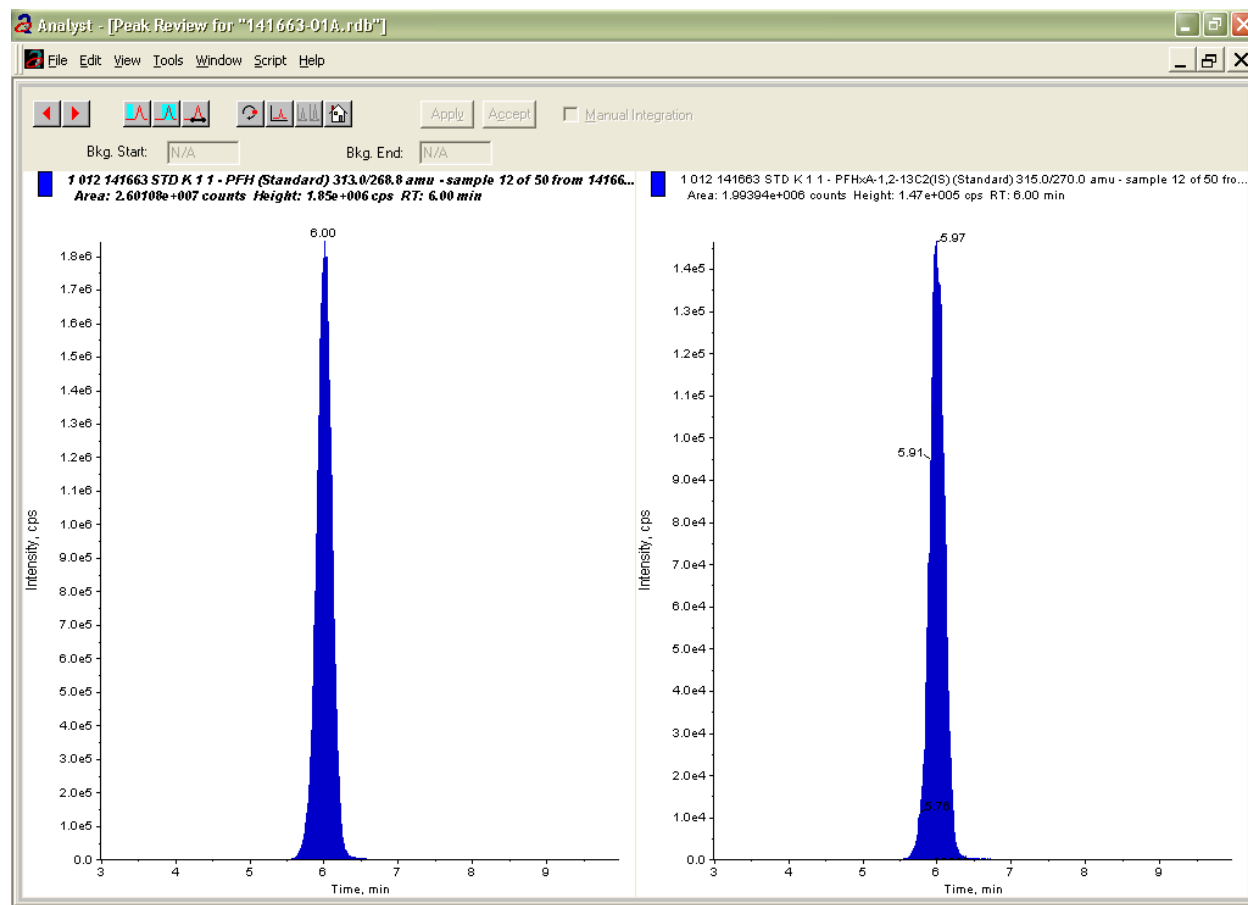


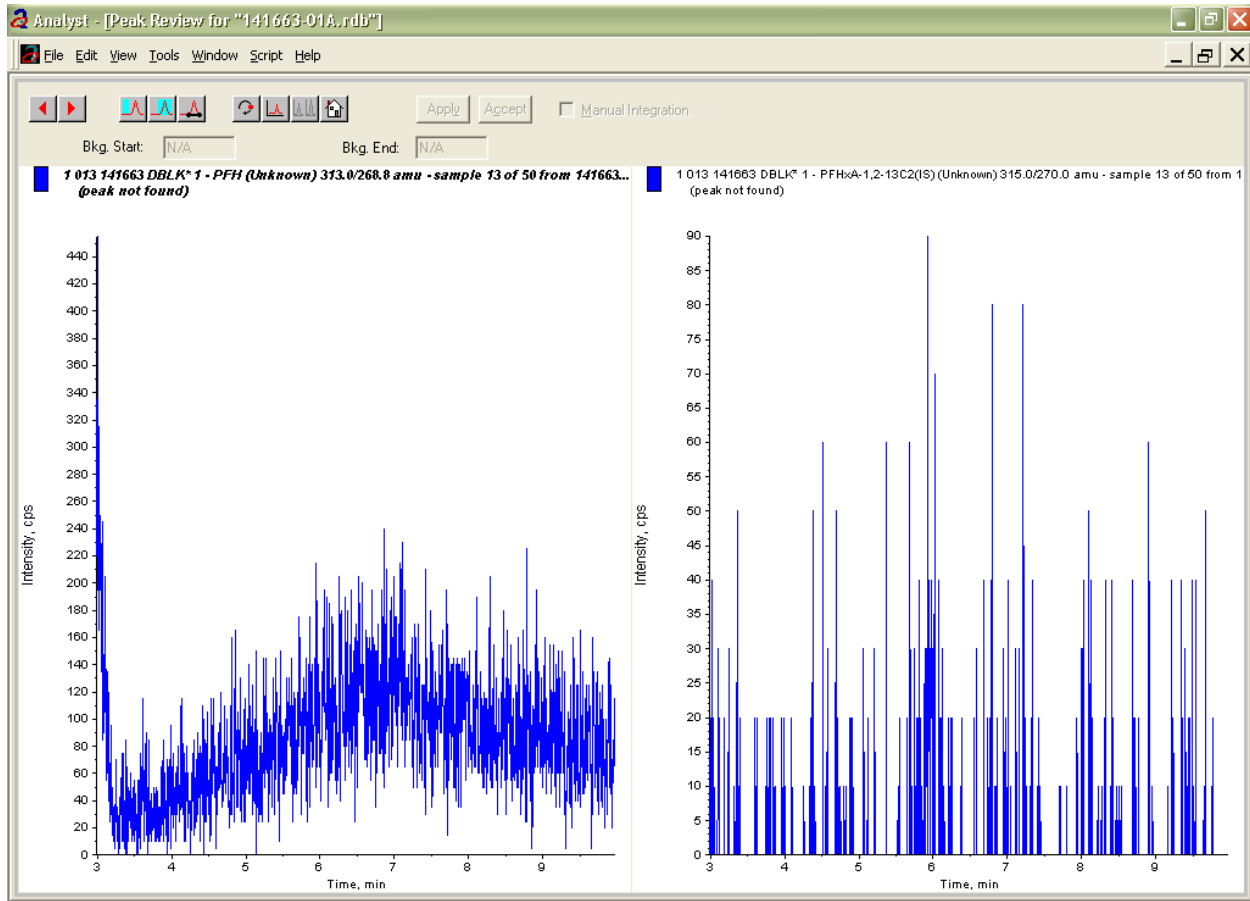
Figure 4 **Representative Double Blank Liver Homogenate Chromatogram**

Figure 5 **Representative Sample Chromatogram (Group 1, Animal 401, Day 21)**

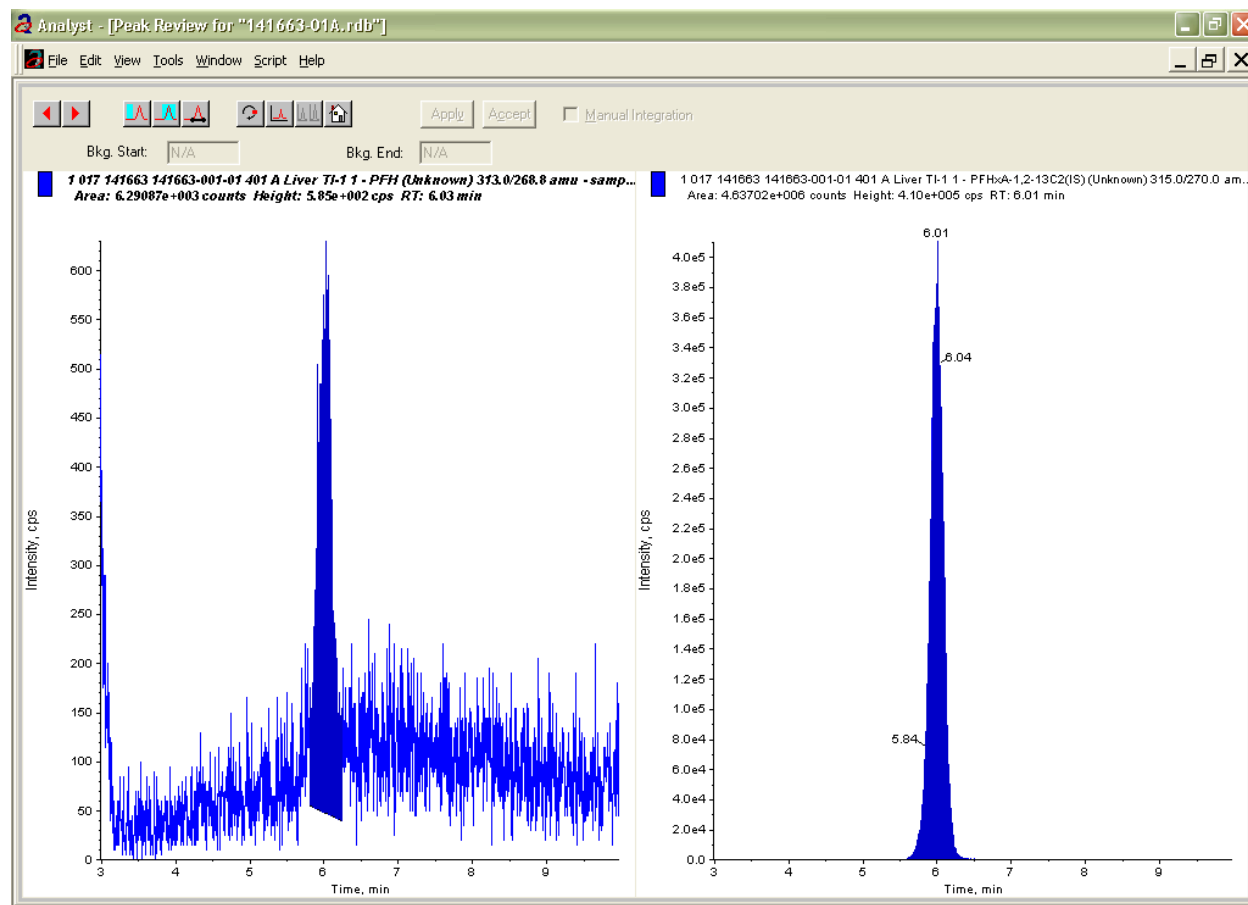


Figure 6 **Representative Sample Chromatogram (Group 1, Animal 507, PND 42)**

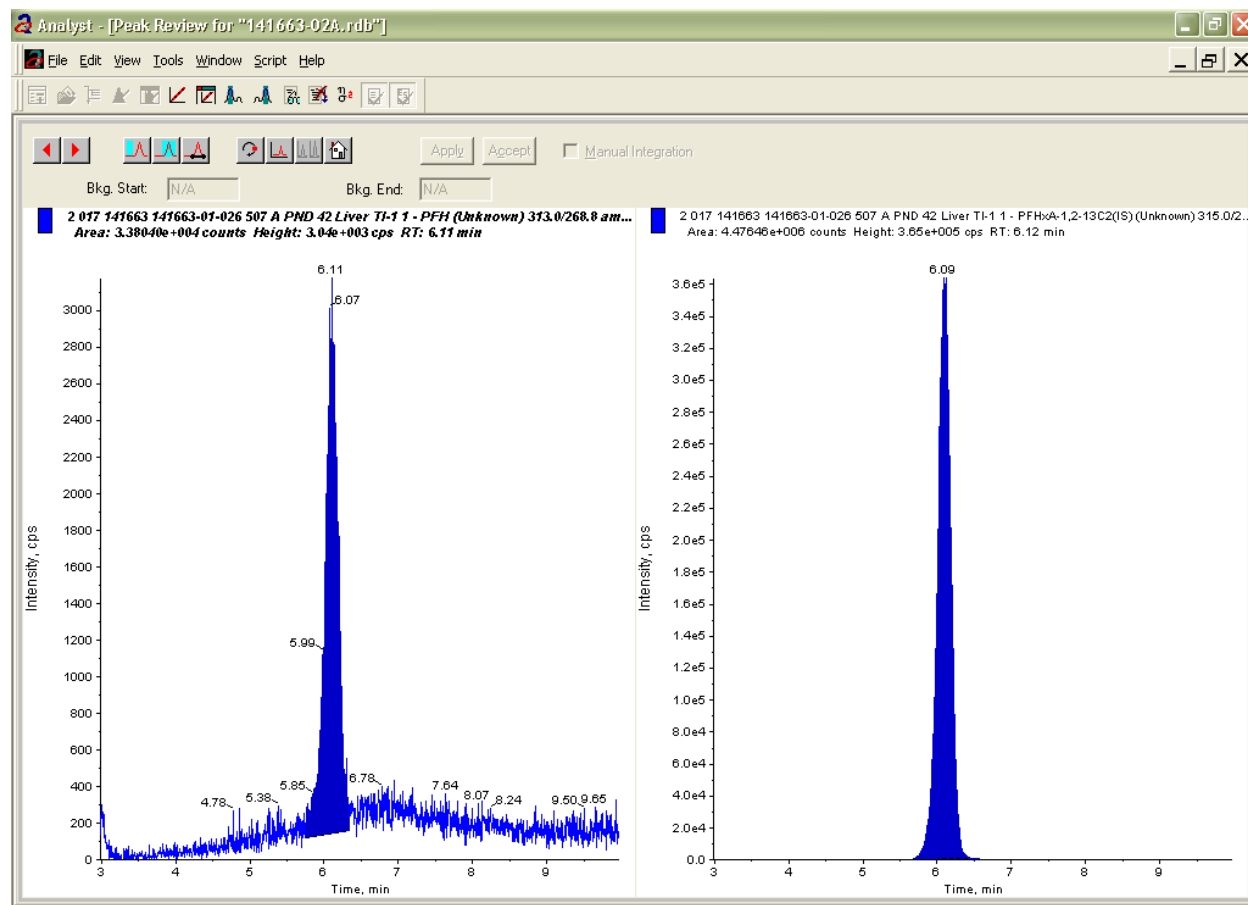


Figure 7 **Representative Sample Chromatogram (Group 2, Animal 421, Day 21)**

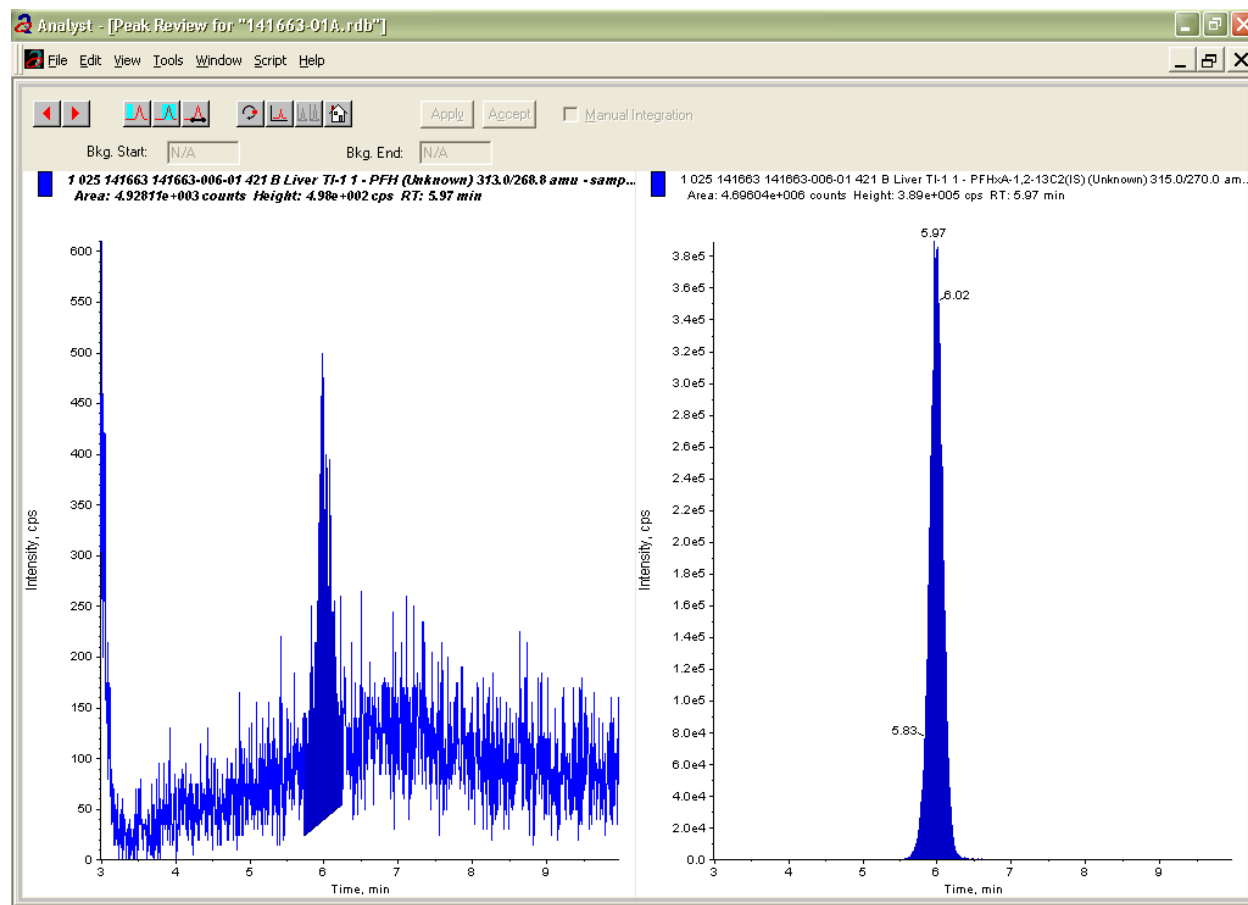


Figure 8 **Representative Sample Chromatogram (Group 2, Animal 528, PND 42)**

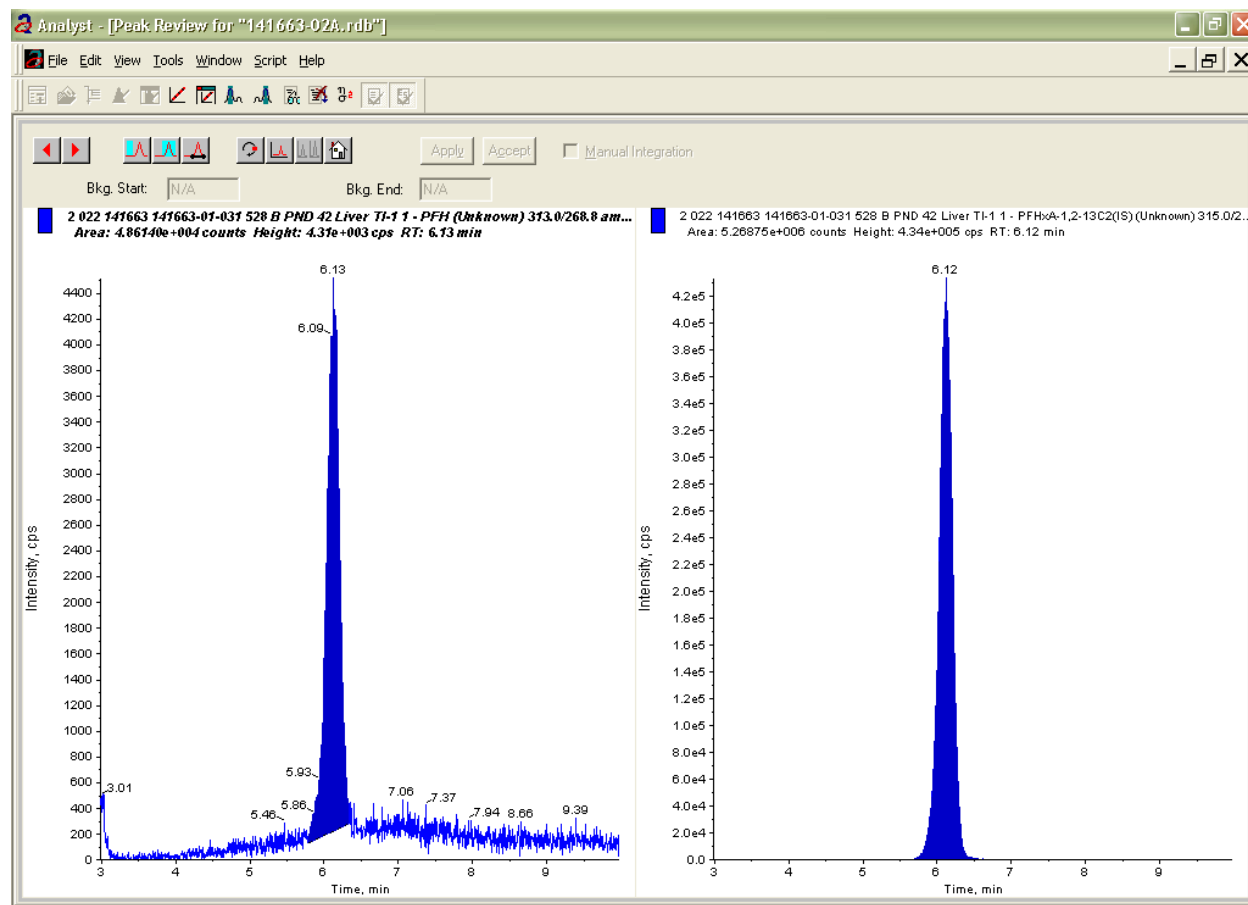
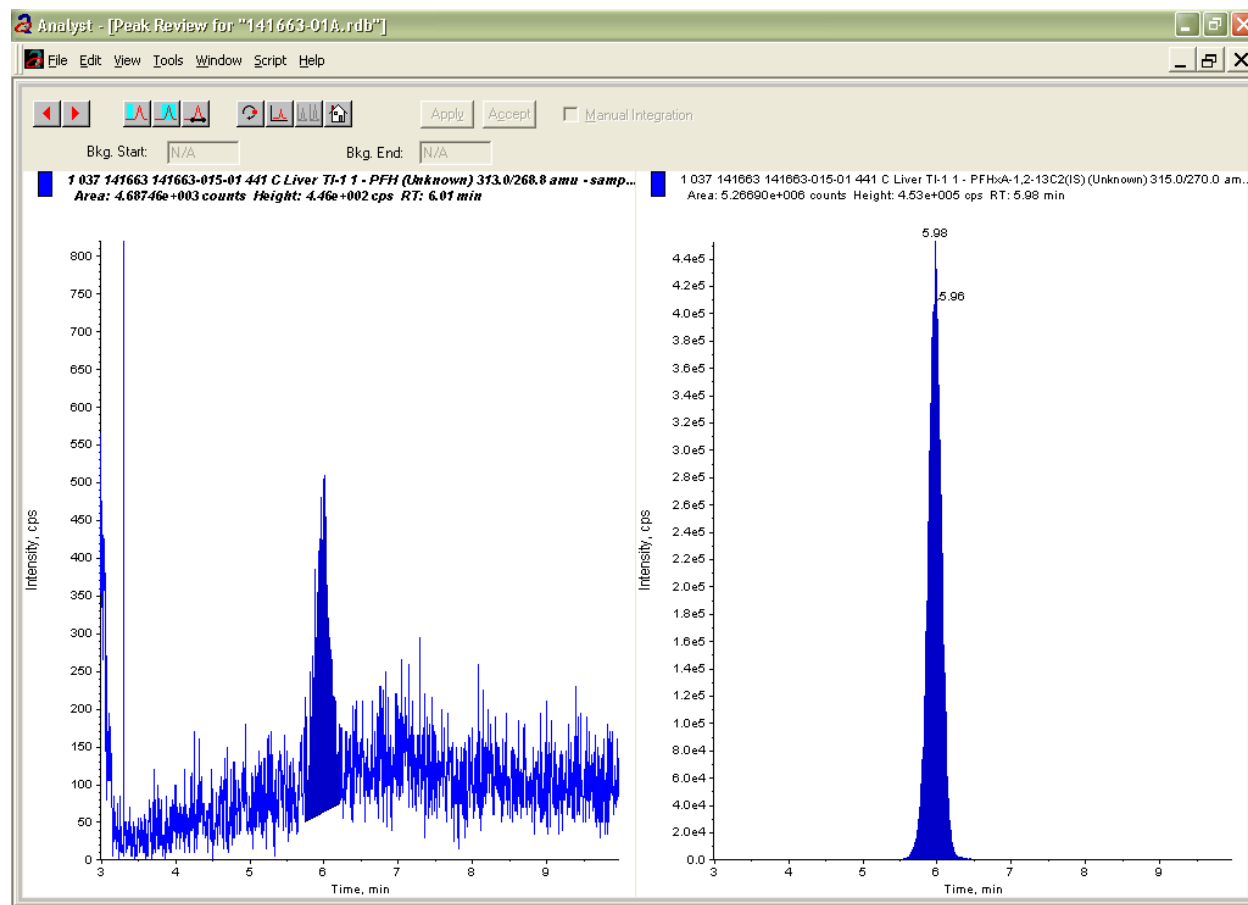


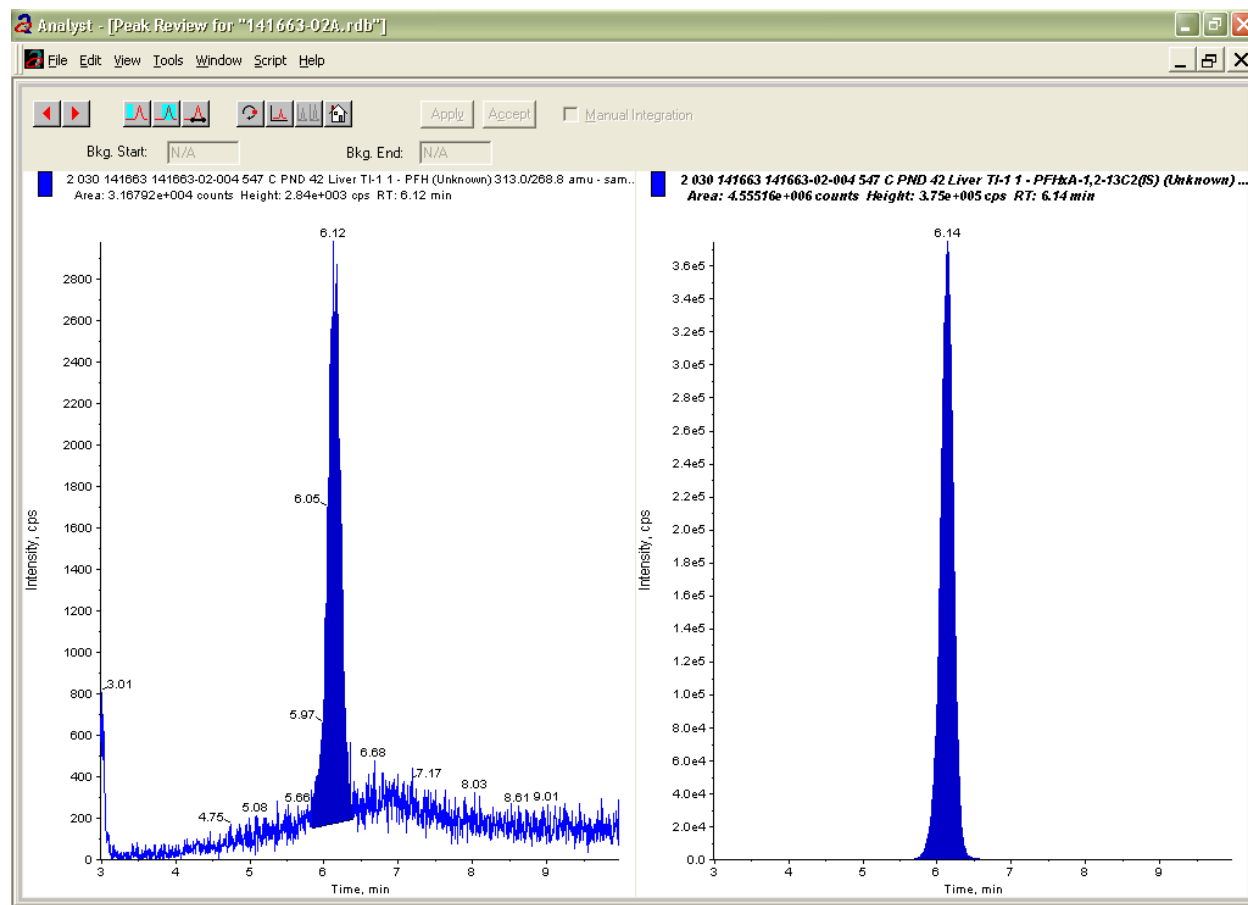
Figure 9 **Representative Sample Chromatogram (Group 3, Animal 441, Day 21)**



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Figure 10 **Representative Sample Chromatogram (Group 3, Animal 547, PND 42)**



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Figure 11 **Representative Sample Chromatogram (Group 4, Animal 463, Day 21)**

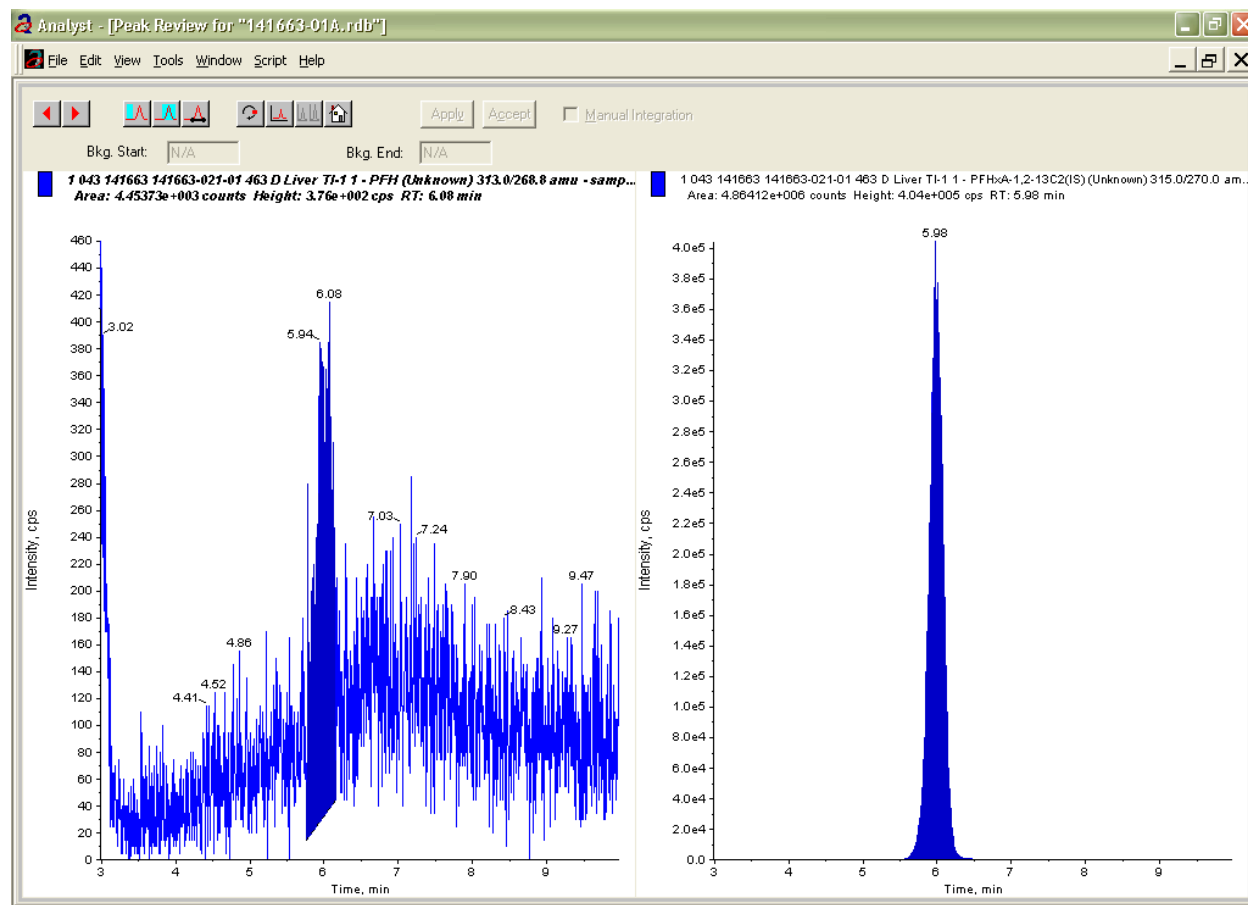
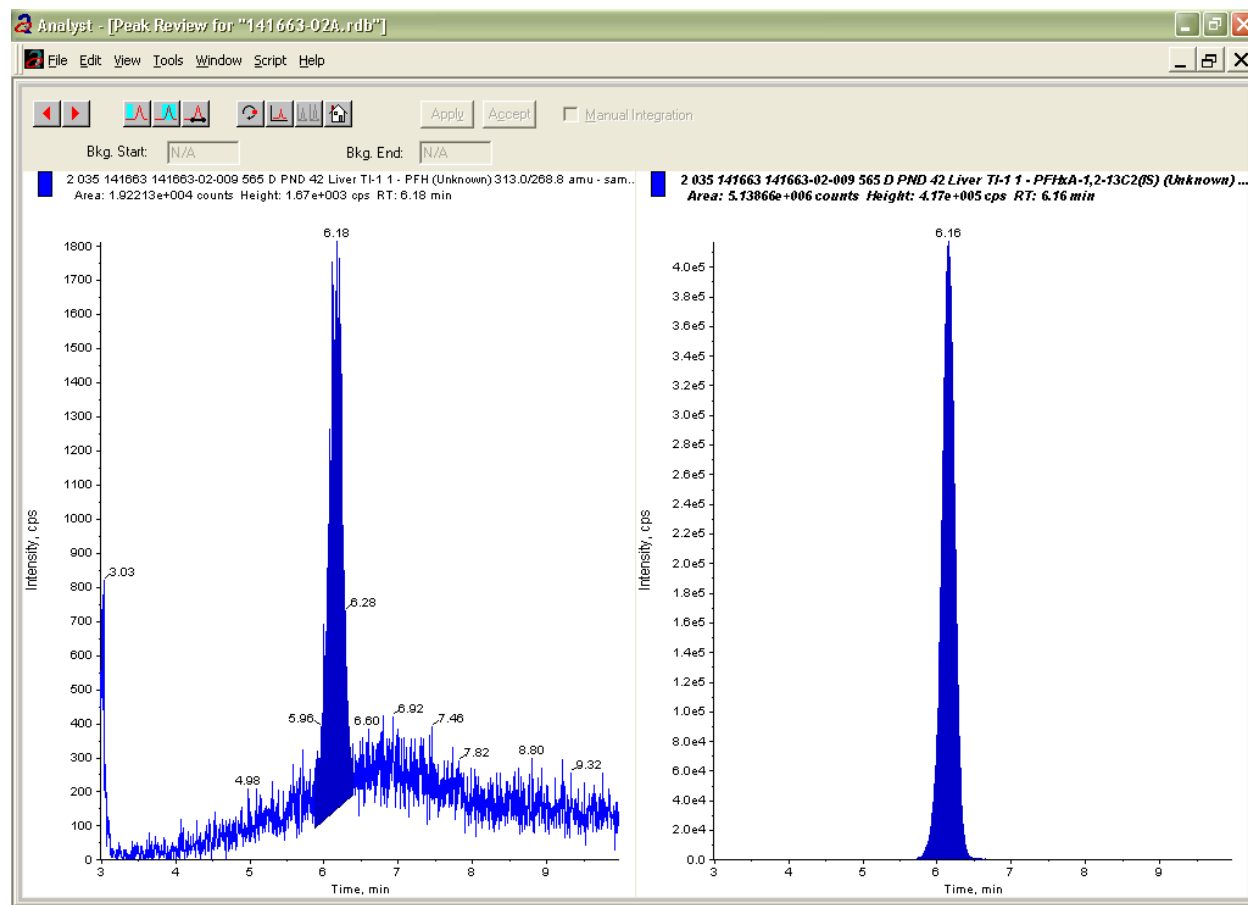


Figure 12 **Representative Sample Chromatogram (Group 4, Animal 565, PND 42)**



Appendix 1

Certificate of Analysis

**Certificate of Analysis***Daikin Industries,LTD.*

Name of Sample *PFH Ammonium Salt (C-1500N)*
Lot. *7005*
Date of Analysis *May 14, 2009*
Purify *47.4% (Effective component in Water)*
 **50.8*0.934%=47.4%*

COMPOSITION

identity		Conc.
#1	Ammonium Perfluorohexanoate CAS RN. 21615-47-4	93.4%
#2	Unknown	6.6%
Total		100%

Analysis system (HPLC)

Equipment : *Waters Alliance2695*
Detector : *Waters 2487UV*
Detection wavelength : *210nm*

Analysis condition

Column : *TOSOH TSKGel ODS120T 4.6mm×150mm*
Temp. : *40 °C*
Mobile phase : *A=acetonitrile , B=Solution of 0.6% perchloric acid in water*
Gradient : *A:B=50:50(mass%) (0-10min.) →90:10(mass%) (15-20min.)*
Injection volume : *20μL*
Injection Concentration : *1% (dilute 50times with water)*

Chemical R&D Center
Unidyne Group
Senior Researcher

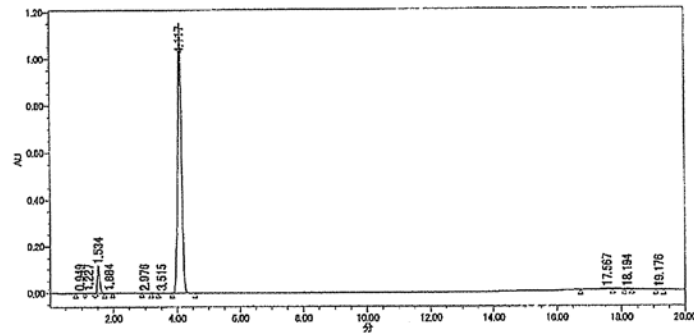
SIGNATURE
DATE : May 18, 2009

Testing Facility Study No. UZS00010

Test Site Ref. No. 141663

Analysis

サンプル名:	C1500N	分析担当者:	System
サンプルの種類:	未知試料	分析日:	2009/05/14 11:40:44
バイアル:	82	取り込みメソッドセット:	080514S
注入量:	1	解析日:	2009/05/14 13:55:17
注入量:	20.00 μ l	解析メソッド:	C1500N
分析時間:	20.00 分	チャンネル名:	2487チャンネル 1
サンプルセット名:		解析チャンネルの説明:	



成分名	Retention Time(min)	Area (μ Vsec)	Area (%)	Height (μ V)		
1	0.049	17634	0.18	2554		
2	1.227	20551	0.20	1027		
3	1.534	574660	5.71	110134		
4	1.884	5543	0.05	710		
5	2.976	2424	0.02	414		
6	3.515	4940	0.05	301		
7	4.117	9390042	93.39	1144210		
8	17.567	29475	0.29	984		
9	18.104	0956	0.07	1090		
10	19.176	3831	0.04	592		

APPENDIX 6 - ENVIRONMENTAL AND HUSBANDRY REPORTS

TEMPERATURE AND RELATIVE HUMIDITY

ARGUS

Temperature and Relative Humidity Report Location: Room 04 Protocol Number: UZS00010			
Range of Dates: 15-Dec-2009 09:05 to 08-Feb-2010 09:59			
Target Range: Species: MOUSE Total Number of Days: Total Number of Hours: Total Number of Data Points:	Temperature 64°F to 79°F 56 1320.5 1321	Relative Humidity 30% to 70% 56 1320.5 1321	
Mean (± SD):	74.7 (± 0.5)	39.3 (± 1.7)	
Maximum:	77.5	48.4	
Median:	74.7	39.5	
Minimum:	73.0	30.3	
Number of Points in Range (%):	1321 (100.0)	1321 (100.0)	
Number of Points High (%):	0 (0.0)	0 (0.0)	
Number of Points Low (%):	0 (0.0)	0 (0.0)	

Report Generated: 26-Feb-2010 at 09:24

COMMENTS: _____

REVIEWED BY: _____ DATE: 26 Feb 10

ARGUS

Temperature and Relative Humidity Report Location: Room 11 Protocol Number: UZS00010			
Range of Dates: 08-Feb-2010 09:05 to 26-Feb-2010 08:59			
Target Range:	Temperature		Relative Humidity
Species: MOUSE	64°F to 79°F		30% to 70%
Total Number of Days:	19		19
Total Number of Hours:	431.5		431.5
Total Number of Data Points:	432		432
Mean (± SD):	71.2	(± 0.9)	37.5 (± 5.4)
Maximum:	78.5		95.6
Median:	71.2		36.8
Minimum:	60.3		33.5
Number of Points in Range (%):	431	(99.8)	427 (98.8)
Number of Points High (%):	0	(0.0)	5 (1.2)
Number of Points Low (%):	1	(0.2)	0 (0.0)

Report Generated: 26-Feb-2010 at 09:26

COMMENTS: _____

REVIEWED BY: _____ DATE: 26 Feb 10



ARGUS**Temperature Deviations Report**
Location: Room 11**Protocol Number: UZS00010****Range of Dates: 08-Feb-2010 09:05 to 26-Feb-2010 08:59****Temperature Target Range:**
Species: MOUSE

64°F to 79°F

Date	Time	Temp.
17-Feb-2010	05:00	60.3 L

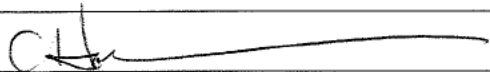
Date	Time	Temp.
------	------	-------

H = Value out of range - High L = Value out of range - Low
Temp. = Temperature °F

Report Generated: 26-Feb-2010 at 09:27

☒ These deviations did not adversely affect the outcome or interpretation of the study.

☐ The following deviation(s) impacted on the outcome of the study as described:

Study Director: 

Date: 17 MAR 2010

ARGUS**Relative Humidity Deviations Report**
Location: Room 11**Protocol Number: UZS00010****Range of Dates: 08-Feb-2010 09:05 to 26-Feb-2010 08:59****Humidity Target Range:**
Species: MOUSE

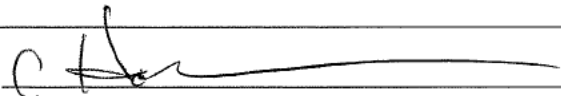
30% to 70%

Date	Time	R.H.	Date	Time	R.H.
17-Feb-2010	06:00	72.7 H			
17-Feb-2010	07:00	91.0 H			
17-Feb-2010	08:00	95.6 H			
17-Feb-2010	09:00	72.4 H			
17-Feb-2010	10:00	88.6 H			

H = Value out of range - High L = Value out of range - Low
R.H. = Relative Humidity (%)**Report Generated: 26-Feb-2010 at 09:28**

☒ These deviations did not adversely affect the outcome or interpretation of the study.

☐ The following deviation(s) impacted on the outcome of the study as described:

Study Director: Date: 17 MAR 2010

FEED ANALYSIS



Return to Certified Analysis Retrieval

Product Code: 5002
 Product Desc: CERTIFIED RODENT DIET
 Lab Number: L0924417-3
 Lot Code: OCT 24 09 2C
 Entered: 11/12/2009

Assay	Analysis	Units
PROTEIN	21.0	%
FAT (ACID HYDRO)	5.57	%
FIBER (CRUDE)	4.28	%
ARSENIC	LESS THAN 0.2	PPM
CADMIUM	0.081	PPM
CALCIUM	0.8409	%
LEAD	0.194	PPM
MERCURY	LESS THAN 0.025	PPM
PHOSPHORUS	0.6642	%
SELENIUM	0.412	PPM

Organophosphates	PPM	Organophosphates	PPM
Diazinon	LESS THAN 0.02	Disulfoton	LESS THAN 0.02
Ethion	LESS THAN 0.02	Malathion	LESS THAN 0.02
Methyl Parathion	LESS THAN 0.02	Parathion	LESS THAN 0.02
Thimet	LESS THAN 0.02	Trithion	LESS THAN 0.02

Chlorinated Hydrocarbons and PCB	PPM	Chlorinated Hydrocarbons and PCB	PPM
Aldrin	LESS THAN 0.02	Alpha-BHC	LESS THAN 0.02
Beta-BHC	LESS THAN 0.02	Chlordane	LESS THAN 0.02
DDE	LESS THAN 0.02	DDT	LESS THAN 0.02
Delta-BHC	LESS THAN 0.02	Dieldrin	LESS THAN 0.02
Endrin	LESS THAN 0.02	HCB	LESS THAN 0.02
Heptachlor	LESS THAN 0.02	Heptachlor Epoxide	LESS THAN 0.02
Lindane	LESS THAN 0.02	Methoxychlor	LESS THAN 0.02
Mirex	LESS THAN 0.02	PCB	LESS THAN 0.15
Thiodan	LESS THAN 0.02		

AFLATOXINS	PPB Aflatoxins	LESS THAN 5
------------	----------------	-------------

Approved
 M. J. [Signature]
 03 Dec 2009

EXACT COPY
 474 Feb 10

No notes.

Approved by: Angela Crutcher

Angela Crutcher

*Approved
M. J. H.
3 Dec 2009*

For additional information, please contact:

- 1) Customer Service at (314) 982-1310 -- for assay methodology
- 2) Dr. Kristi Thompson, (765)894-3104 or Dr. Carrie Schultz, (314)974-6529 -- for nutritional interpretation
- 3) Richmond, IN Manufacturing Plant at (765) 962-9561 -- all other questions

The term "Less Than" is used to signify the lower limit of quantitation of the procedure under the conditions employed.
The use of the term "Less Than" does not imply that traces of analyte were present.

EXACT COPY
LT 4 FEB 10

WATER ANALYSIS



QC Laboratories

Analytical Report



MATTHEW VANEMAN
CHARLES RIVER LAB
905 SHEEHY DRIVE
HORSHAM, PA 19044

Regarding:

MATTHEW VANEMAN
CHARLES RIVER LAB
905 SHEEHY DRIVE
HORSHAM, PA 19044

Account No: W05899, CHARLES RIVER LAB
Project No: W05899, CHARLES RIVER LAB

P.O. No:
PHSID No:

Inv. No: 1166151

Sample Number L3173360-1
Sample Description DRINKING WATER - IN VITRO
Received Temp: 38 F Iced (Y/N): Y

Sample Date/Time/Temp 12/04/09 10:45am NA F
Sampled by Customer Sampled

Parameter	Method	Result	RLs	Test Date, Time, Analyst
-----------	--------	--------	-----	--------------------------

ENVIRONMENTAL MICROBIOLOGY

COLIFORM-MF SM 9222B
STANDARD PLATE COUNT SM 9215B

<1 col/100ml
<1 col/ml

1. col/100ml 12/05/09 05:34AM JJB
1. col/ml 12/05/09 05:34AM AMD

FIELD SERVICES

CHLORINE RESIDUAL LOW LEVEL-
FIELD SM 4500CL G

< 0.02 mg/l

12/04/09 10:45AM CU

Sample Number L3173360-3
Sample Description DRINKING WATER - ANALYTICAL
Received Temp: 38 F Iced (Y/N): Y

Sample Date/Time/Temp 12/04/09 12:00pm NA F
Sampled by Customer Sampled

Parameter	Method	Result	RLs	Test Date, Time, Analyst
-----------	--------	--------	-----	--------------------------

ENVIRONMENTAL MICROBIOLOGY

COLIFORM-MF SM 9222B
STANDARD PLATE COUNT SM 9215B

<1 col/100ml
<1 col/ml

1. col/100ml 12/05/09 05:34AM JJB
1. col/ml 12/05/09 05:34AM AMD

FIELD SERVICES

CHLORINE RESIDUAL LOW LEVEL-
FIELD SM 4500CL G

< 0.02 mg/l

12/04/09 12:00PM CU

Sample Number L3173360-4
Sample Description DRINKING WATER - ROOM 29 RACK 174
Received Temp: 38 F Iced (Y/N): Y

Sample Date/Time/Temp 12/04/09 12:04pm NA F
Sampled by Customer Sampled

Parameter	Method	Result	RLs	Test Date, Time, Analyst
-----------	--------	--------	-----	--------------------------

ENVIRONMENTAL MICROBIOLOGY

COLIFORM-MF SM 9222B

<1 col/100ml

1. col/100ml 12/05/09 05:34AM JJB

Page 1 of 4

Serial Number: 1276129

Approved
Thomas J. Hines
10 Dec 2009
Thomas J. Hines, President

1205 Industrial Blvd., P.O. Box 514, Southampton, PA 18966-0514 Phone: 215-355-3900 Fax: 215-355-7231 www.qclaboratories.com

EXACT COPY

LT 4 Feb 10

QC Laboratories

Analytical Report



Account No: W05899, CHARLES RIVER LAB
Project No: W05899, CHARLES RIVER LAB

P.O. No:
PWSID No:

Inv. No: 1166151

Sample Number L3173360-4	Sample Description DRINKING WATER - ROOM 29 RACK 174	Samp. Date/Time/Temp 12/04/09 12:04pm NA F	Sampled by Customer Sampled
Parameter STANDARD PLATE COUNT	Method SM 9215B	Result <1 col/ml	RLs 1. col/ml
FIELD SERVICES CHLORINE RESIDUAL		0.35 mg/l	0.02 mg/l
		12/04/09 12:04PM CU	
Sample Number L3173360-5	Sample Description DRINKING WATER - FILL STATION Received Temp: 38 F Iced (Y/N): Y	Samp. Date/Time/Temp 12/04/09 12:07pm NA F	Sampled by Customer Sampled
Parameter STANDARD PLATE COUNT	Method SM 9215B	Result <1 col/ml	RLs 1. col/ml
ENVIRONMENTAL MICROBIOLOGY COLIFORM-MF		<1 col/100ml	1. col/100ml
STANDARD PLATE COUNT		<1 col/ml	1. col/ml
FIELD SERVICES CHLORINE RESIDUAL		1.00 mg/l	0.02 mg/l
		12/04/09 12:07PM CU	
Sample Number L3173360-6	Sample Description DRINKING WATER - ROOM 55 RACK 1783 Received Temp: 38 F Iced (Y/N): Y	Samp. Date/Time/Temp 12/04/09 12:11pm NA F	Sampled by Customer Sampled
Parameter STANDARD PLATE COUNT	Method SM 9215B	Result <1 col/ml	RLs 1. col/ml
ENVIRONMENTAL MICROBIOLOGY COLIFORM-MF		<1 col/100ml	1. col/100ml
STANDARD PLATE COUNT		<1 col/ml	1. col/ml
FIELD SERVICES CHLORINE RESIDUAL		0.28 mg/l	0.02 mg/l
		12/04/09 12:11PM CU	
Sample Number L3173360-7	Sample Description DRINKING WATER - FORMULATION Received Temp: 38 F Iced (Y/N): Y	Samp. Date/Time/Temp 12/04/09 12:15pm NA F	Sampled by Customer Sampled
Parameter STANDARD PLATE COUNT	Method SM 9215B	Result <1 col/ml	RLs 1. col/ml
ENVIRONMENTAL MICROBIOLOGY COLIFORM-MF		<1 col/100ml	1. col/100ml
STANDARD PLATE COUNT		<1 col/ml	1. col/ml
FIELD SERVICES CHLORINE RESIDUAL LOW LEVEL- FIELD		< 0.02 mg/l	
		12/04/09 12:15PM CU	

Approved
10 Dec 2009
Thomas J. Hines, President

EXACT COPY

LT 4 Feb 10

QC Laboratories

Analytical Report



Account No: W05899, CHARLES RIVER LAB
Project No: W05899, CHARLES RIVER LAB

P.O. No:
PMSD No:

Inv. No: 1166151

L3173360-1:

1. A water supply is considered bacteriologically "SAFE" if no Coliform bacteria are detected. To be considered "SAFE" your report should indicate "<1 col/100ml" or "NEG" for the Coliform Test. If your report indicates a positive result "POS" or a value of one (1) or greater then your supply is "UNSAFE FOR DRINKING" contact your local Health Dept. or QC for advice.

L3173360-3:

1. A water supply is considered bacteriologically "SAFE" if no Coliform bacteria are detected. To be considered "SAFE" your report should indicate "<1 col/100ml" or "NEG" for the Coliform Test. If your report indicates a positive result "POS" or a value of one (1) or greater then your supply is "UNSAFE FOR DRINKING" contact your local Health Dept. or QC for advice.

L3173360-4:

1. A water supply is considered bacteriologically "SAFE" if no Coliform bacteria are detected. To be considered "SAFE" your report should indicate "<1 col/100ml" or "NEG" for the Coliform Test. If your report indicates a positive result "POS" or a value of one (1) or greater then your supply is "UNSAFE FOR DRINKING" contact your local Health Dept. or QC for advice.

L3173360-5:

1. A water supply is considered bacteriologically "SAFE" if no Coliform bacteria are detected. To be considered "SAFE" your report should indicate "<1 col/100ml" or "NEG" for the Coliform Test. If your report indicates a positive result "POS" or a value of one (1) or greater then your supply is "UNSAFE FOR DRINKING" contact your local Health Dept. or QC for advice.

L3173360-6:

1. A water supply is considered bacteriologically "SAFE" if no Coliform bacteria are detected. To be considered "SAFE" your report should indicate "<1 col/100ml" or "NEG" for the Coliform Test. If your report indicates a positive result "POS" or a value of one (1) or greater then your supply is "UNSAFE FOR DRINKING" contact your local Health Dept. or QC for advice.

L3173360-7:

1. A water supply is considered bacteriologically "SAFE" if no Coliform bacteria are detected. To be considered "SAFE" your report should indicate "<1 col/100ml" or "NEG" for the Coliform Test. If your report indicates a positive result "POS" or a value of one (1) or greater then your supply is "UNSAFE FOR DRINKING" contact your local Health Dept. or QC for advice.

- A result of "ND" indicates the concentration of the analyte tested was either not detected or below the RLS.
- Definitions: ND=not detected; NEG=negative; POS=positive; COL=colonies; RLS=laboratory reporting limits; L/A=laboratory accident; TNTC=too numerous to count
- A result marked with "DRY" indicates that the result was calculated and reported on a dry weight basis.
- All analysis, except field tests are conducted in Southampton, PA unless otherwise identified.
- The test "pH lab" is analyzed upon receipt at the laboratory, the result will not be suitable for regulatory purposes.
- The reported results relate only to the samples.

Page 3 of 4

Serial Number: 1276129

Approved
10 Dec 2009
Thomas J. Hines
Thomas J. Hines, President

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LT 4 Feb 10

QC Laboratories

Analytical Report



Account No: W05899, CHARLES RIVER LAB
Project No: W05899, CHARLES RIVER LAB

P.O. No:
PWSID No:

Inv. No: 1166151

- QC NELAP ID's: PA 09-00131, NJ PA166, FL E87954, NY 11223, CT PH-0768, DE PA-018, KY 90228, MD 206, EPA PA00018, Bioassay: PA 09-03574, NJ PA034, FL E87953, KS E10373, SC 89020001.
- QC STATE ID's: Wind Gap, NJ PA001, PA 48-01334; E RUTHERFORD NJ02015; Vineland NJ06005; Reading PA 06-03543.
- All samples are collected as "grab" samples unless otherwise identified.
- MCL is the EPA recommended "maximum contaminant level" for a parameter. PLS-customer specific permit limits.
- The test results meet all requirements of NELAP unless otherwise specified.
- The report shall not be reproduced except in full without the written consent of the laboratory.
Regulatory authorities are assessing substantial fines for testing omissions. Please track your sample collections and results on a weekly, monthly, or quarterly basis to ensure compliance. QC's internet program 'LIVE ACCESS' will provide you with real-time access to collection dates and results. Please contact Customer Service for further information on acquiring LIVE ACCESS.

Approved
[Signature]
10 Dec 2009

EXACT COPY

LT 4 Feb 10



Analytical Report



Regarding:

MATTHEW VANEMAN
CHARLES RIVER LAB
905 SHEEHY DRIVE
HORSHAM, PA 19044

MATTHEW VANEMAN
CHARLES RIVER LAB
905 SHEEHY DRIVE
HORSHAM, PA 19044

Account No: W05899, CHARLES RIVER LAB
Project No: W05899, CHARLES RIVER LAB

P.O. No:
PWSID No:

Inv. No: 1173373

Sample Number	Sample Description	Samp. Date/Time/Temp	Sampled by
L3195088-1	DRINKING WATER - IN VITRO Received Temp: 35 F Iced (Y/N): Y	01/08/10 11:42am NA F	Customer Sampled

Parameter	Method	Result	RLs	Test Date, Time, Analyst
ENVIRONMENTAL MICROBIOLOGY				
COLIFORM-MF	SM 9222B	<1 col/100ml	1. col/100ml	01/09/10 05:37AM AMD
STANDARD PLATE COUNT	SM 9215B	<1 col/ml	1. col/ml	01/09/10 05:37AM JJB
FIELD SERVICES				
CHLORINE RESIDUAL LOW LEVEL- FIELD	SM 4500CL G	< 0.02 mg/l		01/08/10 11:42AM CU

Sample Number	Sample Description	Samp. Date/Time/Temp	Sampled by
L3195088-2	DRINKING WATER - ANALYTICAL Received Temp: 35 F Iced (Y/N): Y	01/08/10 12:00pm NA F	Customer Sampled

Parameter	Method	Result	RLs	Test Date, Time, Analyst
ENVIRONMENTAL MICROBIOLOGY				
COLIFORM-MF	SM 9222B	<1 col/100ml	1. col/100ml	01/09/10 05:37AM AMD
STANDARD PLATE COUNT	SM 9215B	<1 col/ml	1. col/ml	01/09/10 05:37AM JJB
FIELD SERVICES				
CHLORINE RESIDUAL LOW LEVEL- FIELD	SM 4500CL G	< 0.02 mg/l		01/08/10 12:00PM CU

Sample Number	Sample Description	Samp. Date/Time/Temp	Sampled by
L3195088-3	DRINKING WATER - FILL STATION Received Temp: 35 F Iced (Y/N): Y	01/08/10 12:09pm NA F	Customer Sampled

Parameter	Method	Result	RLs	Test Date, Time, Analyst
ENVIRONMENTAL MICROBIOLOGY				
COLIFORM-MF	SM 9222B	<1 col/100ml	1. col/100ml	01/09/10 05:37AM AMD

Page 1 of 4

Serial Number: 1294992

Approved
Thomas J. Hines
Thomas J. Hines, President
12 JAN 2010

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LT 4 FEB 10

QC Laboratories

Analytical Report



Account No: W05899, CHARLES RIVER LAB
Project No: W05899, CHARLES RIVER LAB

P.O. No:
PWSID No:

Inv. No: 1173373

Sample Number	Sample Description	Samp. Date/Time/Temp	Sampled by	
L3195088-3	DRINKING WATER - FILL STATION	01/08/10 12:09pm NA F	Customer Sampled	
Parameter	Method	Result	RLs	Test Date, Time, Analyst
STANDARD PLATE COUNT	SM 9215B	2 col/ml	1. col/ml	01/09/10 05:37AM JJB
FIELD SERVICES				
CHLORINE RESIDUAL	SM 4500CL G	1.19 mg/l	0.02 mg/l	01/08/10 12:09PM CU
Sample Number	Sample Description	Samp. Date/Time/Temp	Sampled by	
L3195088-4	DRINKING WATER - ROOM 17 RACK 171 Received Temp: 35 F Iced (Y/N): Y	01/08/10 12:16pm NA F	Customer Sampled	
Parameter	Method	Result	RLs	Test Date, Time, Analyst
ENVIRONMENTAL MICROBIOLOGY				
COLIFORM-MF	SM 9222B	<1 col/100ml	1. col/100ml	01/09/10 05:37AM AMD
STANDARD PLATE COUNT	SM 9215B	<1 col/ml	1. col/ml	01/09/10 05:37AM JJB
FIELD SERVICES				
CHLORINE RESIDUAL	SM 4500CL G	0.42 mg/l	0.02 mg/l	01/08/10 12:16PM CU
Sample Number	Sample Description	Samp. Date/Time/Temp	Sampled by	
L3195088-5	DRINKING WATER - ROOM 56 RACK RB2 Received Temp: 35 F Iced (Y/N): Y	01/08/10 12:32pm NA F	Customer Sampled	
Parameter	Method	Result	RLs	Test Date, Time, Analyst
ENVIRONMENTAL MICROBIOLOGY				
COLIFORM-MF	SM 9222B	<1 col/100ml	1. col/100ml	01/09/10 05:37AM AMD
STANDARD PLATE COUNT	SM 9215B	160 col/ml (1)	1. col/ml	01/09/10 05:37AM JJB
FIELD SERVICES				
CHLORINE RESIDUAL	SM 4500CL G	0.40 mg/l	0.02 mg/l	01/08/10 12:32PM CU
Sample Number	Sample Description	Samp. Date/Time/Temp	Sampled by	
L3195088-6	DRINKING WATER - FORMULATION Received Temp: 35 F Iced (Y/N): Y	01/08/10 12:42pm NA F	Customer Sampled	
Parameter	Method	Result	RLs	Test Date, Time, Analyst
ENVIRONMENTAL MICROBIOLOGY				
COLIFORM-MF	SM 9222B	<1 col/100ml	1. col/100ml	01/09/10 05:37AM AMD
STANDARD PLATE COUNT	SM 9215B	<1 col/ml	1. col/ml	01/09/10 05:37AM JJB
FIELD SERVICES				
CHLORINE RESIDUAL LOW LEVEL-FIELD	SM 4500CL G	< 0.02 mg/l		01/08/10 12:42PM CU

Page 2 of 4

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LT 42610

Serial Number: 1294992

Approved
MAY 12 JAN 2010

Thomas J. Hines, President

Chlorine records were reviewed and the injection system appears to be functioning properly. Retest requested 12 Jan 2010

QC Laboratories

Analytical Report



Account No: W05899, CHARLES RIVER LAB
Project No: W05899, CHARLES RIVER LAB

P.O. No:
PWSID No:

Inv. No: 1173373

L3195088-1:

1. A water supply is considered bacteriologically "SAFE" if no Coliform bacteria are detected. To be considered "SAFE" your report should indicate "<1 col/100ml" or "NEG" for the Coliform Test. If your report indicates a positive result "POS" or a value of one (1) or greater then your supply is "UNSAFE FOR DRINKING" contact your local Health Dept. or QC for advice.

L3195088-2:

1. A water supply is considered bacteriologically "SAFE" if no Coliform bacteria are detected. To be considered "SAFE" your report should indicate "<1 col/100ml" or "NEG" for the Coliform Test. If your report indicates a positive result "POS" or a value of one (1) or greater then your supply is "UNSAFE FOR DRINKING" contact your local Health Dept. or QC for advice.

L3195088-3:

1. A water supply is considered bacteriologically "SAFE" if no Coliform bacteria are detected. To be considered "SAFE" your report should indicate "<1 col/100ml" or "NEG" for the Coliform Test. If your report indicates a positive result "POS" or a value of one (1) or greater then your supply is "UNSAFE FOR DRINKING" contact your local Health Dept. or QC for advice.

L3195088-4:

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L3195088-6:

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- Definitions: ND=not detected; NEG=negative; POS=positive; COL=colonies; RLs=laboratory reporting limits; L/A=laboratory accident; TNTC=too numerous to count
- A result marked with "DRY" indicates that the result was calculated and reported on a dry weight basis.
- All analysis, except field tests are conducted in Southampton, PA unless otherwise identified.
- The test "pH lab" is analyzed upon receipt at the laboratory, the result will not be suitable for regulatory purposes.
- The reported results relate only to the samples.

Approved
[Signature]
12 JAN 2010 Thomas J. Hines
Thomas J. Hines, President

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174 Feb 10

QC Laboratories

Analytical Report



Account No: W05899, CHARLES RIVER LAB
Project No: W05899, CHARLES RIVER LAB

P.O. No:
PWSID No:

Inv. No: 1173373

- QC NELAP ID's: PA 09-00131, NJ PA166, FL E87954, NY 11223, CT PH-0768, DE PA-018, KY 90228, MD 206, EPA PA00018. Bioassay: PA 09-03574, NJ PA034, FL E87953, KS E10373, SC 89020001.

- QC STATE ID's: Wind Gap, NJ PA001, PA 48-01334; E RUTHERFORD NJ02015; Vineland NJ06005; Reading PA 06-03543.

- All samples are collected as "grab" samples unless otherwise identified.

- MCL= is the EPA recommended "maximum contaminant level" for a parameter. PLS=customer specific permit limits.

- The test results meet all requirements of NELAC unless otherwise specified.

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Approved
[Signature]
12 JAN 2010

Thomas J. Hines
Thomas J. Hines, President

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LT 4 Feb 10



Analytical Report



MATTHEW VANEMAN
CHARLES RIVER LAB
905 SHEEHY DRIVE
HORSHAM, PA 19044

Regarding:

MATTHEW VANEMAN
CHARLES RIVER LAB
905 SHEEHY DRIVE
HORSHAM, PA 19044

Account No: W05899, CHARLES RIVER LAB
Project No: W05899, CHARLES RIVER LAB

P.O. No:
PWSID No:

Inv. No: 1174397

Sample Number L3227324-1
Sample Description DRINKING WATER - ROOM 56 RACK #037
Received Temp: 38 F Iced (Y/N): Y

Samp. Date/Time/Temp
01/13/10 12:16pm NA F

Sampled by
Customer Sampled

Parameter	Method	Result	RLs	Test Date, Time, Analyst
-----------	--------	--------	-----	--------------------------

ENVIRONMENTAL MICROBIOLOGY

COLIFORM-MF	SM 9222B	<1 col/100ml	1. col/100ml	01/13/10 03:43PM ARD
STANDARD PLATE COUNT	SM 9215B	<1 col/ml	1. col/ml	01/13/10 03:43PM JJB

FIELD SERVICES

CHLORINE RESIDUAL	SM 4500CL G	0.3 mg/l	0.02 mg/l	01/13/10 12:16PM CU
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L3227324-1:

1. A water supply is considered bacteriologically "SAFE" if no Coliform bacteria are detected. To be considered "SAFE" your report should indicate "<1 col/100ml" or "NEG" for the Coliform Test. If your report indicates a positive result "POS" or a value of one (1) or greater then your supply is "UNSAFE FOR DRINKING" contact your local Health Dept. or QC for advice.

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- A result marked with "DRY" indicates that the result was calculated and reported on a dry weight basis.
- All analysis, except field tests are conducted in Southampton, PA unless otherwise identified.
- The test "ph lab" is analyzed upon receipt at the laboratory, the result will not be suitable for regulatory purposes.
- The reported results relate only to the samples.
- QC NELAP ID's: PA 09-00131, NJ PA166, FL E87954, NY 11223, CT PH-0768, DE PA-018, KY 90228, MD 206, EPA PA00018, Bioassay: PA 09-03574, NJ PA034, FL E87953, KS E10373, SC 89020001.
- QC STATE ID's: Wind Gap, NJ PA001, PA 48-01334; E RUTHERFORD NJ02015; Vineland NJ06005; Reading PA 06-03543.
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- MCL= is the EPA recommended "maximum contaminant level" for a parameter. PLs=customer specific permit limits.
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Page 1 of 2

Serial Number: 1297565

Approved
[Signature]
26 JAN 2010
classified date w 26 Jan 2010
Thomas J. Hines, President

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L74 Feb 10

QC Laboratories

Analytical Report



Account No: W05899, CHARLES RIVER LAB
Project No: W05899, CHARLES RIVER LAB

P.O. No:
PWSID No:

Inv. No: 1174397

Regulatory authorities are assessing substantial fines for testing omissions. Please track your sample collections and results on a weekly, monthly, or quarterly basis to ensure compliance. QC's internet program 'LIVE ACCESS' will provide you with real-time access to collection dates and results. Please contact Customer Service for further information on acquiring LIVE ACCESS.

Approved
[Signature]
26 JAN 2010

Thomas J. Hines
Thomas J. Hines, President

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LT 4 Feb 10



Analytical Report



MATTHEW VANEMAN
CHARLES RIVER LABORATORIES, INC.
905 SHEEHY DRIVE
HORSHAM, PA 19044

Regarding:

MATTHEW VANEMAN
CHARLES RIVER LABORATORIES, INC.
905 SHEEHY DRIVE
HORSHAM, PA 19044

Account No: W05899, CHARLES RIVER LABORATORIES, INC.
Project No: W05899, CHARLES RIVER LABORATORIES, INC.

P.O. No: 6600058860
PWSID No:

Inv. No: 1179807

Sample Number	Sample Description	Samp. Date/Time/Temp	Sampled by
L3229813-1	DRINKING WATER - IN VITRO Received Temp: 34 F Iced (Y/N): Y	02/05/10 11:00am NA F	Customer Sampled

Parameter	Method	Result	RLs	Test Date, Time, Analyst
ENVIRONMENTAL MICROBIOLOGY				
COLIFORM-MF	SM 9222B	<1 col/100ml	1. col/100ml	02/05/10 03:44PM AMD
STANDARD PLATE COUNT	SM 9215B	<1 col/ml	1. col/ml	02/05/10 03:44PM TF
FIELD SERVICES				
CHLORINE RESIDUAL LOW LEVEL- FIELD	SM 4500CL G	< 0.02 mg/l		02/05/10 11:01AM CU

Sample Number	Sample Description	Samp. Date/Time/Temp	Sampled by
L3229813-2	DRINKING WATER - FORMULATION Received Temp: 34 F Iced (Y/N): Y	02/05/10 11:21am NA F	Customer Sampled

Parameter	Method	Result	RLs	Test Date, Time, Analyst
ENVIRONMENTAL MICROBIOLOGY				
COLIFORM-MF	SM 9222B	<1 col/100ml	1. col/100ml	02/05/10 03:44PM AMD
STANDARD PLATE COUNT	SM 9215B	<1 col/ml	1. col/ml	02/05/10 03:44PM TF
FIELD SERVICES				
CHLORINE RESIDUAL LOW LEVEL- FIELD	SM 4500CL G	< 0.02 mg/l		02/05/10 11:23AM CU

Sample Number	Sample Description	Samp. Date/Time/Temp	Sampled by
L3229813-3	DRINKING WATER - ROOM 55 RACK 60 Received Temp: 34 F Iced (Y/N): Y	02/05/10 11:27am NA F	Customer Sampled

Parameter	Method	Result	RLs	Test Date, Time, Analyst
ENVIRONMENTAL MICROBIOLOGY				
COLIFORM-MF	SM 9222B	<1 col/100ml	1. col/100ml	02/05/10 03:44PM TF

Page 1 of 4

This report is a revision of report number 1308240
Serial Number: 1320690

Thomas J. Hines
Thomas J. Hines, President

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LT 15A0010

Approved
[Signature]
10 MAR 2010

QC Laboratories

Analytical Report



Account No: W05899, CHARLES RIVER LABORATORIES, INC.
Project No: W05899, CHARLES RIVER LABORATORIES, INC.

P.O. No: 6600058860
PWSID No:

Inv. No: 1179807

Sample Number L3229813-3	Sample Description DRINKING WATER - ROOM 55 RACK 60	Samp. Date/Time/Temp 02/05/10 11:27am NA F	Sampled by Customer Sampled	
Parameter STANDARD PLATE COUNT	Method SM 9215B	Result <1 col/ml	RLs 1. col/ml	Test Date, Time, Analyst 02/05/10 03:44PM TF
FIELD SERVICES				
CHLORINE RESIDUAL	SM 4500CL G	0.50 mg/l	0.02 mg/l	02/05/10 11:28AM CU
Sample Number L3229813-4	Sample Description DRINKING WATER - FILL STATION Received Temp: 34 F Iced (Y/N): Y	Samp. Date/Time/Temp 02/05/10 11:31am NA F	Sampled by Customer Sampled	
Parameter	Method	Result	RLs	Test Date, Time, Analyst
ENVIRONMENTAL MICROBIOLOGY				
COLIFORM-MF	SM 9222B	<1 col/100ml	1. col/100ml	02/05/10 03:44PM AND
STANDARD PLATE COUNT	SM 9215B	<1 col/ml	1. col/ml	02/05/10 03:44PM TF
FIELD SERVICES				
CHLORINE RESIDUAL	SM 4500CL G	0.49 mg/l	0.02 mg/l	02/05/10 11:41AM CU
Sample Number L3229813-5	Sample Description DRINKING WATER - ANALYTICAL Received Temp: 34 F Iced (Y/N): Y	Samp. Date/Time/Temp 02/05/10 11:35am NA F	Sampled by Customer Sampled	
Parameter	Method	Result	RLs	Test Date, Time, Analyst
ENVIRONMENTAL MICROBIOLOGY				
COLIFORM-MF	SM 9222B	<1 col/100ml	1. col/100ml	02/05/10 03:44PM TF
STANDARD PLATE COUNT	SM 9215B	<1 col/ml	1. col/ml	02/05/10 03:44PM TF
FIELD SERVICES				
CHLORINE RESIDUAL LOW LEVEL- FIELD	SM 4500CL G	< 0.02 mg/l		02/05/10 11:38AM CU
Sample Number L3229813-6	Sample Description DRINKING WATER - ROOM 7 RACK 003 Received Temp: 34 F Iced (Y/N): Y	Samp. Date/Time/Temp 02/05/10 11:48am NA F	Sampled by Customer Sampled	
Parameter	Method	Result	RLs	Test Date, Time, Analyst
ENVIRONMENTAL MICROBIOLOGY				
COLIFORM-MF	SM 9222B	<1 col/100ml	1. col/100ml	02/05/10 03:44PM AND
STANDARD PLATE COUNT	SM 9215B	<1 col/ml	1. col/ml	02/05/10 03:44PM TF
FIELD SERVICES				
CHLORINE RESIDUAL	SM 4500CL G	0.50 mg/l	0.02 mg/l	02/05/10 11:50AM CU

Page 2 of 4

This report is a revision of report number 1308240
Serial Number: 1320690

EXACT COPY
LT 15 Apr 10

Approved
Thomas J. Hines, President
10 MAR 2010

QC Laboratories

Analytical Report



Account No: W05899, CHARLES RIVER LABORATORIES, INC.
Project No: W05899, CHARLES RIVER LABORATORIES, INC.

P.O. No: 6600058860
PWSID No:

Inv. No: 1179807

L3229813-1:

1. A water supply is considered bacteriologically "SAFE" if no Coliform bacteria are detected. To be considered "SAFE" your report should indicate "<1 col/100ml" or "NEG" for the Coliform Test. If your report indicates a positive result "POS" or a value of one (1) or greater then your supply is "UNSAFE FOR DRINKING" contact your local Health Dept. or QC for advice.

L3229813-2:

1. A water supply is considered bacteriologically "SAFE" if no Coliform bacteria are detected. To be considered "SAFE" your report should indicate "<1 col/100ml" or "NEG" for the Coliform Test. If your report indicates a positive result "POS" or a value of one (1) or greater then your supply is "UNSAFE FOR DRINKING" contact your local Health Dept. or QC for advice.

L3229813-3:

1. A water supply is considered bacteriologically "SAFE" if no Coliform bacteria are detected. To be considered "SAFE" your report should indicate "<1 col/100ml" or "NEG" for the Coliform Test. If your report indicates a positive result "POS" or a value of one (1) or greater then your supply is "UNSAFE FOR DRINKING" contact your local Health Dept. or QC for advice.

L3229813-4:

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L3229813-6:

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- The reported results relate only to the samples.
- QC NELAP ID's: PA 09-00131, NJ PA166, FL E87954, NY 11223, CT PH-0768, DE PA-018, KY 90228, MD 206, EPA PA00018, Bioassay: PA 09-03574, NJ

Page 3 of 4

This report is a revision of report number 1308240
Serial Number: 1320590

Thomas J. Hines
Thomas J. Hines, President

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Approved
[Signature]
10 MAR 2010

QC Laboratories

Analytical Report



Account No: W05899, CHARLES RIVER LABORATORIES, INC.
Project No: W05899, CHARLES RIVER LABORATORIES, INC.

P.O. No: 6600058860
PWSID No:

Inv. No: 1179807

PA034, FL E87953, KS E10373, SC 89020001.

- QC STATE ID's: Wind Gap, NJ PA001, PA 48-01334; E RUTHERFORD NJ02015; Vineland NJ06005; Reading PA 06-03543.

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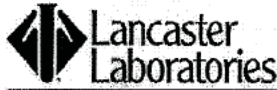
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Thomas J. Hines
Thomas J. Hines, President

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5/15/2010

Approved
[Signature]
10 MAR 2010



2425 New Holland Pike, PO Box 12425, Lancaster, PA 17605-2425 • 717-656-2300 Fax: 717-656-2681 • www.lancasterlabs.com

Analysis Report

Page 1 of 3

Lancaster Laboratories Sample No. WW 5712406

Group No. 1151471
FASample #2 905 Formulation Lab Grab Water Sample
Semi-Annual

Collected: 06/30/2009 09:56 by JF

Account Number: 02423

Submitted: 06/30/2009 16:30
Reported: 07/13/2009 at 14:33
Discard: 07/28/2009Charles River Laboratories
905 Sheehy Dr.
Horsham PA 19044-1297

20905

CAT No.	Analysis Name	CAS Number	As Received Result	As Received Method Detection Limit*	As Received Limit of Quantitation	Dilution Factor
SW-846 8151A	Herbicides		ug/l	ug/l	ug/l	
01856	2,4-D	94-75-7	N.D.	0.16	0.50	1
01856	Dalapon	75-99-0	N.D.	0.25	1.3	1
01856	2,4-DB	94-82-6	N.D.	0.30	1.0	1
01856	Dicamba	1918-00-9	N.D.	0.080	0.30	1
01856	Dinoseb	88-85-7	N.D.	0.10	0.50	1
01856	2,4-DP (Dichlorprop)	120-36-5	N.D.	0.16	0.50	1
01856	MCPA	94-74-6	N.D.	300	1,000	1
01856	MCPP	93-65-2	380	50	200	1
01856	Pentachlorophenol	87-86-5	N.D.	0.027	0.050	1
01856	2,4,5-T	93-76-5	N.D.	0.015	0.050	1
01856	2,4,5-TP	93-72-1	N.D.	0.010	0.050	1
EPA 608	Pesticides/PCBs		ug/l	ug/l	ug/l	
00178	Aldrin	309-00-2	N.D.	0.0040	0.019	1
00178	Alpha BHC	319-84-6	N.D.	0.0026	0.0096	1
00178	Beta BHC	319-85-7	N.D.	0.018	0.057	1
00178	Gamma BHC - Lindane	58-89-9	N.D.	0.0044	0.0096	1
00178	Chlordane	57-74-9	N.D.	0.067	0.48	1
00178	p,p-DDD	72-54-8	N.D.	0.0038	0.019	1
00178	p,p-DDE	72-55-9	N.D.	0.0048	0.019	1
00178	p,p-DDT	50-29-3	N.D.	0.0057	0.019	1
00178	Delta BHC	319-86-8	N.D.	0.0040	0.0096	1
00178	Dieldrin	60-57-1	N.D.	0.0038	0.019	1
00178	Endosulfan I	959-98-8	N.D.	0.0029	0.0096	1
00178	Endosulfan II	33213-65-9	N.D.	0.0038	0.019	1
00178	Endosulfan Sulfate	1031-07-8	N.D.	0.0038	0.019	1
00178	Endrin	72-20-8	N.D.	0.0038	0.019	1
00178	Endrin Aldehyde	7421-93-4	N.D.	0.019	0.096	1
00178	Heptachlor	76-44-8	N.D.	0.0038	0.0096	1
00178	Heptachlor Epoxide	1024-57-3	N.D.	0.0029	0.0096	1
00178	PCB-1016	12674-11-2	N.D.	0.096	0.48	1
00178	PCB-1221	11104-28-2	N.D.	0.15	0.48	1
00178	PCB-1232	11141-16-5	N.D.	0.096	0.48	1
00178	PCB-1242	53469-21-9	N.D.	0.096	0.48	1
00178	PCB-1248	12672-29-6	N.D.	0.096	0.48	1
00178	PCB-1254	11097-69-1	N.D.	0.096	0.48	1
00178	PCB-1260	11096-82-5	N.D.	0.096	0.48	1
00178	Toxaphene	8001-35-2	N.D.	0.29	0.96	1
EPA 200.7 rev 4.4	Metals		mg/l	mg/l	mg/l	
07035	Arsenic	7440-38-2	N.D.	0.0072	0.0200	1
07046	Barium	7440-39-3	N.D.	0.00060	0.0050	1
07049	Cadmium	7440-43-9	N.D.	0.0020	0.0050	1
07051	Chromium	7440-47-3	N.D.	0.0034	0.0150	1
07055	Lead	7439-92-1	N.D.	0.0069	0.0150	1
07036	Selenium	7782-49-2	N.D.	0.0089	0.0200	1
07066	Silver	7440-22-4	N.D.	0.0023	0.0050	1

① No maximum limit has been established by EPA. Amount Limit is minimum acceptable level of no consequence. *Spelling change 2009*

*This limit was used in the evaluation of the final result

Approved by *[Signature]*
21 Jul 2009

11-11-09 6 AUG 09

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Analysis Report

Page 2 of 3

Lancaster Laboratories Sample No. WW 5712406

Group No. 1151471
PASample #2 905 Formulation Lab Grab Water Sample
Semi-Annual

Collected: 06/30/2009 09:56 by JF

Account Number: 02423

Submitted: 06/30/2009 16:30

Charles River Laboratories

Reported: 07/13/2009 at 14:33

905 Sheehy Dr.

Discard: 07/28/2009

Horsham PA 19044-1297

20905

CAT No.	Analysis Name	CAS Number	As Received Result	As Received Method Detection Limit*	As Received Limit of Quantitation	Dilution Factor
EPA 200.7 rev 4.4	Metals		mg/l	mg/l	mg/l	
07072 Zinc		7440-66-6	N.D.	0.0081	0.0200	1
EPA 245.1 rev 3	Metals		mg/l	mg/l	mg/l	
00259 Mercury		7439-97-6	N.D.	0.000056	0.00020	1
EPA 300.0	Wet Chemistry		mg/l	mg/l	mg/l	
01505 Bromide		24959-67-9	N.D.	2.0	2.5	5
224 Chloride		16887-00-6	N.D.	1.0	2.0	5
504 Fluoride		16984-48-8	N.D.	0.40	0.50	5
00368 Nitrate Nitrogen		14797-55-8	N.D.	0.25	0.50	5
01506 Nitrite Nitrogen		14797-65-0	N.D.	0.40	0.50	5
00228 Sulfate		14808-79-8	N.D.	1.5	5.0	5
EPA 365.3	Wet Chemistry		mg/l	mg/l	mg/l	
00226 Ortho-Phosphate as P		7723-14-0	N.D.	0.010	0.030	1

General Sample Comments

PA DEP Lab Certification ID 36-00037, Expiration Date: 1/31/10

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
01856	Herbicides in Water	SW-846 8151A	1	091820017A	07/06/2009 16:23	John W Perkins	1
00178	Pesticides/PCB's in Water	EPA 608	1	091820005A	07/09/2009 02:08	Mark E McNulty	1
10241	Method 608 Water Extraction	EPA 608	1	091820005A	07/01/2009 17:00	JoElla L Rice	1
00816	Water Sample Herbicide Extract	SW-846 8151A	1	091820017A	07/02/2009 01:00	Tracy L Schickel	1
07035	Arsenic	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 01:54	Tara L Snyder	1
07046	Barium	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 01:54	Tara L Snyder	1
07049	Cadmium	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 01:54	Tara L Snyder	1
07051	Chromium	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 01:54	Tara L Snyder	1
07055	Lead	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 01:54	Tara L Snyder	1
07036	Selenium	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 18:55	John P Hook	1
07066	Silver	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 01:54	Tara L Snyder	1
07072	Zinc	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 01:54	Tara L Snyder	1
759	Mercury	EPA 245.1 rev 3	1	091875714003	07/09/2009 17:26	Parker D Lindstrom	1
716	EPA 600 ICP Digest (tot rec)	EPA 200.7 rev 4.4	1	091875716006	07/08/2009 14:26	James L Mertz	1

*This limit was used in the evaluation of the final result

Approved
MAY 11
21 Jun 2009

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Analysis Report

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Lancaster Laboratories Sample No. WW 5712406

Group No. 1151471
PASample #2 905 Formulation Lab Grab Water Sample
Semi-Annual

Collected: 06/30/2009 09:56 by JF

Account Number: 02423

Submitted: 06/30/2009 16:30

Charles River Laboratories

Reported: 07/13/2009 at 14:33

905 Sheehy Dr.

Discard: 07/28/2009

Horsham PA 19044-1297

20905

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05714	PW/WW Hg Digest	EPA 245.1 rev 3	1	091875714003	07/08/2009 15:30	James L Mertz	1
01505	Bromide	EPA 300.0	1	09182196601A	07/01/2009 12:43	Ashley M Adams	5
00224	Chloride	EPA 300.0	1	09182196601A	07/01/2009 12:43	Ashley M Adams	5
01504	Fluoride	EPA 300.0	1	09182196601A	07/01/2009 12:43	Ashley M Adams	5
00368	Nitrate Nitrogen	EPA 300.0	1	09182196601A	07/01/2009 12:43	Ashley M Adams	5
01506	Nitrite Nitrogen	EPA 300.0	1	09182196601A	07/01/2009 12:43	Ashley M Adams	5
00228	Sulfate	EPA 300.0	1	09182196601A	07/01/2009 12:43	Ashley M Adams	5
^226	Ortho-Phosphate as P	EPA 365.3	1	09182022601A	07/01/2009 00:30	Daniel S Smith	1

Approved

 21 Jul 2009

*This limit was used in the evaluation of the final result

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Analysis Report

Page 1 of 3

Lancaster Laboratories Sample No. WW 5712407

Group No. 1151471
PASample #1 905 Analytical Grab Water Sample
Semi-Annual

Collected: 06/30/2009 10:11 by JF

Account Number: 02423

Submitted: 06/30/2009 16:30

Charles River Laboratories

Reported: 07/13/2009 at 14:33

905 Sheehy Dr.

Discard: 07/28/2009

Horsham PA 19044-1297

10905

CAT No.	Analysis Name	CAS Number	As Received Result	As Received Method Detection Limit*	As Received Limit of Quantitation	Dilution Factor
SW-846	8151A	Herbicides	ug/l	ug/l	ug/l	
01856	2,4-D	94-75-7	N.D.	0.16	0.49	1
01856	Dalapon	75-99-0	N.D.	0.25	1.2	1
01856	2,4-DB	94-82-6	N.D.	0.30	0.98	1
01856	Dicamba	1918-00-9	N.D.	0.079	0.30	1
01856	Dinoseb	88-85-7	N.D.	0.098	0.49	1
01856	2,4-DP (Dichlorprop)	120-36-5	N.D.	0.16	0.49	1
01856	MCPA	94-74-6	N.D.	300	980	1
01856	MCPP	93-65-2	N.D.	49	200	1
01856	356 Pentachlorophenol	87-86-5	N.D.	0.027	0.049	1
01856	2,4,5-T	93-76-5	N.D.	0.015	0.049	1
01856	2,4,5-TP	93-72-1	0.024 J	0.0098	0.049	1
EPA 608		Pesticides/PCBs	ug/l	ug/l	ug/l	
00178	Aldrin	309-00-2	N.D.	0.0041	0.019	1
00178	Alpha BHC	319-84-6	N.D.	0.0026	0.0097	1
00178	Beta BHC	319-85-7	N.D.	0.018	0.058	1
00178	Gamma BHC - Lindane	58-89-9	N.D.	0.0044	0.0097	1
00178	Chlordane	57-74-9	N.D.	0.068	0.48	1
00178	p,p-DDD	72-54-8	N.D.	0.0039	0.019	1
00178	p,p-DDE	72-55-9	N.D.	0.0048	0.019	1
00178	p,p-DDT	50-29-3	N.D.	0.0058	0.019	1
00178	Delta BHC	319-86-8	N.D.	0.0041	0.0097	1
00178	Dieldrin	60-57-1	N.D.	0.0039	0.019	1
00178	Endosulfan I	959-90-0	N.D.	0.0029	0.0097	1
00178	Endosulfan II	33213-65-9	N.D.	0.0039	0.019	1
00178	Endosulfan Sulfate	1031-07-8	N.D.	0.0039	0.019	1
00178	Endrin	72-20-8	N.D.	0.0039	0.019	1
00178	Endrin Aldehyde	7421-93-4	N.D.	0.019	0.097	1
00178	Heptachlor	76-44-8	N.D.	0.0039	0.0097	1
00178	Heptachlor Epoxide	1024-57-3	N.D.	0.0029	0.0097	1
00178	PCB-1016	12674-11-2	N.D.	0.097	0.48	1
00178	PCB-1221	11104-28-2	N.D.	0.15	0.48	1
00178	PCB-1232	11141-16-5	N.D.	0.097	0.48	1
00178	PCB-1242	53469-21-9	N.D.	0.097	0.48	1
00178	PCB-1248	12672-29-6	N.D.	0.097	0.48	1
00178	PCB-1254	11097-69-1	N.D.	0.097	0.48	1
00178	PCB-1260	11096-82-5	N.D.	0.097	0.48	1
00178	Toxaphene	8001-35-2	N.D.	0.29	0.97	1
EPA 200.7 rev 4.4		Metals	mg/l	mg/l	mg/l	
07035	Arsenic	7440-38-2	N.D.	0.0072	0.0200	1
07046	Barium	7440-39-3	N.D.	0.00060	0.0050	1
07049	Cadmium	7440-43-9	N.D.	0.0020	0.0050	1
07051	Chromium	7440-47-3	N.D.	0.0034	0.0150	1
07055	Lead	7439-92-1	N.D.	0.0069	0.0150	1
07066	Selenium	7782-49-2	N.D.	0.0089	0.0200	1
07066	Silver	7440-22-4	N.D.	0.0023	0.0050	1

*This limit was used in the evaluation of the final result

Approved
mjs
21 Jul 2009

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Analysis Report

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Lancaster Laboratories Sample No. WW 5712407

Group No. 1151471

Sample #1 905 Analytical Grab Water Sample
Semi-Annual

PA

Collected: 06/30/2009 10:11 by JP

Account Number: 02423

Submitted: 06/30/2009 16:30

Charles River Laboratories

Reported: 07/13/2009 at 14:33

905 Sheehy Dr.

Discard: 07/28/2009

Horsham PA 19044-1297

10905

CAT No.	Analysis Name	CAS Number	As Received Result	As Received Method Detection Limit*	As Received Limit of Quantitation	Dilution Factor
EPA 200.7 rev 4.4	Metals		mg/l	mg/l	mg/l	
07072	Zinc	7440-66-6	N.D.	0.0081	0.0200	1
EPA 245.1 rev 3	Metals		mg/l	mg/l	mg/l	
00259	Mercury	7439-97-6	N.D.	0.000056	0.00020	1
EPA 300.0	Wet Chemistry		mg/l	mg/l	mg/l	
01505	Bromide	24959-67-9	N.D.	2.0	2.5	5
224	Chloride	16887-00-6	2.8	1.0	2.0	5
504	Fluoride	16984-48-8	1.1	0.40	0.50	5
00368	Nitrate Nitrogen	14797-55-8	N.D.	0.25	0.50	5
01506	Nitrite Nitrogen	14797-65-0	N.D.	0.40	0.50	5
00228	Sulfate	14808-79-8	2.7 J	1.5	5.0	5
EPA 365.3	Wet Chemistry		mg/l	mg/l	mg/l	
00226	Ortho-Phosphate as P	7723-14-0	N.D.	0.010	0.030	1

General Sample Comments

PA DEP Lab Certification ID 36-00037, Expiration Date: 1/31/10

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
01856	Herbicides in Water	SW-846 8151A	1	091820017A	07/06/2009 16:51	John W Perkins	1
00178	Pesticides/PCB's in Water	EPA 608	1	091820005A	07/09/2009 02:20	Mark E McNulty	1
10241	Method 608 Water Extraction	EPA 608	1	091820005A	07/01/2009 17:00	JoElla L. Rice	1
00816	Water Sample Herbicide Extract	SW-846 8151A	1	091820017A	07/02/2009 01:00	Tracy L Schickel	1
07035	Arsenic	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 01:59	Tara L Snyder	1
07046	Barium	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 01:59	Tara L Snyder	1
07049	Cadmium	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 01:59	Tara L Snyder	1
07051	Chromium	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 01:59	Tara L Snyder	1
07055	Lead	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 01:59	Tara L Snyder	1
07036	Selenium	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 19:00	John P Hook	1
07066	Silver	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 01:59	Tara L Snyder	1
07072	Zinc	EPA 200.7 rev 4.4	1	091875716006	07/09/2009 01:59	Tara L Snyder	1
00259	Mercury	EPA 245.1 rev 3	1	091875714003	07/09/2009 17:28	Parker D Lindstrom	1
0716	EPA 600 ICP Digest (tot rec)	EPA 200.7 rev 4.4	1	091875716006	07/08/2009 14:26	James L Martz	1

*This limit was used in the evaluation of the final result

Approved

 21 Jul 2009

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Analysis Report

Page 3 of 3

Lancaster Laboratories Sample No. WW 5712407

Group No. 1151471

PA

Sample #1 905 Analytical Grab Water Sample
Semi-Annual

Collected: 06/30/2009 10:11 by JF

Account Number: 02423

Submitted: 06/30/2009 16:30

Charles River Laboratories

Reported: 07/13/2009 at 14:33

905 Sheehy Dr.

Discard: 07/28/2009

Horsham PA 19044-1297

10905

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05714	PW/WW Hg Digest	EPA 245.1 rev 3	1	091875714003	07/08/2009 15:30	James L Mertz	1
01505	Bromide	EPA 300.0	1	09182196601A	07/01/2009 14:05	Ashley M Adams	5
00224	Chloride	EPA 300.0	1	09182196601A	07/01/2009 14:05	Ashley M Adams	5
01504	Fluoride	EPA 300.0	1	09182196601A	07/01/2009 14:05	Ashley M Adams	5
00368	Nitrate Nitrogen	EPA 300.0	1	09182196601A	07/01/2009 14:05	Ashley M Adams	5
01506	Nitrite Nitrogen	EPA 300.0	1	09182196601A	07/01/2009 14:05	Ashley M Adams	5
00228	Sulfate	EPA 300.0	1	09182196601A	07/01/2009 14:05	Ashley M Adams	5
00226	Ortho-Phosphate as P	EPA 365.3	1	09182022601A	07/01/2009 00:30	Daniel S Smith	1

Approved
[Signature]
 21-Jul-2009

*This limit was used in the evaluation of the final result

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Analysis Report

Page 1 of 2

Sample Description: #1 905 Analytical Lab Grab Water Sample
Semi-Annual

LLI Sample # WW 5882618
LLI Group # 1178444
PA

Project Name: Semi-Annual

Collected: 01/13/2010 09:50 by EA

Account Number: 02423

Submitted: 01/13/2010 17:00

Charles River Laboratories

Reported: 02/25/2010 at 16:49

905 Sheehy Dr.

Discard: 03/12/2010

Horsham PA 19044-1297

SEM-1

CAT No.	Analysis Name	CAS Number	As Received Result	As Received Method Detection Limit*	As Received Limit of Quantitation	Dilution Factor
Metals						
	EPA 200.7 rev 4.4		mg/l	mg/l	mg/l	
07035	Arsenic	7440-38-2	N.D.	0.0072	0.0200	1
07046	Barium	7440-39-3	N.D.	0.00060	0.0050	1
07049	Cadmium	7440-43-9	N.D.	0.0020	0.0050	1
07051	Chromium	7440-47-3	N.D.	0.0034	0.0150	1
07055	Lead	7439-92-1	N.D.	0.0069	0.0150	1
07036	Selenium	7782-49-2	N.D.	0.0089	0.0200	1
07066	Silver	7440-22-4	N.D.	0.0023	0.0050	1
07072	Zinc	7440-66-6	N.D.	0.0081	0.0200	1
	EPA 245.1 rev 3		mg/l	mg/l	mg/l	
0259	Mercury	7439-97-6	N.D.	0.000056	0.00020	1
Wet Chemistry						
	EPA 300.0		mg/l	mg/l	mg/l	
01505	Bromide	24959-67-9	N.D.	2.0	2.5	5
00224	Chloride	16887-00-6	N.D.	1.0	2.0	5
01504	Fluoride	16984-48-8	N.D.	0.40	0.50	5
00368	Nitrate Nitrogen	14797-55-8	N.D.	0.25	0.50	5
01506	Nitrite Nitrogen	14797-65-0	N.D.	0.40	0.50	5
00228	Sulfate	14808-79-8	4.9 J	1.5	5.0	5
	EPA 365.3		mg/l	mg/l	mg/l	
00226	Ortho-Phosphate as P	7723-14-0	N.D.	0.030	0.090	1

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General Sample Comments

PA DEP Lab Certification ID 36-00037, Expiration Date: 1/31/11

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
07035	Arsenic	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:02	Joanne M Gates	1
07046	Barium	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:02	Joanne M Gates	1
07049	Cadmium	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:02	Joanne M Gates	1
07051	Chromium	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:02	Joanne M Gates	1
07055	Lead	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:02	Joanne M Gates	1
07036	Selenium	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:02	Joanne M Gates	1
07066	Silver	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:02	Joanne M Gates	1
07072	Zinc	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:02	Joanne M Gates	1
00259	Mercury	EPA 245.1 rev 3	1	100145714001	01/14/2010 20:17	Nelli S Markaryan	1
0716	EPA 600 ICP Digest (tot rec)	EPA 200.7 rev 4.4	1	100145716006	01/14/2010 19:30	Mirit S Shenouda	1
00714	PW/WW Hg Digest	EPA 245.1 rev 3	1	100145714001	01/14/2010 16:00	Nelli S Markaryan	1

*This limit was used in the evaluation of the final result

Approved
Nelli S Markaryan
09/14/2010



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Analysis Report

Page 2 of 2

Sample Description: #1 905 Analytical Lab Grab Water Sample
Semi-Annual

LLI Sample # WW 5882618
LLI Group # 1178444
PA

Project Name: Semi-Annual

Collected: 01/13/2010 09:50 by EA

Account Number: 02423

Submitted: 01/13/2010 17:00

Charles River Laboratories

Reported: 02/25/2010 at 16:49

905 Sheehy Dr.

Discard: 03/12/2010

Horsham PA 19044-1297

SEM-1

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
01505	Bromide	EPA 300.0	1	10014196601A	01/15/2010 01:42	Ashley M Adams	5
00224	Chloride	EPA 300.0	1	10014196601A	01/15/2010 01:42	Ashley M Adams	5
01504	Fluoride	EPA 300.0	1	10014196601A	01/15/2010 01:42	Ashley M Adams	5
00368	Nitrate Nitrogen	EPA 300.0	1	10014196601A	01/15/2010 01:42	Ashley M Adams	5
01506	Nitrite Nitrogen	EPA 300.0	1	10014196601A	01/15/2010 01:42	Ashley M Adams	5
00228	Sulfate	EPA 300.0	1	10014196601A	01/15/2010 01:42	Ashley M Adams	5
00226	Ortho-Phosphate as P	EPA 365.3	1	10015022601A	01/15/2010 01:35	Daniel S Smith	1

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L715A0510

Approved
[Signature]
9 Apr 2010

*This limit was used in the evaluation of the final result



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Analysis Report

Page 1 of 3

Sample Description: #2 905 Formulation Lab Grab Water Sample
Semi-Annual

LLI Sample # WW 5882619
LLI Group # 1178444
PA

Project Name: Semi-Annual

Collected: 01/13/2010 10:00 by EA

Account Number: 02423

Submitted: 01/13/2010 17:00
Reported: 02/25/2010 at 16:49
Discard: 03/12/2010

Charles River Laboratories
905 Sheehy Dr.
Horsham PA 19044-1297

SEM-2

CAT No.	Analysis Name	CAS Number	As Received Result	As Received Method Detection Limit*	As Received Limit of Quantitation	Dilution Factor
Herbicides						
01856	2,4-D	94-75-7	N.D.	0.15	0.47	1
01856	Dalapon	75-99-0	N.D.	0.24	1.2	1
01856	2,4-DE	94-82-6	N.D.	0.28	0.94	1
01856	Dicamba	1918-00-9	N.D.	0.076	0.28	1
01856	Dinoseb	88-85-7	N.D.	0.094	0.47	1
01856	2,4-DP (Dichlorprop)	120-36-5	N.D.	0.15	0.47	1
01856	MCPA	94-74-6	N.D.	280	940	1
01856	MCPP	93-65-2	N.D.	47	190	1
01856	Pentachlorophenol	87-86-5	N.D.	0.025	0.047	1
856	2,4,5-T	93-76-5	N.D.	0.014	0.047	1
856	2,4,5-TP	93-72-1	N.D.	0.0094	0.047	1

The LCS and/or LCSD recovery for dalapon and pentachlorophenol is outside the QC limits. The client was notified and the results are reported.

Pesticides/PCBs						
	EPA 608		ug/l	ug/l	ug/l	
00178	Aldrin	309-00-2	N.D.	0.0041	0.020	1
00178	Alpha BHC	319-84-6	N.D.	0.0027	0.0098	1
00178	Beta BHC	319-85-7	N.D.	0.018	0.059	1
00178	Gamma BHC - Lindane	58-89-9	N.D.	0.0045	0.0098	1
00178	Chlordane	57-74-9	N.D.	0.069	0.49	1
00178	p,p-DDD	72-54-8	N.D.	0.0039	0.020	1
00178	p,p-DDE	72-55-9	N.D.	0.0049	0.020	1
00178	p,p-DDT	50-29-3	N.D.	0.011	0.029	1
00178	Delta BHC	319-86-8	N.D.	0.0041	0.0098	1
00178	Dieldrin	60-57-1	N.D.	0.0039	0.020	1
00178	Endosulfan I	959-98-8	N.D.	0.0029	0.0098	1
00178	Endosulfan II	33213-65-9	N.D.	0.0039	0.020	1
00178	Endosulfan Sulfate	1031-07-8	N.D.	0.0049	0.020	1
00178	Endrin	72-20-8	N.D.	0.0039	0.020	1
00178	Endrin Aldehyde	7421-93-4	N.D.	0.020	0.098	1
00178	Heptachlor	76-44-8	N.D.	0.0039	0.0098	1
00178	Heptachlor Epoxide	1024-57-3	N.D.	0.0029	0.0098	1
00178	PCB-1016	12674-11-2	N.D.	0.098	0.49	1
00178	PCB-1221	11104-28-2	N.D.	0.16	0.49	1
00178	PCB-1232	11141-16-5	N.D.	0.14	0.49	1
00178	PCB-1242	53469-21-9	N.D.	0.098	0.49	1
00178	PCB-1248	12672-29-6	N.D.	0.098	0.49	1
00178	PCB-1254	11097-69-1	N.D.	0.098	0.49	1
00178	PCB-1260	11096-82-5	N.D.	0.098	0.49	1
00178	Toxaphene	8001-35-2	N.D.	0.29	0.98	1

Metals						
	EPA 200.7 rev 4.4		mg/l	mg/l	mg/l	
07035	Arsenic	7440-38-2	N.D.	0.0072	0.0200	1
07046	Barium	7440-39-3	N.D.	0.0060	0.0050	1
07049	Cadmium	7440-43-9	N.D.	0.0020	0.0050	1
051	Chromium	7440-47-3	N.D.	0.0034	0.0150	1
055	Lead	7439-92-1	N.D.	0.0069	0.0150	1
07036	Selenium	7782-49-2	N.D.	0.0089	0.0200	1
07066	Silver	7440-22-4	N.D.	0.0023	0.0050	1

*This limit was used in the evaluation of the final result

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LT/S/2/10

Approved
MAY 11 2010
09 APR 2010



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Analysis Report

Page 2 of 3

Sample Description: #2 905 Formulation Lab Grab Water Sample
Semi-Annual

LLI Sample # WW 5882619
LLI Group # 1178444
PA

Project Name: Semi-Annual

Collected: 01/13/2010 10:00 by EA

Account Number: 02423

Submitted: 01/13/2010 17:00

Charles River Laboratories

Reported: 02/25/2010 at 16:49

905 Sheehy Dr.

Discard: 03/12/2010

Horsham PA 19044-1297

SEM-2

CAT No.	Analysis Name	CAS Number	As Received Result	As Received Method Detection Limit*	As Received Limit of Quantitation	Dilution Factor
Metals						
07072	Zinc	EPA 200.7 rev 4.4 7440-66-6	mg/l N.D.	mg/l 0.0081	mg/l 0.0200	1
00259	Mercury	EPA 245.1 rev 3 7439-97-6	mg/l N.D.	mg/l 0.000056	mg/l 0.00020	1
Wet Chemistry						
		EPA 300.0	mg/l	mg/l	mg/l	
01505	Bromide	24959-67-9	N.D.	2.0	2.5	5
00224	Chloride	16887-00-6	N.D.	1.0	2.0	5
504	Fluoride	16984-48-8	N.D.	0.40	0.50	5
368	Nitrate Nitrogen	14797-55-8	N.D.	0.25	0.50	5
01506	Nitrite Nitrogen	14797-65-0	N.D.	0.40	0.50	5
00228	Sulfate	14808-79-8	1.5 J	1.5	5.0	5
		EPA 365.3	mg/l	mg/l	mg/l	
00226	Ortho-Phosphate as P	7723-14-0	N.D.	0.030	0.090	1

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4/15/2010

General Sample Comments

PA DEP Lab Certification ID 36-00037, Expiration Date: 1/31/11

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
01856	Herbicides in Water	SW-846 8151A	1	100160007A	01/19/2010 16:05	Michele D Hamilton	1
00178	Pesticides/PCB's in Water	EPA 608	1	100160003A	01/19/2010 03:29	Lisa A Reinert	1
10241	Method 608 Water Extraction	EPA 608	1	100160003A	01/18/2010 04:30	Roman Kuropatkin	1
00816	Water Sample Herbicide Extract	SW-846 8151A	1	100160007A	01/18/2010 09:30	Olivia I Santiago	1
07035	Arsenic	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:05	Joanne M Gates	1
07046	Barium	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:05	Joanne M Gates	1
07049	Cadmium	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:05	Joanne M Gates	1
07051	Chromium	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:05	Joanne M Gates	1
07055	Lead	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:05	Joanne M Gates	1
07036	Selenium	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:05	Joanne M Gates	1
07066	Silver	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:05	Joanne M Gates	1
07072	Zinc	EPA 200.7 rev 4.4	1	100145716006	01/15/2010 09:05	Joanne M Gates	1
00259	Mercury	EPA 245.1 rev 3	1	100145714001	01/14/2010 20:19	Nelli S Markaryan	1
16	EPA 600 ICP Digest (tot rec)	EPA 200.7 rev 4.4	1	100145716006	01/14/2010 19:30	Mirit S Shenouda	1
05714	PW/WW Hg Digest	EPA 245.1 rev 3	1	100145714001	01/14/2010 16:00	Nelli S Markaryan	1

*This limit was used in the evaluation of the final result

Approved
Nelli S Markaryan
09/12/2010



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Analysis Report

Page 3 of 3

Sample Description: #2 905 Formulation Lab Grab Water Sample
Semi-Annual

LLI Sample # WW 5882619
LLI Group # 1178444
PA

Project Name: Semi-Annual

Collected: 01/13/2010 10:00 by EA

Account Number: 02423

Submitted: 01/13/2010 17:00

Charles River Laboratories

Reported: 02/25/2010 at 16:49

905 Sheehy Dr.

Discard: 03/12/2010

Horsham PA 19044-1297

SEM-2

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
01505	Bromide	EPA 300.0	1	10014196601A	01/15/2010 02:29	Ashley M Adams	5
00224	Chloride	EPA 300.0	1	10014196601A	01/15/2010 02:29	Ashley M Adams	5
01504	Fluoride	EPA 300.0	1	10014196601A	01/15/2010 02:29	Ashley M Adams	5
00368	Nitrate Nitrogen	EPA 300.0	1	10014196601A	01/15/2010 02:29	Ashley M Adams	5
01506	Nitrite Nitrogen	EPA 300.0	1	10014196601A	01/15/2010 02:29	Ashley M Adams	5
00228	Sulfate	EPA 300.0	1	10014196601A	01/15/2010 02:29	Ashley M Adams	5
00226	Ortho-Phosphate as P	EPA 365.3	1	10015022601A	01/15/2010 01:35	Daniel S Smith	1

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*This limit was used in the evaluation of the final result

Approved
[Signature]
09 APR 2010



Explanation of Symbols and Abbreviations

The following defines common symbols and abbreviations used in reporting technical data:

N.D.	none detected	BMQL	Below Minimum Quantitation Level
TNTC	Too Numerous To Count	MPN	Most Probable Number
IU	International Units	CP Units	cobalt-chloroplatinate units
umhos/cm	micromhos/cm	NTU	nephelometric turbidity units
C	degrees Celsius	F	degrees Fahrenheit
meq	milliequivalents	lb.	pound(s)
g	gram(s)	kg	kilogram(s)
ug	microgram(s)	mg	milligram(s)
ml	milliliter(s)	l	liter(s)
m3	cubic meter(s)	ul	microliter(s)
<	less than - The number following the sign is the <u>limit of quantitation</u> , the smallest amount of analyte which can be reliably determined using this specific test.		
>	greater than		
J	estimated value - The result is $\geq$ the Method Detection Limit (MDL) and $<$ the Limit of Quantitation (LOQ).		
ppm	parts per million - One ppm is equivalent to one milligram per kilogram (mg/kg), or one gram per million grams. For aqueous liquids, ppm is usually taken to be equivalent to milligrams per liter (mg/l), because one liter of water has a weight very close to a kilogram. For gases or vapors, one ppm is equivalent to one microliter of gas per liter of gas.		
ppb	parts per billion		
Dry weight basis	Results printed under this heading have been adjusted for moisture content. This increases the analyte weight concentration to approximate the value present in a similar sample without moisture. All other results are reported on an as-received basis.		

U.S. EPA CLP Data Qualifiers:

Organic Qualifiers		Inorganic Qualifiers	
A	TIC is a possible aldol-condensation product	B	Value is $<$ CRDL, but $\geq$ IDL
B	Analyte was also detected in the blank	E	Estimated due to interference
C	Pesticide result confirmed by GC/MS	M	Duplicate injection precision not met
D	Compound quantitated on a diluted sample	N	Spike sample not within control limits
E	Concentration exceeds the calibration range of the instrument	S	Method of standard additions (MSA) used for calculation
N	Presumptive evidence of a compound (TICs only)	U	Compound was not detected
P	Concentration difference between primary and confirmation columns $>25\%$	W	Post digestion spike out of control limits
U	Compound was not detected	*	Duplicate analysis not within control limits
X,Y,Z	Defined in case narrative	+	Correlation coefficient for MSA <0.995

Analytical test results for methods listed on the laboratories' accreditation scope meet all requirements of NELAC unless otherwise noted under the individual analysis.

Measurement uncertainty values, as applicable, are available upon request.

Tests results relate only to the sample tested. Clients should be aware that a critical step in a chemical or microbiological analysis is the collection of the sample. Unless the sample analyzed is truly representative of the bulk of material involved, the test results will be meaningless. If you have questions regarding the proper techniques of collecting samples, please contact us. We cannot be held responsible for sample integrity, however, unless sampling has been performed by a member of our staff. This report shall not be reproduced except in full, without the written approval of the laboratory.

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BEDDING ANALYSIS



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Analysis Report

Page 1 of 2

Sample Description: Bedding Sample Lot#110209

LLI Sample # G5 5842078

Project Name: Analysis of Bedding

LLI Group # 1171753

PA

Collected: 11/17/2009

Account Number: 02423

Submitted: 11/18/2009 18:20

Charles River Laboratories

Reported: 12/14/2009 at 15:32

905 Sheehy Dr.

Discard: 12/29/2009

Horsham PA 19044-1297

10209

CAT No.	Analysis Name	CAS Number	As Received Result	As Received Method Detection Limit*	As Received Limit of Quantitation	Dilution Factor
Herbicides						
01863	2,4-D	94-75-7	N.D.	12	36	1
01863	2,4,5-TP	93-72-1	N.D.	0.75	1.7	1
Pesticides/PCBs						
06005	Aldrin	309-00-2	N.D.	0.33	0.83	1
06005	Alpha BHC	319-84-6	N.D.	0.17	0.83	1
06005	Beta BHC	319-85-7	N.D.	0.63	1.9	1
06005	Gamma BHC - Lindane	58-89-9	0.58 J	0.17	0.83	1
06005	Chlordane	57-74-9	N.D.	4.0	17	1
06005	p,p-DDD	72-54-8	N.D.	0.33	1.7	1
06005	p,p-DDE	72-55-9	N.D.	0.33	1.7	1
06005	p,p-DDT	50-29-3	N.D.	0.33	1.7	1
06005	Delta BHC	319-86-8	0.82 J	0.31	0.83	1
06005	Dieldrin	60-57-1	N.D.	0.33	1.7	1
06005	Endosulfan I	959-98-8	N.D.	0.22	0.83	1
06005	Endosulfan II	33213-65-9	N.D.	0.33	1.7	1
06005	Endosulfan Sulfate	1031-07-8	N.D.	0.33	1.7	1
06005	Endrin	72-20-8	N.D.	0.33	1.7	1
06005	Endrin Aldehyde	7421-93-4	N.D.	0.33	1.7	1
06005	Heptachlor	76-44-8	N.D.	0.17	0.83	1
06005	Heptachlor Epoxide	1024-57-3	N.D.	0.17	0.83	1
06005	Methoxychlor	72-43-5	N.D.	1.7	8.3	1
06005	Toxaphene	8001-35-2	N.D.	11	33	1
Delta-BHC was detected in the method blank at a concentration of 0.71 ug/kg and in the sample at 0.82 ug/kg. The sample was reextracted outside of hold time. Delta-BHC was not detected in reextracted blank or sample. The in hold data is reported.						
Pesticides/PCBs						
02033	PCB-1016	12674-11-2	N.D.	3.30	17.0	1
02033	PCB-1221	11104-28-2	N.D.	3.30	17.0	1
02033	PCB-1232	11141-16-5	N.D.	3.30	17.0	1
02033	PCB-1242	53469-21-9	N.D.	3.30	17.0	1
02033	PCB-1248	12672-29-6	N.D.	3.30	17.0	1
02033	PCB-1254	11097-69-1	N.D.	3.30	17.0	1
02033	PCB-1260	11096-82-5	N.D.	3.30	17.0	1
Metals						
06935	Arsenic	7440-38-2	N.D.	0.941	1.98	1
06946	Barium	7440-39-3	0.528	0.0396	0.495	1
06949	Cadmium	7440-43-9	N.D.	0.139	0.495	1
06951	Chromium	7440-47-3	N.D.	0.584	1.49	1
06955	Lead	7439-92-1	N.D.	0.594	1.49	1
06936	Selenium	7782-49-2	N.D.	0.970	1.98	1
06966	Silver	7440-22-4	N.D.	0.178	0.495	1
SW-846 7471A						
00159	Mercury	7439-97-6	N.D.	0.0115	0.100	1

*This limit was used in the evaluation of the final result

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LT 4/26/10

351 of 355

Approved
15 Dec 2009



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Analysis Report

Page 2 of 2

Sample Description: Bedding Sample Lot#110209

LLI Sample # G5 5842078

Project Name: Analysis of Bedding

LLI Group # 1171753
PA

Collected: 11/17/2009

Account Number: 02423

Submitted: 11/18/2009 18:20

Charles River Laboratories

Reported: 12/14/2009 at 15:32

905 Sheehy Dr.

Discard: 12/29/2009

Horsham PA 19044-1297

10209

General Sample Comments

PA DEP Lab Certification ID 36-00037, Expiration Date: 1/31/10

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
01863	Appendix IX Herbicides in Soil	SW-846 8151A	1	093280009A	11/25/2009 11:40	Michele D Hamilton	1
06005	Pesticides in Solids	SW-846 8081A	1	093280011A	11/30/2009 14:43	Lindsey K Lafferty	1
02033	PCBs in Soil	SW-846 8082	1	093280015A	11/30/2009 23:41	Douglas D Seitz	1
06006	PPL Pesticide Solid Extraction	SW-846 3550B	1	093280011A	11/25/2009 03:20	David V Hershey Jr	1
06006	PPL Pesticide Solid Extraction	SW-846 3550B	2	093280015A	11/25/2009 03:45	Roman Kuropatkin	1
04181	Herbicide Soil Extraction	SW-846 3550B/SW-846 8151A	1	093280009A	11/24/2009 20:15	Karen L Beyer	1
06935	Arsenic	SW-846 6010B	1	093245708007	12/01/2009 23:41	John W Yanzuk II	1
06946	Barium	SW-846 6010B	1	093245708007	12/01/2009 23:41	John W Yanzuk II	1
06949	Cadmium	SW-846 6010B	1	093245708007	12/01/2009 23:41	John W Yanzuk II	1
06951	Chromium	SW-846 6010B	1	093245708007	12/01/2009 23:41	John W Yanzuk II	1
06955	Lead	SW-846 6010B	1	093245708007	12/01/2009 23:41	John W Yanzuk II	1
06936	Selenium	SW-846 6010B	1	093245708007	12/01/2009 23:41	John W Yanzuk II	1
06966	Silver	SW-846 6010B	1	093245708007	12/01/2009 23:41	John W Yanzuk II	1
00159	Mercury	SW-846 7471A	1	093245711004	11/23/2009 22:05	Nelli S Markaryan	1
05708	SW SW846 ICP Digest	SW-846 3050B	1	093245708007	11/22/2009 13:10	James L Mertz	1
05711	SW SW846 Hg Digest	SW-846 7471A modified	1	093245711004	11/22/2009 16:00	James L Mertz	1

Approved

 15 Dec 2009

*This limit was used in the evaluation of the final result

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Analysis Report

Page 1 of 2

Sample Description: Bedding Sample Lot# Jan 18 10
1940 grams

LLI Sample # G5 5893358
LLI Group # 1180261
PA

Project Name: Analysis of Bedding

Collected: 01/26/2010

Account Number: 02423

Submitted: 01/27/2010 15:45

Reported: 02/09/2010 at 15:56

Discard: 02/24/2010

Charles River Laboratories

905 Sheehy Dr.

Horsham PA 19044-1297

BED26

CAT No.	Analysis Name	CAS Number	As Received Result	As Received Method Detection Limit*	As Received Limit of Quantitation	Dilution Factor
Herbicides						
01863	2,4-D	94-75-7	N.D.	12	36	1
01863	2,4,5-TP	93-72-1	N.D.	0.75	1.7	1
The recovery for Dinoseb is outside the QC limits. However, this compound does not recover well with this method. Since the recovery is within our laboratory statistical limits of 0-36%, the data is reported.						
Pesticides/PCBs						
06005	Aldrin	309-00-2	N.D.	0.33	0.83	1
06005	Alpha BHC	319-84-6	N.D.	0.17	0.83	1
06005	Beta BHC	319-85-7	N.D.	0.63	1.9	1
06005	Gamma BHC - Lindane	58-89-9	N.D.	0.17	0.83	1
06005	Chlordane	57-74-9	N.D.	4.0	17	1
06005	p,p-DDD	72-54-8	N.D.	0.33	1.7	1
06005	p,p-DDE	72-55-9	N.D.	0.33	1.7	1
06005	p,p-DDT	50-29-3	N.D.	0.33	1.7	1
06005	Delta BHC	319-86-8	N.D.	0.31	0.83	1
06005	Dieldrin	60-57-1	N.D.	0.33	1.7	1
06005	Endosulfan I	959-98-8	N.D.	0.22	0.83	1
06005	Endosulfan II	33213-65-9	N.D.	0.33	1.7	1
06005	Endosulfan Sulfate	1031-07-8	N.D.	0.33	1.7	1
06005	Endrin	72-20-8	N.D.	0.33	1.7	1
06005	Endrin Aldehyde	7421-93-4	N.D.	0.33	1.7	1
06005	Heptachlor	76-44-8	N.D.	0.17	0.83	1
06005	Heptachlor Epoxide	1024-57-3	N.D.	0.17	0.83	1
06005	Methoxychlor	72-43-5	N.D.	1.7	8.3	1
06005	Toxaphene	8001-35-2	N.D.	11	33	1
Pesticides/PCBs						
02033	PCB-1016	12674-11-2	N.D.	3.30	17.0	1
02033	PCB-1221	11104-28-2	N.D.	5.00	17.0	1
02033	PCB-1232	11141-16-5	N.D.	5.20	17.0	1
02033	PCB-1242	53469-21-9	N.D.	5.00	17.0	1
02033	PCB-1248	12672-29-6	N.D.	3.30	17.0	1
02033	PCB-1254	11097-69-1	N.D.	3.30	17.0	1
02033	PCB-1260	11096-82-5	N.D.	3.30	17.0	1
Metals						
06935	Arsenic	7440-38-2	N.D.	0.931	1.96	1
06946	Barium	7440-39-3	0.918 (1)	0.0392	0.490	1
06949	Cadmium	7440-43-9	N.D.	0.137	0.490	1
06951	Chromium	7440-47-3	N.D.	0.578	1.47	1
06955	Lead	7439-92-1	N.D.	0.588	1.47	1
06936	Selenium	7782-49-2	1.09 (2)	0.961	1.96	1
06966	Silver	7440-22-4	N.D.	0.176	0.490	1
Metals						
00159	Mercury	7439-97-6	N.D.	0.0108	0.0941	1

*This limit was used in the evaluation of the final result

(1) within SOP limit on 13 APR 2010

(2) within 107.0% of SOP limit on 13 APR 2010

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Approved
13 APR 2010



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Analysis Report

Page 2 of 2

Sample Description: Bedding Sample Lot# Jan 18 10
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LLI Sample # G5 5893358
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905 Sheehy Dr.

Discard: 02/24/2010

Horsham PA 19044-1297

BED26

General Sample Comments

PA DEP Lab Certification ID 36-00037, Expiration Date: 1/31/11

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
01863	Appendix IX Herbicides in Soil	SW-846 8151A	1	100300016A	02/03/2010 05:50	John W Perkins	1
06005	Pesticides in Solids	SW-846 8081A	1	100320010A	02/04/2010 18:40	Jamie L Brillhart	1
02033	PCBs in Soil	SW-846 8082	1	100330008A	02/04/2010 06:54	Jamie L Brillhart	1
06006	PPL Pesticide Solid Extraction	SW-846 3550B	1	100330008A	02/02/2010 17:00	Sally L Appleyard	1
06006	PPL Pesticide Solid Extraction	SW-846 3550B	2	100320010A	02/01/2010 17:00	Sally L Appleyard	1
04181	Herbicide Soil Extraction	SW-846 3550B/SW-846 8151A	1	100300016A	02/01/2010 10:00	Olivia I Santiago	1
06935	Arsenic	SW-846 6010B	1	100355708002	02/08/2010 14:39	Joanne M Gates	1
06946	Barium	SW-846 6010B	1	100355708002	02/08/2010 14:39	Joanne M Gates	1
06949	Cadmium	SW-846 6010B	1	100355708002	02/08/2010 14:39	Joanne M Gates	1
06951	Chromium	SW-846 6010B	1	100355708002	02/08/2010 14:39	Joanne M Gates	1
06955	Lead	SW-846 6010B	1	100355708002	02/08/2010 14:39	Joanne M Gates	1
06936	Selenium	SW-846 6010B	1	100355708002	02/08/2010 14:39	Joanne M Gates	1
06966	Silver	SW-846 6010B	1	100355708002	02/08/2010 14:39	Joanne M Gates	1
00159	Mercury	SW-846 7471A	1	100355711002	02/05/2010 10:32	Damary Valentin	1
05708	SW SW846 ICP Digest	SW-846 3050B	1	100355708002	02/04/2010 13:06	James L Mertz	1
05711	SW SW846 Hg Digest	SW-846 7471A modified	1	100355711002	02/04/2010 15:40	James L Mertz	1

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Approved
M. J. [Signature]
13 APR 2010

*This limit was used in the evaluation of the final result



Explanation of Symbols and Abbreviations

The following defines common symbols and abbreviations used in reporting technical data:

N.D.	none detected	BMQL	Below Minimum Quantitation Level
TNTC	Too Numerous To Count	MPN	Most Probable Number
IU	International Units	CP Units	cobalt-chloroplatinate units
umhos/cm	micromhos/cm	NTU	nephelometric turbidity units
C	degrees Celsius	F	degrees Fahrenheit
meq	milliequivalents	lb.	pound(s)
g	gram(s)	kg	kilogram(s)
ug	microgram(s)	mg	milligram(s)
ml	milliliter(s)	l	liter(s)
m3	cubic meter(s)	ul	microliter(s)
<	less than - The number following the sign is the <u>limit of quantitation</u> , the smallest amount of analyte which can be reliably determined using this specific test.		
>	greater than		
J	estimated value -- The result is $\geq$ the Method Detection Limit (MDL) and $<$ the Limit of Quantitation (LOQ).		
ppm	parts per million - One ppm is equivalent to one milligram per kilogram (mg/kg), or one gram per million grams. For aqueous liquids, ppm is usually taken to be equivalent to milligrams per liter (mg/l), because one liter of water has a weight very close to a kilogram. For gases or vapors, one ppm is equivalent to one microliter of gas per liter of gas.		
ppb	parts per billion		
Dry weight basis	Results printed under this heading have been adjusted for moisture content. This increases the analyte weight concentration to approximate the value present in a similar sample without moisture. All other results are reported on an as-received basis.		

U.S. EPA CLP Data Qualifiers:

Organic Qualifiers		Inorganic Qualifiers	
A	TIC is a possible aldol-condensation product	B	Value is $<$ CRDL, but $\geq$ IDL
B	Analyte was also detected in the blank	E	Estimated due to interference
C	Pesticide result confirmed by GC/MS	M	Duplicate injection precision not met
D	Compound quantitated on a diluted sample	N	Spike sample not within control limits
E	Concentration exceeds the calibration range of the instrument	S	Method of standard additions (MSA) used for calculation
N	Presumptive evidence of a compound (TICs only)	U	Compound was not detected
P	Concentration difference between primary and confirmation columns $>25\%$	W	Post digestion spike out of control limits
U	Compound was not detected	*	Duplicate analysis not within control limits
X,Y,Z	Defined in case narrative	+	Correlation coefficient for MSA <0.995

Analytical test results for methods listed on the laboratories' accreditation scope meet all requirements of NELAC unless otherwise noted under the individual analysis.

Measurement uncertainty values, as applicable, are available upon request.

Tests results relate only to the sample tested. Clients should be aware that a critical step in a chemical or microbiological analysis is the collection of the sample. Unless the sample analyzed is truly representative of the bulk of material involved, the test results will be meaningless. If you have questions regarding the proper techniques of collecting samples, please contact us. We cannot be held responsible for sample integrity, however, unless sampling has been performed by a member of our staff. This report shall not be reproduced except in full, without the written approval of the laboratory.

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