**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 26 July 2011

**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

**Subcontractor Facility**
Charles River Laboratories
Preclinical Services
22022 Transcanadienne Senneville
Montreal, Quebec H9X 3R3
CANADA

**Charles River Laboratories Preclinical Services Protocol Number: 20005045**

## 1. STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentially 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. GOOD LABORATORY PRACTICE 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 OECD Principles of GLP. The OECD regulations were appropriate for these analyses.

- Health monitoring analysis conducted by Zoologix Inc., for *clostridium perfringens* was conducted non-GLP. The non-GLP conduct of this portion was appropriate for health monitoring.

Submitter:

---

Date

Sponsor:

---

Date

FEB 2011

Date

Executive Director, Site Operations and Toxicology
Study Director

---

a. U.S. Environmental Protection Agency. Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); Good Laboratory Practice Standards; Final Rule. 40 CFR Part 160.

b. Japanese Ministry of Agriculture, Forestry and Fisheries (1999). Notification on the Good Laboratory Practice (GLP) Standards for Agricultural Chemicals. 11 Nousan No. 6283.

c. 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

## QUALITY ASSURANCE STATEMENT

This study has been inspected by the QAU to assure conformance with the GLP regulations US Environmental Protection Agency, Good Laboratory Practice Regulations, Final Rule, 40 CFR Part 160/792; Organisation for Economic Co-operation and Development (1998), The Revised OECD Principles of Good Laboratory Practices [C(97)186/Final]; and Japanese Ministry of Agriculture, Forestry and Fisheries (2003), Good Laboratory Practice Standards for Agricultural Chemicals. Reports were submitted in accordance with SOPs as follows.

QAU INSPECTION DATES

| | | Dates Findings Submitted to: | |
|---|---|---|---|
| Dates of Inspection | Phase(s) Inspected | Study Director | Study Director Management |
| 15 Sep 2010 | Protocol | 15 Sep 2010 | 15 Sep 2010 |
| 01 Dec 2010 | Amendment 1 | 01 Dec 2010 | 01 Dec 2010 |
| 13 Jun 2011 | Amendment 2 | 13 Jun 2011 | 13 Jun 2011 |
| 04 Oct 2010 | Test Substance Preparation | 04 Oct 2010 | 04 Oct 2010 |
| 08 Oct 2010 | Test Substance Administration | 11 Oct 2010 | 11 Oct 2010 |
| 10 Nov 2010 | Dam/Litter Euthanasia | 11 Nov 2010 | 11 Nov 2010 |
| 02 Dec 2010 | F1 Necropsy | 02 Dec 2010 | 02 Dec 2010 |
| 22-24 Dec 2010<br>28 Feb 2011 | In-life Data | 24 Dec 2010<br>28 Feb 2011 | 24 Dec 2010<br>28 Feb 2011 |
| 23-24 Dec 2010<br>31 Jan 2011 | Necropsy Data | 24 Dec 2010<br>31 Jan 2011 | 24 Dec 2010<br>31 Jan 2011 |
| 24 Dec 2010 | Formulations Data | 24 Dec 2010 | 24 Dec 2010 |
| 28 Feb 2011, 01 Mar 2011<br>18 Mar 2011 | Tables | 01 Mar 2011<br>18 Mar 2011 | 01 Mar 2011<br>18 Mar 2011 |

| Dates of Inspection | Phase(s) Inspected | Dates Findings Submitted to: Study Director | Study Director Management |
|---|---|---|---|
| 02, 04 Mar 2011 | Methods | 04 Mar 2011 | 04 Mar 2011 |
| 14 Mar 2011 | Results | 14 Mar 2011 | 14 Mar 2011 |
| 17 Mar 2011 | Summary | 17 Mar 2011 | 17 Mar 2011 |
| 23 May 2011 | Revised Report | 23 May 2011 | 23 May 2011 |
| 20 Jul 2011 | Final Report | 20 Jul 2011 | 20 Jul 2011 |

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

| Test Site(s) | Phase | QA Statement Location |
|---|---|---|
| Charles River Laboratories, Preclinical Services, Montreal | Test Substance Analysis | Appendix 4 |
| Charles River Laboratories, Preclinical Services, Montreal | Bioanalysis | 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 JUL 2011

Date

Quality Assurance Auditor
Charles River Laboratories
Preclinical Services, Pennsylvania

## TABLE OF CONTENTS

## LIST OF FIGURES

## LIST OF TABLES

## LIST OF APPENDICES

# 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 ICH Harmonised Tripartite Guideline stages C through F of the reproductive process and should permit detection of 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 via gavage daily to these naturally bred mice on day 6 of presumed gestation (DG 6) through DG 18 at dosages of 0 (Vehicle), 100, 350 and 500 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

Totals of 3, 6, 1 and 3 F0 generation mice were found dead in the 0, 100, 350 and 500 mg/kg/day dosage groups, respectively. Single deaths that occurred in the mid dosage and high dosage groups during the gestation period appear to have been related to administration of the test substance based on the timing of the deaths (DGs 8 and 13). No other mortality related to PFH ammonium salt occurred. The deaths in the control and low dosage group all occurred between days 13 and 16 of lactation (DLs 13 to 16). These deaths and possibly two of the three deaths that occurred in the highest dosage group appeared to be due to the stress of nursing which is known to occur in mice. All unscheduled deaths are described in the following text table.

| Summary Mortality Information | | | | |
|---|---|---|---|---|
| Dosage (mg/kg/day) | 0 (Vehicle) | 100 | 350 | 500 |
| Number (N) | 20 | 20 | 20 | 20 |
| Pregnant | 19 | 19 | 20 | 18 |
| Litters Delivered | 19 | 19 | 19 | 17 |
| Found Dead | 3 | 6 | 1 | 3 |

Additionally, Totals of 1, 0, 2 and 6 mice in the 0, 100, 350 and 500 mg/kg/day dosage groups, respectively, were sacrificed due to no surviving pups.

During the gestation period, the only clinical observations considered related to the test substance was slight* excess salivation in 3 mice in the 350 mg/kg/day dosage group mice and slight** to moderate salivation in 6 mice 500 mg/kg/day dosage group mice.

A purple area on the abdomen occurred in 10, 12, 13 and 9 mice in the four respective dosage groups. Abdominal distention occurred in three mice in the 0 and 100 mg/kg/day dosage groups. These observations were considered secondary to the stress of nursing as the sign occurred late in lactation.

Body weights and body weight gains during the gestation period and body weights during the lactation period were unaffected by dosages of the test substance as high as 500 mg/kg/day. All values were comparable among the four dosage groups and did not differ significantly.

Body weight gains during lactation were significantly reduced for days 0 to 4 of lactation in the 350 and 500 mg/kg/day dosage groups compared to the control group value. Although no additional significant differences occurred among the groups for body weight gain during lactation, the average gain during the entire lactation period was reduced in the 500 mg/kg/day dosage group compared to the control group value. Body weight gains from DL 0 to 20 were 97.7%, 110.3% and 64.4% of the control group value.

---

* Significantly different from the control group value ($p \leq 0.05$).

** Significantly different from the control group value ($p \leq 0.01$).

Pregnancy occurred in 19, 19, 20 and 18 of the 20 mated female mice in the 0 (Vehicle), 100, 350 and 500 mg/kg/day dosage groups, respectively. All mated mice were pregnant and delivered a litter. The number of pups dying on days 1 to 4 in the 350 and 500 mg/kg/day dosage groups was significantly increased compared to the control group. The number of pups dying on PPD 0 was increased in the 300 mg/kg/day dosage group and significantly increased in the 500 mg/kg/day dosage group compared to the control group. The number of mice with stillborn pups and the number of mice with all pups dying on PPD 0 to 3 were significantly increased in the 500 mg/kg/day dosage group compared to the control group values. The following additional effects occurred in the 500 mg/kg/day dosage group: the average litter size was reduced at birth and throughout the lactation period (with a significant reduction on PPD 4); and the day 4 and day 7 viability indices were significantly reduced compared to the control group value. The day 7 viability index was significantly reduced in the 350 mg/kg/day dosage group. The average number of surviving pups per litter was significantly reduced ($p \leq 0.01$) in the 500 mg/kg/day dosage group for PPDs 4, 7, 14 and 20 compared to the control group values.

Pup body weights in all treated groups were generally lower in the treated groups compared to the control group values. Pup body weights were significantly reduced on PPD 0 in the 100 mg/kg/day and higher dosage groups compared to the control group value. Statistically significantly reduced pup body weights persisted in the 350 mg/kg/day dosage group through PPD 7 and in the 500 mg/kg/day dosage group through PPD 4. On PPD 20 average pup weights per litter were 89%, 80% and 88% of the control group value. The lack of dosage-dependency can be attributed to the differences in litter size among the groups.

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. Tan areas in the liver occurred in one mouse in the 350 mg/kg/day dosage group and five[**] of 20 mice in the 500 mg/kg/day dosage group.

No clinical observations in the F1 generation pups were attributed to dosages of the test substance as high as 500 mg/kg/day. The average day that 50% of the pups had open eyes was significantly longer in the 350 mg/kg/day dosage group compared to the control group value. The lack of a significant difference in the 500 mg/kg/day dosage group may be related to the higher number of early pups deaths and reduced litter size in this group. The percentage of pups per litter with open eyes was significantly reduced in the 350 and 500 mg/kg/day dosage groups on PPD 14 compared to the control group value. An increased number of pups in the 500 mg/kg/day dosage group that were found dead or stillborn in the 500 mg/kg/day dosage group had no milk in the stomach. All pups that survived to PPD 20, and were not continued on study appeared normal at necropsy.

** Significantly different from the control group value ($p \leq 0.01$).

### 5.3.1. Pharmacokinetic Analysis

In the 100 mg/kg/day dosage group, all liver homogenates analyzed were below the lower limit of quantitation. In the 350 mg/kg/day dosage group, three of eight samples had analytical results that were quantifiable. The highest level (87.5 ug/mL) occurred in a mouse that was found dead on DG 13. The other mice had much lower levels of PFH but it is interesting that both of these mice were sacrificed early after their litters had died off. These were the only mice in this group that lost their litters. In the 500 mg/kg/day dosage group five of 16 samples had analytical results that were quantifiable. The highest level (98.4 ug/mL) occurred in a mouse that was found dead on DG 6. Other mice had much lower levels of PFH but each of these mice had litters that died early. Two samples that were below the lower limit of quantitation were from mice that lost their litters.

### 5.3.2. Postweaning Period

Postweaning, one F1 generation male mouse in the 350 mg/kg/day maternal dosage group was found dead on PPD 23. There were no clinical signs noted during the postweaning period. This mouse had the lowest body weight in its group. At necropsy, all tissues appeared normal for a moderate degree of autolysis. This mouse apparently did not thrive postweaning. All other 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. All F1 generation male mice appeared normal at necropsy. One F1 generation female mouse in the 100 mg/kg/day dosage group had a small left kidney. No other necropsy observations occurred in these mice.

Body weights and body weight gains of the F1 generation male mice were unaffected by maternal dosages of the test substance as high as 500 mg/kg/day. The only significant difference that occurred among the groups were significantly reduced body weights on PPD 21 in the 100 and 350 mg/kg/day dosage groups and increased body weight gains in the 100 and 350 mg/kg/day dosage group on PPDs 28 to 35 compared to the control group value. No other significant differences occurred among the groups during the postweaning period (PPD 21 to 41). Body weights were significantly reduced in the F1 generation female mice on PPDs 21 and 28 in the 100 and 350 mg/kg/day dosage group and on PPDs 35 and 41 (350 mg/kg/day only); and body weights were significantly reduced in the 500 mg/kg/day dosage group on PPD 35 compared to the control group values. Body weight gains did not significantly different among the groups for the postweaning period.

Sexual maturation was unaffected by maternal dosages of the test substance as high as 500 mg/kg/day. The average day on which preputial separation or vaginal patency occurred was comparable among the four dosage groups.

Terminal body weights in the F1 generation male mice were comparable among the four groups. The ratio of the liver weight to the terminal body weight was significantly reduced in the 500 mg/kg/day dosage group compared to the control group value. Terminal body weights in the F1 generation female mice were significantly reduced in the 350 mg/kg/day dosage group compared to the control group value. Maternal dosages of the test substance as high as 500 mg/kg/day did not affect the liver weights or the ratio of liver weights to the terminal body weight.

No detectable level of PFH was found in the liver homogenate from any F1 generation male or female pup.

## 6. DISCUSSION AND CONCLUSION

Administration of PFH Ammonium Salt to pregnant mice at dosages of 0 (Vehicle), 100, 350 and 500 mg/kg/day resulted in minimal adverse effects. Toxicity was seen only in the highest dose group and included single mortalities, excess salivation and changes in body weight gains during the lactation period in the 350 and 500 mg/kg/day dosage groups. No adverse effects occurred in the maternal mice in the 100 mg/kg/day dosage group compared to the control group values.

In the F1 generation litters, pup body weights were significantly reduced on PPD 0 in the 100 mg/kg/day and higher dosage groups, but this decrease in body weights persisted only in the 350 and 500 mg/kg/day dosage groups. On PPD 20, average pup weights per litter were 89%, 80% and 88% of the control group value. The lack of dosage-dependency can be attributed to the differences in litter size among the groups.

Additional effects, including stillbirths, reductions in viability indices, and delays in physical development in F1 generation mice occurred only in the 350 and 500 mg/kg/day dosage groups.

Levels PFH Ammonium salt in the livers from dams administered the 100 mg/kg/day dosage were all below the lower limit of quantization (0.02 µg/mL). In the 350 mg/kg/day dosage group, three of eight samples had analytical results that were quantifiable. The highest level (87.5 ug/mL) occurred in a mouse that was found dead on DG 13. The other mice had much lower levels of PFH Ammonium salt, but it is interesting that both of these mice were sacrificed early after their litters had died off. These were the only mice in this group that lost their litters. In the 500 mg/kg/day dosage group five of 16 samples had analytical results that were quantifiable. The highest level (98.4 ug/mL) occurred in a mouse that was found dead on DG 6. The other mice had much lower levels of PFH but each of these mice had litters that died early. Two samples that were below the lower limit of quantization were from mice that lost their litters. Based on these results, the variability in the quantization of PFH ammonium salt in the liver may be due to the time of sampling post the start of dosing.

In a previously conducted study with the same study design but at dosage levels of 0 (Vehicle), 7, 35 and 175 mg/kg/day (Protocol UZS00010), no PFH Ammonium salt

was found in any liver sample and adverse effects occurred only in the 175 mg/kg/day dosage group (increased number stillborn pups and pups dying day 1 along with a reduction in pup weights on PPD 1, two litters with pups with corneal opacity).

The results from the previous study (Charles River Labs Study No. UZS00010) coincide with the results in this study and indicate a very minimal effect of PFH at 100 mg/kg/day with a clear no-observable-effect-level at 35 mg/kg/day.

On the basis of these data from this study, the maternal no-observable-adverse-effect-level (NOEL) for PFH Ammonium Salt is 100 mg/kg/day. The NOAEL in the F1 generation is below 100 mg/kg/day. None of the effects observed in the pups preweaning persisted into the postweaning period.

6-JUL-2011

Date

Executive Director, Site Operations and Toxicology
Study Director

# 7. DESCRIPTION OF TEST PROCEDURES[a]

## 7.1. Conduct of Study

### 7.1.1. Sponsor

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

### 7.1.2. Testing Facility

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

### 7.1.3. Study Number

20005045

### 7.1.4. 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 ICH Harmonised Tripartite Guideline stages C through F of the reproductive process and should permit detection of 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.

### 7.1.5. Study Design

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

---

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. Deviations are available in APPENDIX 2 and in the raw data.

### 7.1.6. Ownership of the Study

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

### 7.1.7. Study Monitor

(Daikin Industries, LTD, Chemical Division, Settsu City, Osaka, Japan)

### 7.1.8. Study Director

(Executive Director, Site Operations and Toxicology)
Address as cited previously for Testing Facility

### 7.1.9. Technical Performance

### 7.1.9.1. Charles River Laboratories Preclinical Services, Pennsylvania, USA

### 7.1.9.2. Charles River Laboratories Preclinical Services, Montreal, CANADA

(Principal Investigator) - Test substance analysis

(Principal Investigator) - Pharmacokinetic analysis

### 7.1.10. Report Preparation

### 7.1.11. Report Review

### 7.1.12. Date Protocol Signed

21 September 2010

### 7.1.13. Dates of Technical Performance

| | |
|---|---|
| Experimental Start Date (OECD) | 21 SEP 2010 |
| Experimental Start Date (EPA) | 06 OCT 2010 |
| Experimental Completion/Termination Date | 03 JAN 2011 |

#### 7.1.13.1. F0 Generation Mice

| | |
|---|---|
| Mouse Arrival | 21 SEP 2010 |
| Cohabitation Period | 29 SEP 2010 PM – 04 OCT 2010 AM |
| DG[a] 0 | 30 SEP 2010 – 04 OCT 2010 |
| Dosage Period (DGs 6 through 18) | 06 OCT 2010 – 22 OCT 2010 |
| Delivery Period (DL[b] 0) | 18 OCT 2010 – 23 OCT 2010 |
| DG 23 Sacrifice (Mice that did not deliver a litter) | 10 OCT 2010 – 25 OCT 2010 |
| DL 20 Sacrifice (Dams and pups not selected for continued observation) | 07 NOV 2010 – 12 NOV 2010 |

#### 7.1.13.2. F1 Generation Mice

| | |
|---|---|
| Sexual Maturation | |
| Female Mice | 07 NOV 2010 – 30 NOV 2010 |
| Male Mice | 13 NOV 2010 – 26 NOV 2010 |
| Blood Collection | 29 NOV 2010 – 30 NOV 2010 |
| Scheduled Sacrifice and Tissue Collection F1 Generation (PPD[c] 41) | 28 NOV 2010 – 03 DEC 2010 |

### 7.1.14. 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. Backup samples shipped to Charles River Laboratories Preclinical Services, Montreal (PCS-MTL) were discarded at the Test Site. The remaining bulk test substance was discarded at the Testing Facility and documented in the raw data. Remaining unused blood, serum and liver 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. DG is an abbreviation used for day of (presumed) gestation.
b. DL is an abbreviation used for day of lactation (dams).
c. PPD is an abbreviation used for day postpartum (litters).

## 7.2. 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 |

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

| Vehicle | | | | | | |
|---|---|---|---|---|---|---|
| Name | Description | Lot Number | Supplier | Date Received | Storage | Expiration |
| R.O. Deionized Water[b] | c | | | | | |

b. R.O. deionized water is an abbreviation used for reverse osmosis membrane processed deionized water.
c. Reverse osmosis membrane processed deionized water (R.O. deionized water) is available from a continuous source at the Testing Facility and is maintained at room temperature.

| Sampling | | | |
|---|---|---|---|
| Bulk Test Substance Stability | | | |
| Sample Size: 10 mL | | | |
| Date Sampled | Date Shipped | Recipient | Shipping Conditions |
| 22 OCT 2010 | 22 OCT 2010 | CRL - Montreal[a] | Ambient temperature |

| Bulk Test Substance Reserve | | |
|---|---|---|
| Sample Size: 5 mL | | |
| Date Sampled | Storage Condition | Date Archived |
| 04 OCT 2010 | Room temperature | 16 NOV 2010 |

| Bulk Vehicle Reserve | | | |
|---|---|---|---|
| Sample Size: 5 mL | | | |
| Name | Date Sampled | Storage Conditions | Date Archived |
| R.O. Deionized Water | 04 OCT 2010 | Room temperature | 16 NOV 2010 |

| Concentration and Homogeneity[b] | | | | |
|---|---|---|---|---|
| Sample Size: 2 mL | | | | |
| Date Sampled | Date Shipped | Recipient | Shipping Conditions | Purpose |
| 05 OCT 2010 | 05 OCT 2010 | CRL - Montreal[a] | Ambient temperature | C, H |
| 05 OCT 2010 | 13 OCT 2010 | | | C, H (backup) |
| 09 OCT 2010 | 11 OCT 2010 | | | C |
| 09 OCT 2010 | 19 OCT 2010 | | | C (backup) |
| 16 OCT 2010 | 18 OCT 2010 | | | C |
| 16 OCT 2010 | 26 OCT 2010 | | | C (backup) |

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 were prepared 24 hours or more after preparation, and no more than 24 hours before dosing. Two samples from each quadruplicate set were shipped for analysis; the remaining samples were stored at room temperature at the Testing Facility as backup samples and shipped one week after successful delivery of the initial shipment. Backup samples were stored room temperature until the results of the initial analyses were available and were discarded at the Test Site.

C - Concentration
H - Homogeneity

### 7.2.1. Special Handling Instructions

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

### 7.2.2. 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.

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.

### 7.2.3. Test Substance and Vehicle 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 and during 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.

### 7.2.4. Analytical Results

The study samples analyzed were within the acceptance criteria of ±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 ≤ 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 211053 (Testing Facility Study No. UZS00009). Stability was demonstrated for 10 days at room temperature from 7 mg/mL to 70 mg/mL, and for at least 8 days at up to 200 mg/mL under Charles River Laboratories Preclinical Services Montreal Validation study CAD-001.

## 7.3. Test System

### 7.3.1. Species/Strain

Mouse/Crl:CD1(ICR)

### 7.3.2. Supplier (Source)

Charles River Laboratories, Inc., Kingston, NY,USA

### 7.3.3. Sex

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

### 7.3.4. 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.

### 7.3.5. Test System Data

| | |
|---|---|
| Number of Mice Acclimated | 100 |
| Number of Mice Assigned to Study | 80 |
| Approximate Date of Birth | 23 JUL 2010 |
| Approximate Age at Arrival | 61 days |
| Weight (g) the Day after Arrival | 24.3 – 28.2 |
| Weight (g) at Study Assignment (DG 0) | 26.1 – 30.0 |

### 7.3.6. Method of Randomization

#### 7.3.6.1. 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.

#### 7.3.6.2. 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 PPD 20.

At weaning, a table of random units was 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, was selected.

### 7.3.7. System of Identification

#### 7.3.7.1. 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. 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, species, test substance identification, group number and dosage level.

#### 7.3.7.2. 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.

### 7.4. Husbandry

### 7.4.1. Research Facility Registration

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

### 7.4.2. Veterinary Treatment

During the course of the study, individual mice were examined by the veterinary staff when needed. Records of examinations, treatments and feed supplementation are maintained in the raw data. Feed supplementation included a deionized water soaked feed pellet. Treatments included the provision of a warming pad under half of the nesting box. None of the medical examinations, treatments or feed supplementations had an adverse impact on the integrity of the study data or on the interpretation of the study results. None of the medical examinations, treatments, and/or feed supplementation had an adverse impact on the integrity of the study data or on the interpretation of the study results.

Due to the unexpected number of deaths in lactating dams, as described in the results, fecal samples were collected for health monitoring of viral status and to check for *clostridium perfringens*. Samples for *clostridium perfringens* were sent to Zoologix Inc., to rule out any other cause of death except stress from nursing. No adverse results were reported. Results of these analysis are available in APPENDIX 7.

### 7.4.3. Study Room

The study room was maintained under conditions of positive airflow relative to a hallway and independently supplied with a minimum of 10 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 64ºF to 79ºF (18ºC to 26ºC); relative humidity was targeted at 30% to 70%.[a]

### 7.4.4. Housing

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

#### 7.4.4.1. F0 Generation Mice

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

#### 7.4.4.2. F1 Generation Mice

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

### 7.4.5. Light

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

### 7.4.6. Sanitization

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

---

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

### 7.4.7. Feed

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

### 7.4.8. 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 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 feed that would have interfered with the results of this study.

### 7.4.9. 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.

### 7.4.10. 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.

### 7.4.11. Bedding Material

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

### 7.4.12. 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.

### 7.4.13. Day Numbering System

Gestation day 0 is defined as the day a copulatory plug observed *in situ*.

The day of birth is designated postpartum 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 PPD 1 (DL 1) 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.

## 7.5. Methods

### 7.5.1. Dosage Administration

#### 7.5.1.1. F0 Generation Mice

| Dosage Group | Number of Mice Assigned to Study | Dosage (mg/kg/day) | Concentration (mg/mL) | Dosage Volume (mL/kg) | Assigned Mice Numbers |
|---|---|---|---|---|---|
| I | 20 | 0 (Vehicle) | 0 | 5 | 8311 – 8330 |
| II | 20 | 100 | 20 | 5 | 8331 – 8350 |
| III | 20 | 350 | 70 | 5 | 8351 – 8370 |
| IV | 20 | 500 | 100 | 5 | 8371 – 8390 |

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

#### 7.5.1.2. 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 | 9001 – 9020 | 9081 – 9100 |
| II | 100 | 20 | 9021 – 9034, 9036 – 9040, 9102[b] | 9035[a] , 9101, 9103 – 9120, |
| III | 350 | 20 | 9041 – 9060 | 9121 – 9140 |
| IV | 500 | 20 | 9061 – 9080 | 9141 – 9160 |

a. Mouse 9035 was discovered to be female after originally being weaned as a male.
b. Mouse 9102 was discovered to be male after originally being weaned as a female.

### 7.5.2. Rationale for Dosage Selection

In the combined developmental and perinatal/postnatal reproduction toxicity study (UZS00010[5]), mice were administered the test substance at doses of 7, 35 and 175 mg/kg on DGs 6 through 18. No mortality related to the test substance occurred on study, and no adverse clinical signs occurred during this study. Due to a lack of observed toxicity, dosages of 100, 350 and 500 mg/kg/day were selected for this study.

### 7.5.3. 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.

### 7.5.4. Method and Frequency of Administration

#### 7.5.4.1. 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 adminstered the test substance or vehicle in order to preclude possible disruption to maternal behavior and/or cannibalization of the pups.

#### 7.5.4.2. 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.

### 7.5.5. Method of Study Performance

#### 7.5.5.1. F0 Generation Mice

After acclimation, 100 virgin female mice were cohabitated with 100 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 once 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 daily during the postdosage period.

Body weights were recorded once 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.

#### 7.5.5.2. 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 and general appearance at least twice daily. The pups in each litter were counted once daily. Clinical observations were recorded once daily during the preweaning period. 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.

#### 7.5.5.3. 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.

### 7.5.6. Gross Necropsy[a]

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

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

#### 7.5.6.1. F0 Generation Mice

After completion of the 21-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 (≤-70°C) until shipment for analysis to 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)] to confirm the absence of implantation sites. Livers were excised, weighed and frozen on dry ice. Livers were maintained frozen (≤-70°C) until shipment for analysis to PCS-MTL.

Dams with no surviving pups were sacrificed after the last pup was found dead or missing, presumed cannibalized. A gross necropsy of the thoracic, abdominal and pelvic viscera was performed and implantation sites were recorded after staining with 10% ammonium sulfide[(6)]. Livers were excised, weighed and frozen on dry ice. Livers were maintained frozen (≤-70°C) until shipped for analysis to PCS-MTL.

Mice that died before scheduled termination were examined for the cause of death as soon as possible after the observation was made. The mice were 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. Gravid uterine weights were recorded. Pregnancy status and uterine contents of female mice were recorded. Conceptuses *in utero* were examined to the extent possible, using the same methods described for term fetuses/pups. The livers were excised, weighed and frozen on dry ice. Livers were maintained frozen (≤-70°C) until shipped for analysis to PCS-MTL.

---

a. 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.

The liver samples were analyzed at PCS-MTL (test site reference no. 142578) 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.

### 7.5.6.2. 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 as soon as possible. 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.

One male mouse that died before scheduled termination was examined for the cause of death as soon as possible after the observation was made. The mouse was examined for gross lesions. The heart, kidneys, lungs, stomach and spleen were retained in neutral buffered 10% formalin for possible histological evaluation. The liver was excised, weighed and frozen on dry ice. The liver sample was maintained frozen (≤-70ºC) until shipped for analysis to PCS-MTL.

### 7.5.6.3. 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$^{o}$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 (≤-70$^{o}$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 (≤-70$^{o}$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. 142577) 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.

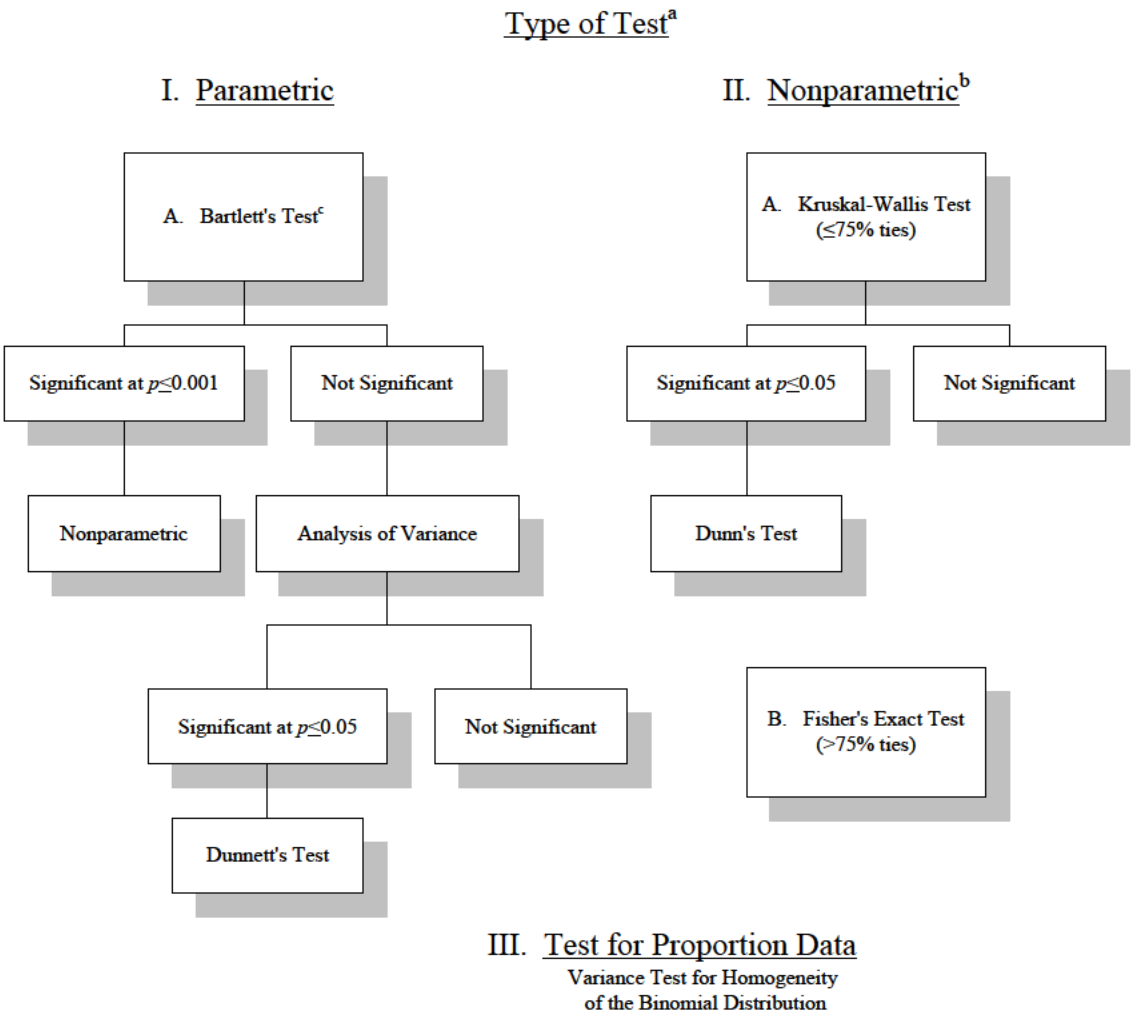
### 7.5.7. Data Collection and Statistical Analyses

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 2003 or later versions) 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 ($p\leq0.05$), 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 ($p\leq0.05$), 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.

## 8. RESULTS - F0 GENERATION FEMALE MICE

### 8.1. Mortality and Clinical Observations (Summaries - Tables 1 and 8; Individual Data - Tables 24 and 31)

Totals of 3, 6, 1 and 3 F0 generation mice were found dead in the 0, 100, 350 and 500 mg/kg/day dosage groups, respectively. Single deaths that occurred in the mid dosage and high dosage groups during the gestation period appear to have been related to administration of the test substance based on the timing of the deaths [days 8 and 13 of gestation (DGs 8 and 13)]. No other mortality related to PFH ammonium salt occurred. The deaths in the control and low dosage group all occurred between days 13 and 16 of lactation (DLs 13 to 16). These deaths and possibly two of the three deaths that occurred in the highest dosage group appeared to be due to the stress of nursing which is known to occur in mice[11-15]. All unscheduled deaths are described in the following text tables.

| Summary Mortality Information | | | | |
|---|---|---|---|---|
| Dosage (mg/kg/day) | 0 (Vehicle) | 100 | 350 | 500 |
| Number (N) | 20 | 20 | 20 | 20 |
| Pregnant | 19 | 19 | 20 | 18 |
| Litters Delivered | 19 | 19 | 19 | 17 |
| Found Dead | 3 | 6 | 1 | 3 |

| Group Number/ Dosage Level | Mouse Number | Day of Study | Mode of Death | Litter | Clinical Observations, Body Weights and Necropsy Observations |
|---|---|---|---|---|---|
| I/ 0 mg/kg/day | 8314 | DL 16 | Found Dead | 11 live pups | **Clinical Observations**: Appeared normal<br>**Body Weights**: Body weights were unremarkable.<br>**Necropsy Observations**: All tissues appeared normal for a moderate degree of autolysis. |
| | 8316 | DL 16 | Found Dead | 14 live pups | **Clinical Observations**: Appeared normal<br>**Body Weights**: Body weights were unremarkable.<br>**Necropsy Observations**: All tissues appeared normal for a moderate degree of autolysis. |
| | 8328 | DL 14 | Found Dead | 13 live pups | **Clinical Observations**: Appeared normal<br>**Body Weights**: Body weights were generally unremarkable.<br>**Necropsy Observations**: All tissues appeared normal for a moderate degree of autolysis. |
| II/ 100 mg/kg/day | 8333 | DL 16 | Found Dead | 14 live pups | **Clinical Observations**: Appeared normal<br>**Body Weights**: Body weights were generally unremarkable.<br>**Necropsy Observations**: All tissues appeared normal for a slight degree of autolysis. |
| | 8343 | DL 13 | Found Dead | 11 live pups | **Clinical Observations**: Appeared normal<br>**Body Weights**: Body weights were generally unremarkable.<br>**Necropsy Observations**: All tissues appeared normal for a moderate degree of autolysis. |
| II/ 100 mg/kg/day (continued) | 8344 | DL 14 | Found Dead | 15 live pups | **Clinical Observations**: Decreased motor activity, ptosis, mild to moderate dehydration, pale ears, pale extremities<br>**Body Weights**: Lost body weight from DL 11 to 14 (9.4 g).<br>**Necropsy Observations**: All tissues appeared normal for a moderate degree of autolysis. |

| Group Number/ Dosage Level | Mouse Number | Day of Study | Mode of Death | Litter | Clinical Observations, Body Weights and Necropsy Observations |
|---|---|---|---|---|---|
| | 8346 | DL 13 | Found Dead | 13 live pups | **Clinical Observations**: Appeared normal<br>**Body Weights**: Lost body weight from DL 11 to 12 (7.1 g).<br>**Necropsy Observations**: All tissues appeared normal for a moderate degree of autolysis. |
| | 8347 | DL 13 | Found Dead | 17 live pups | **Clinical Observations**: Appeared normal<br>**Body Weights**: Body weights were generally unremarkable.<br>**Necropsy Observations**: All tissues appeared normal for a moderate degree of autolysis. |
| | 8348 | DL 13 | Found Dead | 15 live pups | **Clinical Observations**: Soft or liquid feces<br>**Body Weights**: Lost body weight from DL 11 to 12 (8.7 g).<br>**Necropsy Observations**: All tissues appeared normal for a moderate degree of autolysis. |
| III/ 350 mg/kg/day | 8361 | DG 13 | Found Dead | 14 embryos | **Clinical Observations**: Dyspnea, decreased motor activity, tremors, ptosis, mild to moderate dehydration, cold to touch, pale ears, red perivaginal substance, pale extremities, scant feces<br>**Body Weights**: Body weights were unremarkable.<br>**Necropsy Observations**: All tissues appeared normal. |
| IV/ 500 mg/kg/day | 8386 | DG 8 | Found Dead | 12 embryos | **Clinical Observations**: Appeared normal<br>**Body Weights**: Body weights were unremarkable.<br>**Necropsy Observations**: All tissues appeared normal for a slight degree of autolysis. |
| | 8387 | DL 13 | Found Dead | 14 live pups (4 pups were born alive but found dead) | **Clinical Observations**: Tachypnea<br>**Body Weights**: Lost body weight from DL 11 to 12 (6.3 g).<br>**Necropsy Observations**: All tissues appeared normal for a moderate degree of autolysis. |
| | 8388 | DL 13 | Found Dead | 11 live pups (1 pup was born alive but found dead) | **Clinical Observations**: Appeared normal<br>**Body Weights**: Lost body weight from DL 11 to 12 (5.4 g).<br>**Necropsy Observations**: All tissues appeared normal for a moderate degree of autolysis. |

Additionally, Totals of 1, 0, 2 and 6 mice in the 0, 100, 350 and 500 mg/kg/day dosage groups, respectively, were sacrificed due to no surviving pups.

During the gestation period, the only clinical observations considered related to the test substance was slight* excess salivation in 3, 350 mg/kg/day dosage group mice and slight** to moderate salivation in 6, 500 mg/kg/day dosage group mice.

A purple area on the abdomen occurred in 10, 12, 13 and 9 mice in the four respective dosage groups. Abdominal distention occurred in three mice in the 0 and 100 mg/kg/day dosage groups. These observations were considered secondary to the stress of nursing as the sign occurred late in lactation[14-18].

* Significantly different from the control group value ($p \leq 0.05$).
** Significantly different from the control group value ($p \leq 0.01$).

All other clinical observations during the gestation and lactation periods, with the exception of those described above for mice that were found dead, were considered unrelated to the test substance because: 1) the incidences were not dosage dependent; and 2) the observations occurred in only one or two mice in a group. These clinical observations included slight/mild dehydration, dyspnea, tachypnea, decreased motor activity, ptosis, a red or dried red perivaginal substance, scant feces, hyperpnea, gasping and rales.

### 8.2. 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 period and body weights during the lactation period were unaffected by dosages of the test substance as high as 500 mg/kg/day. All values were comparable among the four dosage groups and did not differ significantly.

Body weights gains during lactation were significantly reduced ($p \leq 0.05$ to $p \leq 0.01$) for LDs 0 to 4 in the 350 and 500 mg/kg/day dosage groups compared to the control group value. Although no additional significant differences occurred among the groups for body weight gain during lactation, the average gain during the entire lactation period was reduced in the 500 mg/kg/day dosage group compared to the control group value. Body weight gains from DL 0 to 20 were 97.7%, 110.3% and 64.4% of the control group value.

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

Pregnancy occurred in 19, 19, 20 and 18 of the 20 mated female mice in the 0 (Vehicle), 100, 350 and 500 mg/kg/day dosage groups, respectively. All pregnant dams delivered litters, with the exception of one mouse in each of Groups III and IV that died during gestation, as previously described. All mated mice were pregnant and delivered a litter.

The number of pups dying on PPDs 1 to 4 in the 350 and 500 mg/kg/day dosage groups was significantly increased ($p \leq 0.01$) compared to the control group. The number of pups dying on PPD 0 was increased in the 300 mg/kg/day dosage group and significantly increased ($p \leq 0.01$) in the 500 mg/kg/day dosage group compared to the control group.

The number of mice with stillborn pups and the number of mice with all pups dying on PPDs 0 to 3 were significantly increased ($p \leq 0.01$) in the 500 mg/kg/day dosage group compared to the control group values. The following additional effects occurred in the 500 mg/kg/day dosage group: the average litter size was reduced at birth and throughout the lactation period with a significant reduction ($p \leq 0.05$) on PPD 4; and the PPD 4 and 7 viability indices were significantly reduced ($p \leq 0.01$) compared to the control group value. The day 7 viability index was significantly reduced ($p \leq 0.05$) in the 350 mg/kg/day dosage group. The average number of surviving pups per litters was significantly

reduced ($p \leq 0.01$) in the 500 mg/kg/day dosage group for PPDs 4, 7, 14 and 20 compared to the control group values.

Pup body weights in all treated groups were generally lower in the treated groups compared to the control group values. Pup body weights were significantly reduced ($p \leq 0.05$ to $p \leq 0.01$) on PPD 0 in the 100 mg/kg/day and higher dosage groups compared to the control group value. Statistically significantly reduced pup body weights persisted in the 350 mg/kg/day dosage group through PPD 7 and in the 500 mg/kg/day dosage group through PPD 4. On PPD 20 average pup weights per litter were 89%, 80% and 88% of the control group value. The lack of dosage-dependency can be attributed to the differences in litter size among the groups.

All other natural delivery and litter observations were unaffected by dosages of the test substance as high as 500 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), total litter sizes, lactation index and percent male pups per number of pups sexed per litter, were comparable among the four dosage groups and did not significantly differ.

### 8.4. 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.

### 8.5. Necropsy Observations (Summary - Table 8; Individual Data - Table 31)

Tan areas in the liver occurred in one mouse in the 350 mg/kg/day dosage group and five** of 20 mice in the 500 mg/kg/day dosage group.

There were no other test substance related necropsy observations. One mouse each in the 0 and 100 mg/kg/day dosage group had a bent sternum proximal to the xiphoid process and one mouse in the 500 mg/kg/day dosage group had intestines that were distended with gas.

** Significantly different from the control group value ($p \leq 0.01$).

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

No clinical observations in the F1 generation pups were attributed to dosages of the test substance as high as 500 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 scab, dehydration, tip of tail red or missing, not nursing, not nesting and ungroomed coat.

The average day that 50% of the pups had open eyes was significantly longer ($p \leq 0.01$) in the 350 mg/kg/day dosage group compared to the control group value. The lack of a significant difference in the 500 mg/kg/day dosage group may be related to the higher number of early pups deaths and reduced litter size in this group. The percentage of pups per litter with open eyes was significantly reduced ($p \leq 0.05$ to $p \leq 0.01$) in the 350 and 500 mg/kg/day dosage groups on PPD 14 compared to the control group value.

An increased number of pups in the 500 mg/kg/day dosage group that were found dead or stillborn in the 500 mg/kg/day dosage group had no milk in the stomach. All pups that survived to PPD 20, and were not continued on study appeared normal at necropsy.

## 8.7. Levels of PFH in Liver Homogenates (APPENDIX 5)

Results of analyses of liver homogenates from 10 F0 generation control group mice were all below the lower limit of quantitation with the exception of mouse 8316 for which a detectable level was found. This level appeared to be the result of cross contamination of the sample during collection and/or processing. This mouse was found dead on LD 17 and the liver was taken at approximately the same time as liver from other early deaths in treated groups was being taken.

In the 100 mg/kg/day dosage group, all liver homogenates analyzed were below the lower limit of quantitation.

In the 350 mg/kg/day dosage group, three of eight samples had analytical results that were quantifiable. The highest level (87.5 ug/mL) occurred in a mouse that was found dead on DG 13. The other mice had much lower levels of PFH but it is interesting that both of these mice were sacrificed early after their litters had died off. These were the only mice in this group that lost their litters.

In the 500 mg/kg/day dosage group five of 16 samples had analytical results that were quantifiable. The highest level (98.4 ug/mL) occurred in a mouse that found dead on day 6 of gestation. The other mice had much lower levels of PFH but each of these mice had

litters that died early. Two samples that were below the lower limit of quantitation were from mice that lost their litters.

Sample "animal no. 8316" was initially analyzed in run 02 which had concentration above the lower limit of detection. This was considered an anomalous sample value as the sample was from a control dosing group and was not expected to have quantifiable concentration. The sample was repeated in duplicate in run 04. Both repeated values were within 20% of each other and the initial value.

## 9. RESULTS - F1 GENERATION MICE - POSTWEANING

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

One male mouse in the 350 mg/kg/day maternal dosage group was found dead on PPD 23. There were no clinical signs noted during the postweaning period. This mouse had the lowest body weight in its group. At necropsy, all tissues appeared normal for a moderate degree of autolysis. This mouse apparently did not thrive postweaning.

All other 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 were limited to common findings in the tail including constricted, bent, missing or purple.

All F1 generation male mice appeared normal at necropsy. One F1 generation female mouse in the 100 mg/kg/day dosage group had a small left kidney. No other necropsy observations occurred in these mice.

### 9.2. 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 mice were unaffected by maternal dosages of the test substance as high as 500 mg/kg/day. The only significant difference that occurred among the groups were significantly reduced ($p \leq 0.05$) body weights on PPD 21 in the 100 and 350 mg/kg/day dosage groups and increased ($p \leq 0.05$ to $p \leq 0.01$) body weight gains in the 100 and 350 mg/kg/day dosage group on PPDs 28 to 35 compared to the control group value. No other significant differences occurred among the groups during the postweaning period (PPD 21 to 41).

Body weights were significantly reduced ($p \leq 0.05$ to $p \leq 0.01$) in the F1 generation female mice on PPDs 21 and 28 in the 100 and 350 mg/kg/day dosage group and on PPDs 35

and 41 (350 mg/kg/day only); and body weights were significantly reduced ($p \leq 0.05$) in the 500 mg/kg/day dosage group on PPD 35 compared to the control group values. Body weight gains did not significantly different among the groups for the postweaning period.

### 9.3. 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 500 mg/kg/day. The average day on which preputial separation or vaginal patency occurred was comparable among the four dosage groups.

### 9.4. 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 in the F1 generation male mice were comparable among the four groups. The ratio of the liver weight to the terminal body weight was significantly reduced ($p \leq 0.05$) in the 500 mg/kg/day dosage group compared to the control group value.

Terminal body weights in the F1 generation female mice were significantly reduced ($p \leq 0.05$) in the 350 mg/kg/day dosage group compared to the control group value. Maternal dosages of the test substance as high as 500 mg/kg/day did not affect the liver weights or the ratio of liver weights to the terminal body weight.

### 9.5. Levels of PFH in Liver Homogenates (APPENDIX 5)

No detectable level of PFH was found in the liver homogenate from any F1 generation male or female pup.

## 10. DISCUSSION AND CONCLUSION

Administration of PFH Ammonium Salt to pregnant mice at dosages of 0 (Vehicle), 100, 350 and 500 mg/kg/day resulted in minimal adverse effects. Toxicity was seen only in the highest dose group and included single mortalities, excess salivation and changes in body weight gains during the lactation period in the 350 and 500 mg/kg/day dosage groups. No adverse effects occurred in the maternal mice in the 100 mg/kg/day dosage group compared to the control group values.

In the F1 generation litters, pup body weights were significantly reduced on PPD 0 in the 100 mg/kg/day and higher dosage groups, but this decrease in body weights persisted only in the 350 and 500 mg/kg/day dosage groups. On PPD 20, average pup weights per litter were 89%, 80% and 88% of the control group value. The lack of dosage-dependency can be attributed to the differences in litter size among the groups.

Additional effects, including stillbirths, reductions in viability indices, and delays in physical development in F1 generation mice occurred only in the 350 and 500 mg/kg/day dosage groups.

Levels PFH Ammonium salt in the livers from dams administered the 100 mg/kg/day dosage were all below the lower limit of quantization (0.02 µg/mL). In the 350 mg/kg/day dosage group, three of eight samples had analytical results that were quantifiable. The highest level (87.5 ug/mL) occurred in a mouse that was found dead on DG 13. The other mice had much lower levels of PFH Ammonium salt, but it is interesting that both of these mice were sacrificed early after their litters had died off. These were the only mice in this group that lost their litters. In the 500 mg/kg/day dosage group five of 16 samples had analytical results that were quantifiable. The highest level (98.4 ug/mL) occurred in a mouse that was found dead on DG 6. The other mice had much lower levels of PFH but each of these mice had litters that died early. Two samples that were below the lower limit of quantization were from mice that lost their litters. Based on these results, the variability in the quantization of PFH ammonium salt in the liver may be due to the time of sampling post the start of dosing.

In a previously conducted study with the same study design but at dosage levels of 0 (Vehicle), 7, 35 and 175 mg/kg/day (Protocol UZS00010), no PFH Ammonium salt was found in any liver sample and adverse effects occurred only in the 175 mg/kg/day dosage group (increased number stillborn pups and pups dying day 1 along with a reduction in pup weights on PPD 1, two litters with pups with corneal opacity).

The results from the previous study (Charles River Labs Study No. UZS00010) coincide with the results in this study and indicate a very minimal effect of PFH at 100 mg/kg/day with a clear no-observable-effect-level at 35 mg/kg/day.

On the basis of these data from this study, the maternal no-observable-adverse-effect-level (NOEL) for PFH Ammonium Salt is 100 mg/kg/day. The NOAEL in the F1 generation is below 100 mg/kg/day. None of the effects observed in the pups preweaning persisted into the postweaning period.

## 11. 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 Pharmakol* 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.

(14) Dagnaes-Hansen, F., Moser, J.M., Smith-John, T., Aarup, M. Sudden death in lacating mice. *Lab Animal*; 2010;205.

(15) Feinstein, R.E., Morris, W.E., Waldemarson, A.H.Hedenqvist, P., and Lindberg, R. Fatal Acute intestinal pseudoobstruction in mice. *J Am Assoc for Lab Animal Science*. 2008;58-63.

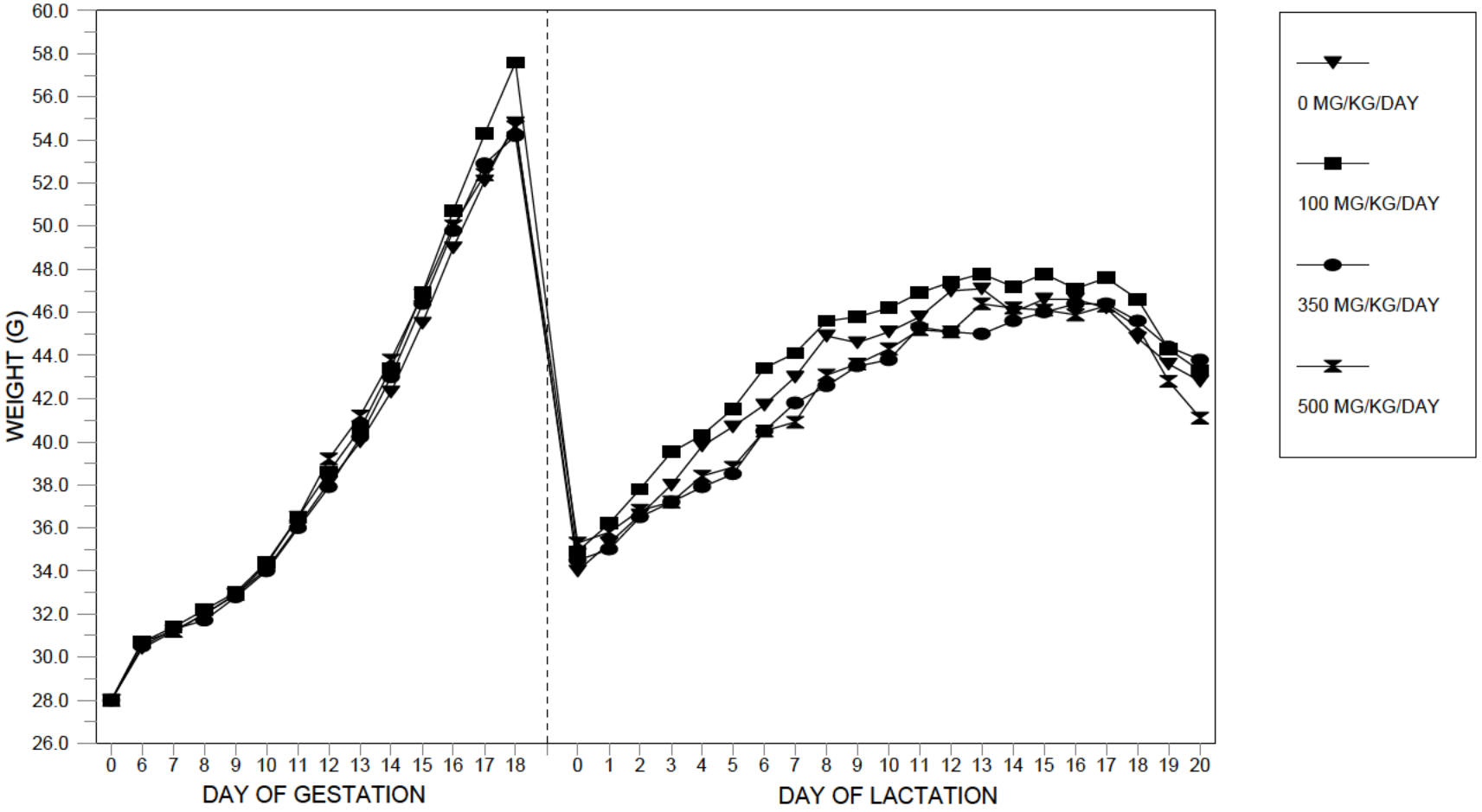
(16) Krugner-Higby, L., Girard, I., Welter, et al. Clostridial enteropathy in lactating outbred Swiss-derived (ICR) mice. *J Am Assoc for Lab Animal Science.* 2006;80-87.

(17) Kunstyr, I. Paresis of peristalsis and ileus lead to death in lactating mice. *Laboratory Animals*. 1986;32-35.

(18) Rollman, C. Olshan, K., and Hammer, J. Abdominal Distension in Lactating Mice. *Lab Animal*. 1998;19.

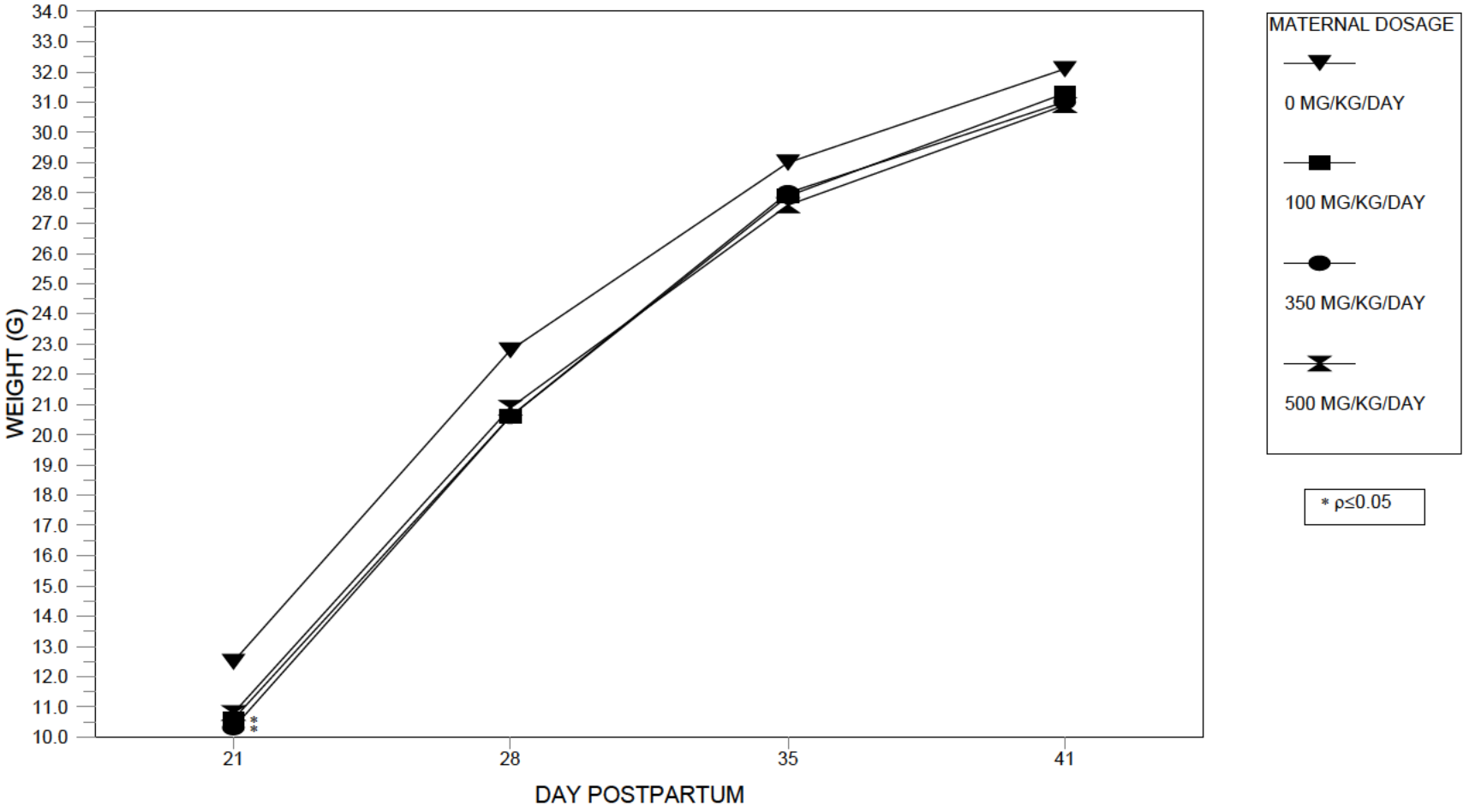
# MATERNAL BODY WEIGHTS - F0 GENERATION FEMALE MICE

Figure 1



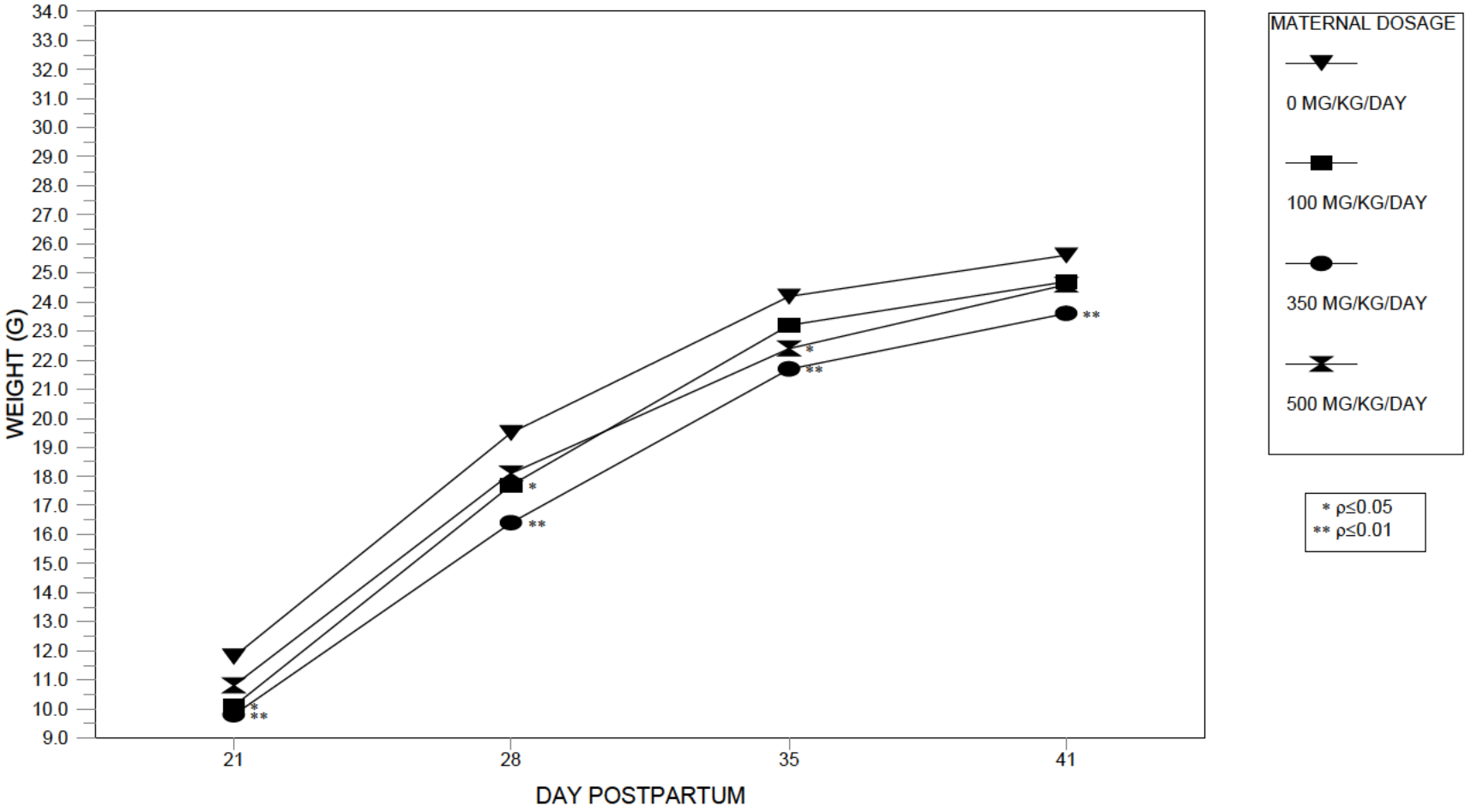
# BODY WEIGHTS - F1 GENERATION MALE MICE

Figure 2



# BODY WEIGHTS - F1 GENERATION FEMALE MICE

Figure 3



PROTOCOL 20005045: 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
(See footnotes on the last page of this table.)

| DOSAGE GROUP | I | II | III | IV |
|---|---|---|---|---|
| DOSAGE (MG/KG/DAY)a | 0 | 100 | 350 | 500 |
| FOUND DEAD | 3b-d | 6e-j | 1k | 3L-n |
| PRESUMED GESTATION: | | | | |
| MAXIMUM POSSIBLE INCIDENCE | 266/ 20 | 264/ 20 | 253/ 20 | 266/ 20 |
| EXCESS SALIVATION: TOTAL | 0/ 0 | 0/ 0 | 3/ 3 | 7/ 6** |
| SLIGHT | 0/ 0 | 0/ 0 | 3/ 3* | 6/ 5** |
| MODERATE | 0/ 0 | 0/ 0 | 0/ 0 | 1/ 1 |
| DEHYDRATION: TOTAL | 0/ 0 | 0/ 0 | 1/ 1 | 8/ 2 |
| SLIGHT/MILD | 0/ 0 | 0/ 0 | 1/ 1k | 8/ 2 |
| MODERATE | 0/ 0 | 0/ 0 | 1/ 1k | 0/ 0 |
| DYSPNEA | 0/ 0 | 0/ 0 | 2/ 1k | 4/ 2 |
| TACHYPNEA | 0/ 0 | 0/ 0 | 0/ 0 | 2/ 2m |
| DECREASED MOTOR ACTIVITY | 0/ 0 | 0/ 0 | 1/ 1k | 2/ 1 |
| PTOSIS | 0/ 0 | 0/ 0 | 1/ 1k | 2/ 1 |
| RED OR DRIED RED PERIVAGINAL SUBSTANCE | 0/ 0 | 0/ 0 | 1/ 1k | 2/ 1 |
| SCANT FECES | 0/ 0 | 0/ 0 | 1/ 1k | 1/ 1 |
| HYPERPNEA | 0/ 0 | 0/ 0 | 0/ 0 | 2/ 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
* Significantly different from the control group value ($p \leq 0.05$).
** Significantly different from the control group value ($p \leq 0.01$).

PROTOCOL 20005045: 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 2): CLINICAL OBSERVATIONS - SUMMARY - F0 GENERATION FEMALE MICE
(See footnotes on the last page of this table.)

| DOSAGE GROUP | I | II | III | IV |
|---|---|---|---|---|
| DOSAGE (MG/KG/DAY)a | 0 | 100 | 350 | 500 |
| FOUND DEAD | 3b-d | 6e-j | 1k | 3L-n |
| PRESUMED GESTATION: (CONT.) | | | | |
| GASPING | 0/ 0 | 0/ 0 | 2/ 2 | 0/ 0 |
| TREMORS | 0/ 0 | 0/ 0 | 1/ 1k | 0/ 0 |
| COLD TO TOUCH | 0/ 0 | 0/ 0 | 1/ 1k | 0/ 0 |
| BOTH EARS: PALE | 0/ 0 | 0/ 0 | 1/ 1k | 0/ 0 |
| PALE EXTREMITIES | 0/ 0 | 0/ 0 | 1/ 1k | 0/ 0 |
| RALES | 0/ 0 | 0/ 0 | 1/ 1 | 0/ 0 |

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 20005045: 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 3): CLINICAL OBSERVATIONS - SUMMARY - F0 GENERATION FEMALE MICE

| DOSAGE GROUP | I | II | III | IV |
|---|---|---|---|---|
| DOSAGE (MG/KG/DAY)a | 0 | 100 | 350 | 500 |
| FOUND DEAD | 3b-d | 6e-j | 1k | 3L-n |
| LACTATION: | | | | |
| MAXIMUM POSSIBLE INCIDENCE | 368/ 19 | 361/ 19 | 361/ 19 | 225/ 17 |
| ABDOMINAL AREA: PURPLE | 30/ 10 | 39/ 12 | 46/ 13 | 32/ 9 |
| SOFT OR LIQUID FECES | 1/ 1 | 1/ 1j | 1/ 1 | 0/ 0 |
| ABDOMINAL DISTENTION | 8/ 3 | 9/ 3 | 0/ 0 | 0/ 0 |
| BOTH EARS: PALE | 0/ 0 | 3/ 2g | 0/ 0 | 0/ 0 |
| HYPERPNEA | 2/ 1 | 2/ 1 | 0/ 0 | 0/ 0 |
| DEHYDRATION: TOTAL | 1/ 1 | 1/ 1 | 0/ 0 | 0/ 0 |
| MILD | 1/ 1 | 1/ 1g | 0/ 0 | 0/ 0 |
| MODERATE | 0/ 0 | 1/ 1g | 0/ 0 | 0/ 0 |
| DECREASED MOTOR ACTIVITY | 0/ 0 | 1/ 1g | 0/ 0 | 0/ 0 |
| PTOSIS | 0/ 0 | 1/ 1g | 0/ 0 | 0/ 0 |
| PALE EXTREMITIES | 0/ 0 | 1/ 1g | 0/ 0 | 0/ 0 |

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
a. Dosage occurred on days 6 through 18 of presumed gestation.
b. Mouse 8314 was found dead on day 16 of lactation.
c. Mouse 8316 was found dead on day 16 of lactation.
d. Mouse 8328 was found dead on day 14 of lactation.
e. Mouse 8333 was found dead on day 16 of lactation.
f. Mouse 8343 was found dead on day 13 of lactation.
g. Mouse 8344 was found dead on day 14 of lactation.
h. Mouse 8346 was found dead on day 13 of lactation.
i. Mouse 8347 was found dead on day 13 of lactation.
j. Mouse 8348 was found dead on day 13 of lactation.
k. Mouse 8361 was found dead on day 13 of gestation.
L. Mouse 8386 was found dead on day 8 of gestation.
m. Mouse 8387 was found dead on day 13 of lactation.
n. Mouse 8388 was found dead on day 13 of lactation.

PROTOCOL 20005045: 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 | | I | II | III | IV |
|---|---|---|---|---|---|
| DOSAGE (MG/KG/DAY)a | | 0 | 100 | 350 | 500 |
| MICE TESTED | N | 20 | 20 | 20 | 20 |
| PREGNANT | N | 19 | 19 | 20 | 18 |
| MATERNAL BODY WEIGHT (G) | | | | | |
| DAY 0 | MEAN±S.D. | 28.0 ± 0.9 | 28.0 ± 1.0 | 28.0 ± 0.9 | 28.0 ± 1.0 |
| DAY 6 | MEAN±S.D. | 30.4 ± 1.0 | 30.7 ± 1.2 | 30.5 ± 1.4 | 30.7 ± 1.4 |
| DAY 7 | MEAN±S.D. | 31.2 ± 1.3 | 31.4 ± 1.3 | 31.3 ± 1.4 | 31.2 ± 1.2 |
| DAY 8 | MEAN±S.D. | 32.0 ± 1.4 | 32.2 ± 1.6 | 31.7 ± 1.8 | 32.0 ± 1.3 [ 17]b |
| DAY 9 | MEAN±S.D. | 32.9 ± 1.6 | 33.0 ± 1.8 | 32.8 ± 2.0 | 32.9 ± 1.7 [ 17]b |
| DAY 10 | MEAN±S.D. | 34.1 ± 1.8 | 34.4 ± 1.9 | 34.0 ± 2.4 | 34.3 ± 2.5 [ 17]b |
| DAY 11 | MEAN±S.D. | 36.1 ± 2.2 | 36.5 ± 1.9 | 36.0 ± 2.6 | 36.5 ± 2.4 [ 17]b |
| DAY 12 | MEAN±S.D. | 38.1 ± 2.5 | 38.6 ± 2.1 | 37.9 ± 3.1 | 39.2 ± 2.8 [ 17]b |
| DAY 13 | MEAN±S.D. | 40.0 ± 3.2 | 40.6 ± 2.4 | 40.2 ± 3.4 [ 19]b | 41.2 ± 3.4 [ 17]b |
| DAY 14 | MEAN±S.D. | 42.3 ± 3.8 | 43.4 ± 2.5 | 43.0 ± 4.2 [ 19]b | 43.8 ± 4.5 [ 17]b |
| DAY 15 | MEAN±S.D. | 45.5 ± 4.9 | 46.9 ± 2.8 | 46.4 ± 5.2 [ 19]b | 46.8 ± 5.9 [ 17]b |
| DAY 16 | MEAN±S.D. | 49.0 ± 6.0 | 50.7 ± 3.1 | 49.8 ± 5.8 [ 19]b | 50.0 ± 6.0 [ 17]b |
| DAY 17 | MEAN±S.D. | 52.1 ± 6.9 | 54.3 ± 3.6 | 52.9 ± 6.3 [ 19]b | 52.4 ± 5.8 [ 17]b |
| DAY 18 | MEAN±S.D. | 54.8 ± 7.9 [ 18]c | 57.6 ± 3.9 [ 18]c | 54.2 ± 7.0 [ 15]b,c | 54.6 ± 7.7 [ 15]b,c |

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 found dead.
c. Excludes values for mice that were in the process of delivering or had delivered.

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MICE TESTED | N | 20 | 20 | 20 | 20 |
| PREGNANT | N | 19 | 19 | 20 | 18 |
| MATERNAL BODY WEIGHT CHANGE (G) | | | | | |
| DAYS 0 - 6 | MEAN±S.D. | +2.4 ± 0.7 | +2.6 ± 0.7 | +2.5 ± 1.0 | +2.7 ± 0.8 |
| DAYS 6 - 9 | MEAN±S.D. | +2.5 ± 1.0 | +2.3 ± 0.9 | +2.2 ± 1.2 | +2.3 ± 0.9 [ 17]b |
| DAYS 9 - 12 | MEAN±S.D. | +5.2 ± 1.6 | +5.7 ± 0.7 | +5.2 ± 2.6 | +6.3 ± 1.6 [ 17]b |
| DAYS 12 - 16 | MEAN±S.D. | +10.9 ± 3.8 | +12.0 ± 1.4 | +11.7 ± 3.0 [ 19]b | +10.7 ± 4.7 [ 17]b |
| DAYS 16 - 18 | MEAN±S.D. | +6.1 ± 2.0 [ 18]c | +6.8 ± 1.1 [ 18]c | +5.2 ± 1.6 [ 15]b,c | +4.2 ± 3.8 [ 15]b,c |
| DAYS 6 - 18 | MEAN±S.D. | +24.4 ± 7.8 [ 18]c | +27.0 ± 3.1 [ 18]c | +23.8 ± 6.1 [ 15]b,c | +23.9 ± 7.5 [ 15]b,c |
| DAYS 0 - 18 | MEAN±S.D. | +26.7 ± 7.8 [ 18]c | +29.6 ± 3.6 [ 18]c | +26.2 ± 6.5 [ 15]b,c | +26.6 ± 7.6 [ 15]b,c |

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 found dead.
c. Excludes values for mice that were in the process of delivering or had delivered.

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MICE TESTED | | N | 20 | 20 | 20 | 20 |
| PREGNANT | | N | 19 | 19 | 20 | 18 |
| INCLUDED IN ANALYSES | | N | 19 | 19 | 19b | 17b |
| DELIVERED A LITTER | | N | 19 | 19 | 19 | 17 |
| MATERNAL BODY WEIGHT (G) | | | | | | |
| DAY 0 | | MEAN±S.D. | 34.0 ± 1.8 | 34.9 ± 2.1 | 34.5 ± 3.0 | 35.3 ± 3.0 |
| DAY 1 | | MEAN±S.D. | 35.3 ± 2.4 | 36.2 ± 2.2 | 35.0 ± 2.4 | 35.8 ± 2.5 |
| | | | | | | [ 13]c |
| DAY 2 | | MEAN±S.D. | 36.6 ± 3.1 | 37.8 ± 2.3 | 36.5 ± 2.7 | 36.8 ± 2.6 |
| | | | | | [ 17]c | [ 11]c |
| DAY 3 | | MEAN±S.D. | 38.0 ± 3.4 | 39.5 ± 2.6 | 37.2 ± 2.8 | 37.2 ± 2.3 |
| | | | | | [ 17]c | [ 11]c |
| DAY 4 | | MEAN±S.D. | 39.8 ± 3.2 | 40.3 ± 2.8 | 37.9 ± 3.4 | 38.4 ± 2.3 |
| | | | [ 18]c | | [ 17]c | [ 11]c |
| DAY 5 | | MEAN±S.D. | 40.7 ± 2.8 | 41.5 ± 3.4 | 38.5 ± 2.8 | 38.8 ± 2.5 |
| | | | [ 18]c | | [ 17]c | [ 11]c |
| DAY 6 | | MEAN±S.D. | 41.7 ± 3.6 | 43.4 ± 3.7 | 40.5 ± 3.3 | 40.5 ± 3.4 |
| | | | [ 18]c | | [ 17]c | [ 11]c |
| DAY 7 | | MEAN±S.D. | 43.0 ± 3.7 | 44.1 ± 3.6 | 41.8 ± 3.1 | 40.9 ± 3.2 |
| | | | [ 18]c | | [ 17]c | [ 11]c |
| DAY 8 | | MEAN±S.D. | 44.9 ± 3.7 | 45.6 ± 3.0 | 42.6 ± 3.4 | 43.1 ± 2.8 |
| | | | [ 18]c | | [ 17]c | [ 11]c |
| DAY 9 | | MEAN±S.D. | 44.6 ± 3.7 | 45.8 ± 3.5 | 43.5 ± 3.9 | 43.6 ± 3.0 |
| | | | [ 18]c | | [ 17]c | [ 11]c |
| DAY 10 | | MEAN±S.D. | 45.1 ± 3.7 | 46.2 ± 4.0 | 43.8 ± 3.7 | 44.3 ± 2.7 |
| | | | [ 18]c | | [ 17]c | [ 11]c |
| DAY 11 | | MEAN±S.D. | 45.8 ± 4.1 | 46.9 ± 4.1 | 45.3 ± 4.1 | 45.2 ± 3.2 |
| | | | [ 18]c | | [ 17]c | [ 11]c |
| DAY 12 | | MEAN±S.D. | 47.0 ± 3.9 | 47.4 ± 4.6 | 45.1 ± 3.8 | 45.1 ± 3.1 |
| | | | [ 18]c | | [ 17]c | [ 11]c |

DAY = DAY OF LACTATION
[ ] = NUMBER OF VALUES AVERAGED
a. Dosage occurred on days 6 through 18 of gestation.
b. Excludes mice that were found dead before delivery.
c. Excludes values for mice that were sacrificed due to no surviving pups or found dead.

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MICE TESTED | | N | 20 | 20 | 20 | 20 |
| PREGNANT | | N | 19 | 19 | 20 | 18 |
| INCLUDED IN ANALYSES | | N | 19 | 19 | 19b | 17b |
| DELIVERED A LITTER | | N | 19 | 19 | 19 | 17 |
| MATERNAL BODY WEIGHT (G) | | | | | | |
| DAY 13 | | MEAN±S.D. | 47.1 ± 4.0 [ 18]c | 47.8 ± 3.7 [ 15]c | 45.0 ± 4.4 [ 17]c | 46.4 ± 2.0 [ 9]c |
| DAY 14 | | MEAN±S.D. | 46.0 ± 4.8 [ 17]c | 47.2 ± 3.7 [ 14]c | 45.6 ± 4.0 [ 17]c | 46.2 ± 2.6 [ 9]c |
| DAY 15 | | MEAN±S.D. | 46.6 ± 4.2 [ 17]c | 47.8 ± 3.4 [ 14]c | 46.0 ± 4.0 [ 17]c | 46.1 ± 3.3 [ 9]c |
| DAY 16 | | MEAN±S.D. | 46.6 ± 4.4 [ 15]c | 47.1 ± 3.3 [ 13]c | 46.4 ± 4.5 [ 17]c | 45.9 ± 3.3 [ 9]c |
| DAY 17 | | MEAN±S.D. | 46.2 ± 4.4 [ 15]c | 47.6 ± 3.3 [ 13]c | 46.4 ± 4.5 [ 17]c | 46.3 ± 3.4 [ 9]c |
| DAY 18 | | MEAN±S.D. | 44.8 ± 4.0 [ 15]c | 46.6 ± 3.2 [ 13]c | 45.6 ± 4.9 [ 17]c | 45.3 ± 3.4 [ 9]c |
| DAY 19 | | MEAN±S.D. | 43.6 ± 4.6 [ 15]c | 44.3 ± 3.4 [ 13]c | 44.4 ± 4.7 [ 17]c | 42.8 ± 3.6 [ 9]c |
| DAY 20 | | MEAN±S.D. | 42.8 ± 3.7 [ 15]c | 43.3 ± 2.9 [ 13]c | 43.8 ± 4.5 [ 17]c | 41.1 ± 3.8 [ 9]c |

DAY = DAY OF LACTATION
[ ] = NUMBER OF VALUES AVERAGED
a. Dosage occurred on days 6 through 18 of gestation.
b. Excludes mice that were found dead before delivery.
c. Excludes values for mice that were sacrificed due to no surviving pups or found dead.

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MICE TESTED | N | 20 | 20 | 20 | 20 |
| PREGNANT | N | 19 | 19 | 20 | 18 |
| INCLUDED IN ANALYSES | N | 19 | 19 | 19b | 17b |
| DELIVERED A LITTER | N | 19 | 19 | 19 | 17 |
| MATERNAL BODY WEIGHT CHANGE (G) | | | | | |
| DAYS 0 - 4 | MEAN±S.D. | +5.7 ± 2.1 [ 18]c | +5.4 ± 1.8 | +3.8 ± 2.6* [ 17]c | +2.8 ± 2.0** [ 11]c |
| DAYS 4 - 7 | MEAN±S.D. | +3.3 ± 2.1 [ 18]c | +3.8 ± 1.8 | +3.9 ± 2.5 [ 17]c | +2.4 ± 2.0 [ 11]c |
| DAYS 7 - 14 | MEAN±S.D. | +2.9 ± 3.3 [ 17]c | +3.3 ± 1.6 [ 14]c | +3.7 ± 3.0 [ 17]c | +5.3 ± 1.7 [ 9]c |
| DAYS 14 - 20 | MEAN±S.D. | -2.9 ± 4.7 [ 15]c | -4.2 ± 2.2 [ 13]c | -1.8 ± 3.6 [ 17]c | -5.1 ± 4.5 [ 9]c |
| DAYS 0 - 20 | MEAN±S.D. | +8.7 ± 2.7 [ 15]c | +8.5 ± 1.9 [ 13]c | +9.6 ± 4.8 [ 17]c | +5.6 ± 4.2 [ 9]c |

DAYS = DAYS OF LACTATION
[ ] = NUMBER OF VALUES AVERAGED
a. Dosage occurred on days 6 through 18 of gestation.
b. Excludes mice that were found dead before delivery.
c. Excludes values for mice that were sacrificed due to no surviving pups or found dead.
* Significantly different from the control group value ($p \leq 0.05$).
** Significantly different from the control group value ($p \leq 0.01$).

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MICE ASSIGNED TO NATURAL DELIVERY | N | 20 | 20 | 20 | 20 |
| PREGNANT | N(%) | 19( 95.0) | 19( 95.0) | 20(100.0) | 18( 90.0) |
| INCLUDED IN ANALYSES | N | 19 | 19 | 19b | 17b |
| DELIVERED A LITTER | N(%) | 19(100.0) | 19(100.0) | 19(100.0) | 17(100.0) |
| DURATION OF GESTATION c | MEAN±S.D. | 19.9 ± 0.6 | 19.9 ± 0.2 | 19.9 ± 0.6 | 20.2 ± 1.1 |
| IMPLANTATION SITES | N | 245 | 276 | 266 | 239 |
| PER DELIVERED LITTER | MEAN±S.D. | 12.9 ± 4.3 | 14.5 ± 1.8 | 14.0 ± 3.6 | 14.0 ± 2.4 |
| DAMS WITH STILLBORN PUPS | N(%) | 2( 10.5) | 0( 0.0) | 5( 26.3) | 7( 41.2)** |
| DAMS WITH NO LIVEBORN PUPS | N(%) | 0( 0.0) | 0( 0.0) | 0( 0.0) | 1( 5.9) |
| GESTATION INDEX d | % | 100.0 | 100.0 | 100.0 | 94.1 |
| | N/N | 19/ 19 | 19/ 19 | 19/ 19 | 16/ 17 |
| DAMS WITH ALL PUPS DYING DAYS 0-3 POSTPARTUM | N(%) | 1( 5.3) | 0( 0.0) | 2( 10.5) | 5( 31.3)** |
| DAMS 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 mice that were found dead before 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.
** Significantly different from the control group value ($p \leq 0.01$).

PROTOCOL 20005045: 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 | | I | II | III | IV |
|---|---|---|---|---|---|
| DOSAGE (MG/KG/DAY)a | | 0 | 100 | 350 | 500 |
| DELIVERED LITTERS WITH ONE OR MORE LIVEBORN PUPS | N | 19 | 19 | 19 | 16 |
| PUPS DELIVERED (TOTAL) | N | 221 | 250 | 245 | 177 |
| | MEAN±S.D. | 11.6 ± 4.2 | 13.2 ± 1.6 | 12.9 ± 3.8 | 11.1 ± 2.4 |
| LIVEBORN | MEAN±S.D. | 11.4 ± 4.5 | 13.2 ± 1.6 | 12.2 ± 3.4 | 9.4 ± 3.9 |
| | N(%) | 217( 98.2) | 250(100.0) | 232( 94.7) | 150( 84.7)** |
| STILLBORN | MEAN±S.D. | 0.2 ± 0.7 | 0.0 ± 0.0 | 0.3 ± 0.4 | 1.0 ± 2.2 |
| | N(%) | 4( 1.8) | 0( 0.0) | 5( 2.0) | 16( 9.0)** |
| UNKNOWN VITAL STATUS b | N | 0 | 0 | 8 | 11 |
| PUPS FOUND DEAD OR PRESUMED CANNIBALIZED | | | | | |
| DAY 0 | N/N(%) | 0/217( 0.0) | 0/250( 0.0) | 3/232( 1.3) | 21/150( 14.0)** |
| DAYS 1- 4 | N/N(%) | 2/217( 0.9) | 3/250( 1.2) | 25/229( 10.9)** | 20/129( 15.5)** |
| DAYS 5- 7 | N/N(%) | 1/215( 0.5) | 1/247( 0.4) | 3/204( 1.5) | 0/109( 0.0) |
| DAYS 8-14 | N/N(%) | 0/214( 0.0) | 1/244( 0.4)c | 3/201( 1.5) | 0/109( 0.0) |
| DAYS 15-20 | N/N(%) | 0/214( 0.0) | 2/215( 0.9)c | 0/198( 0.0) | 0/109( 0.0) |
| DAY 4 VIABILITY INDEX d | % | 99.1 | 98.8 | 87.9 | 72.7** |
| | N/N | 215/217 | 247/250 | 204/232 | 109/150 |
| DAY 7 VIABILITY INDEX e | % | 98.6 | 98.4 | 86.6* | 72.7** |
| | N/N | 214/217 | 246/250 | 201/232 | 109/150 |
| LACTATION INDEX f | % | 99.5 | 98.2c | 97.0 | 100.0 |
| | N/N | 214/215 | 213/217c | 198/204 | 109/109 |

DAY(S) = DAY(S) POSTPARTUM
a. Dosage occurred on days 6 through 18 of gestation.
b. Maternal cannibalization or autolysis precluded identification of vital status at birth.
c. Excludes mortality of pups that remained on study after dam was found dead.
d. Number of live pups on day 4 postpartum/number of liveborn pups on day 0 postpartum.
e. Number of live pups on day 7 postpartum/number of liveborn pups on day 0 postpartum.
f. Number of live pups on day 20 (weaning) postpartum/number of live pups on day 4 postpartum.
* Significantly different from the control group value ($p \leq 0.05$).
** Significantly different from the control group value ($p \leq 0.01$).

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| DELIVERED LITTERS WITH ONE OR MORE LIVEBORN PUPS | N | 19 | 19 | 19 | 16 |
| SURVIVING PUPS/LITTER b | | | | | |
| DAY 0c | MEAN±S.D. | 11.4 ± 4.5 | 13.2 ± 1.6 | 12.2 ± 3.4 | 9.4 ± 3.9 |
| DAY 4 | MEAN±S.D. | 11.3 ± 4.6 | 13.0 ± 1.7 | 10.7 ± 5.1 | 6.8 ± 5.0** |
| DAY 7 | MEAN±S.D. | 11.3 ± 4.6 | 12.9 ± 1.6 | 10.6 ± 5.0 | 6.8 ± 5.0** |
| DAY 14 | MEAN±S.D. | 11.3 ± 4.6 | 12.4 ± 1.4 [ 15]d | 10.4 ± 4.9 | 6.8 ± 5.0** |
| DAY 20 | MEAN±S.D. | 11.3 ± 4.6 | 12.3 ± 1.2 [ 15]d | 10.4 ± 4.9 | 6.8 ± 5.0** |
| PERCENT MALE PUPS PER NUMBER OF PUPS SEXED | | | | | |
| DAY 0c | MEAN±S.D. | 45.8 ± 18.6 | 48.8 ± 10.5 | 55.4 ± 16.2 | 44.0 ± 17.3 |
| DAY 4 | MEAN±S.D. | 48.6 ± 15.2 [ 18]e | 49.5 ± 11.1 | 56.1 ± 16.7 [ 17]e | 47.6 ± 11.3 [ 11]e |
| DAY 7 | MEAN±S.D. | 48.3 ± 15.3 [ 18]e | 49.2 ± 12.0 | 56.3 ± 16.4 [ 17]e | 47.6 ± 11.3 [ 11]e |
| DAY 14 | MEAN±S.D. | 48.3 ± 15.3 [ 18]e | 51.7 ± 9.5 [ 15]d | 56.0 ± 16.5 [ 17]e | 47.6 ± 11.3 [ 11]e |
| DAY 20 | MEAN±S.D. | 48.3 ± 15.3 [ 18]e | 52.3 ± 9.7 [ 15]d | 56.0 ± 16.5 [ 17]e | 47.6 ± 11.3 [ 11]e |

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. Includes liveborn pups and pups that died before weighing on day 0 postpartum.
d. Excludes litters with mortality of pups that remained on study after dam was found dead.
e. Excludes values for litters that had no surviving pups.
** Significantly different from the control group value ($p \leq 0.01$).

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| DELIVERED LITTERS WITH ONE OR MORE LIVEBORN PUPS | N | 19 | 19 | 19 | 16 |
| LIVE LITTER SIZE AT WEIGHING | | | | | |
| DAY 0 | MEAN±S.D. | 11.4 ± 4.5 | 13.2 ± 1.6 | 12.0 ± 3.5 | 9.9 ± 2.9 |
| | | | | | [ 13]b |
| DAY 4 | MEAN±S.D. | 11.9 ± 3.8 | 13.0 ± 1.7 | 12.0 ± 3.6 | 9.9 ± 2.0* |
| | | [ 18]b | | [ 17]b | [ 11]b |
| DAY 7 | MEAN±S.D. | 11.9 ± 3.8 | 12.9 ± 1.6 | 11.8 ± 3.6 | 9.9 ± 2.0 |
| | | [ 18]b | | [ 17]b | [ 11]b |
| DAY 14 | MEAN±S.D. | 11.9 ± 3.8 | 12.4 ± 1.4 | 11.6 ± 3.4 | 9.9 ± 2.0 |
| | | [ 18]b | [ 15]c | [ 17]b | [ 11]b |
| DAY 20 | MEAN±S.D. | 11.9 ± 3.8 | 12.3 ± 1.2 | 11.6 ± 3.4 | 9.9 ± 2.0 |
| | | [ 18]b | [ 15]c | [ 17]b | [ 11]b |
| PUP WEIGHT/LITTER (GRAMS) | | | | | |
| DAY 0 | MEAN±S.D. | 1.6 ± 0.2 | 1.5 ± 0.1* | 1.4 ± 0.2** | 1.4 ± 0.2** |
| | | | | | [ 13]b |
| DAY 4 | MEAN±S.D. | 3.0 ± 0.4 | 2.8 ± 0.2 | 2.2 ± 0.6** | 2.4 ± 0.5** |
| | | [ 18]b | | [ 17]b | [ 11]b |
| DAY 7 | MEAN±S.D. | 4.4 ± 0.8 | 4.1 ± 0.4 | 3.6 ± 1.0** | 3.9 ± 0.8 |
| | | [ 18]b | | [ 17]b | [ 11]b |
| DAY 14 | MEAN±S.D. | 7.4 ± 1.9 | 6.8 ± 0.8 | 6.4 ± 1.4 | 6.8 ± 1.1 |
| | | [ 18]b | [ 15]c | [ 17]b | [ 11]b |
| DAY 20 | MEAN±S.D. | 11.0 ± 3.0 | 9.8 ± 1.5 | 8.8 ± 2.7 | 9.7 ± 2.0 |
| | | [ 18]b | [ 15]c | [ 17]b | [ 11]b |

DAY = DAY POSTPARTUM
[ ] = NUMBER OF VALUES AVERAGED
a. Dosage occurred on days 6 through 18 of gestation.
b. Excludes values for litters that had no surviving pups.
c. Excludes litters with mortality of pups that remained on study after dam was found dead.
* Significantly different from the control group value ($p \leq 0.05$).
** Significantly different from the control group value ($p \leq 0.01$).

PROTOCOL 20005045: 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 | | I | II | III | IV |
|---|---|---|---|---|---|
| DOSAGE (MG/KG/DAY)a | | 0 | 100 | 350 | 500 |
| MICE EXAMINED b | N | 20 | 20 | 20 | 20 |
| FOUND DEAD | N | 3c-e | 6f-k | 1L | 3m-o |
| APPEARED NORMAL | N | 19 | 19 | 19 | 14** |
| STERNUM: | | | | | |
| BENT PROXIMAL TO XIPHOID PROCESS | N | 1 | 1 | 0 | 0 |
| LIVER: | | | | | |
| LOBE(S), TAN AREA(S) | N | 0 | 0 | 1 | 5** |
| INTESTINES: | | | | | |
| DISTENDED WITH GAS | N | 0 | 0 | 0 | 1 |

a. Dosage occurred on days 6 through 18 of presumed gestation.
b. Refer to the individual clinical observations table (Table 24) for external observations confirmed at necropsy.
c. Mouse 8314 was found dead on day 16 of lactation.
d. Mouse 8316 was found dead on day 16 of lactation.
e. Mouse 8328 was found dead on day 14 of lactation.
f. Mouse 8333 was found dead on day 16 of lactation.
g. Mouse 8343 was found dead on day 13 of lactation.
h. Mouse 8344 was found dead on day 14 of lactation.
i. Mouse 8346 was found dead on day 13 of lactation.
j. Mouse 8347 was found dead on day 13 of lactation.
k. Mouse 8348 was found dead on day 13 of lactation.
L. Mouse 8361 was found dead on day 13 of gestation.
m. Mouse 8386 was found dead on day 8 of gestation.
n. Mouse 8387 was found dead on day 13 of lactation.
o. Mouse 8388 was found dead on day 13 of lactation.
** Significantly different from the control group value ($p \leq 0.01$).

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MICE TESTED | N | 10 | 12 | 8 | 16 |
| PREGNANT | N | 9 | 11 | 8 | 14 |
| INCLUDED IN ANALYSES | N | 5b | 5b | 5b | 5b |
| TERMINAL BODY WEIGHT | MEAN±S.D. | 43.8 ± 2.8 | 43.1 ± 3.1 | 45.7 ± 4.4 | 40.1 ± 3.6 |
| LIVER | MEAN±S.D. | 3.124 ± 0.252 | 3.200 ± 0.340 | 3.272 ± 0.321 | 2.866 ± 0.157 |
| LIVER (%) | MEAN±S.D. | 7.136 ± 0.515 | 7.438 ± 0.685 | 7.178 ± 0.572 | 7.188 ± 0.772 |

ALL WEIGHTS WERE RECORDED IN GRAMS (G). RATIOS (%) = (LIVER WEIGHT/TERMINAL BODY WEIGHT) X 100.

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

b. Excludes values for mice that were sacrificed due to no surviving pups or found dead.

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| LITTERS EXAMINED (N) | | 19 | 19 | 19 | 17 |
| TOTAL FREQUENCY (DAYS X PUPS)/LITTERS WITH OBSERVATIONS a,b | | | | | |
| TAIL OR RIGHT HINDLIMB OR LEFT SIDE OF BACK, SCAB | N/N | 1/1 | 0/0 | 2/1 | 2/1 |
| DEHYDRATION, TOTAL | N/N | 0/0 | 1/1 | 7/4 | 1/1 |
| MILD | N/N | 0/0 | 1/1 | 6/3 | 0/0 |
| MODERATE | N/N | 0/0 | 0/0 | 1/1 | 1/1 |
| TIP OF TAIL MISSING | N/N | 0/0 | 0/0 | 8/2 | 0/0 |
| TIP OF TAIL RED | N/N | 0/0 | 6/1 | 7/1 | 0/0 |
| NOT NURSING | N/N | 0/0 | 0/0 | 11/1 | 0/0 |
| NOT NESTING | N/N | 0/0 | 0/0 | 11/1 | 0/0 |
| UNGROOMED COAT | N/N | 16/1 | 0/0 | 0/0 | 0/0 |

a. Tabulation restricted to adverse observations; all other pups appeared normal.
b. Excludes clinical observations of pups that remained on study after dam was found dead.

PROTOCOL 20005045: 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)a | | 0 | 100 | 350 | 500 |
| LITTERS DELIVERED | N | 19 | 19 | 19 | 17 |
| LITTERS TESTED | N | 18b | 19 | 17b | 11b |
| PERCENTAGE OF PUPS MEETING CRITERION | | | | | |
| DAY 10 | MEAN±S.D. | 0.4 ± 1.7 | 0.4 ± 1.5 | 0.5 ± 2.2 | 0.0 ± 0.0 |
| DAY 11 | MEAN±S.D. | 0.4 ± 1.7 | 0.4 ± 1.5 | 0.5 ± 2.2 | 0.0 ± 0.0 |
| DAY 12 | MEAN±S.D. | 6.8 ± 23.4 | 0.8 ± 2.4 | 1.1 ± 3.0 | 1.3 ± 4.3 |
| DAY 13 | MEAN±S.D. | 31.7 ± 37.9 | 14.0 ± 19.2 | 13.2 ± 25.8 | 14.2 ± 29.4 |
| DAY 14 | MEAN±S.D. | 82.5 ± 24.4 | 68.6 ± 34.9 | 42.0 ± 39.5** | 50.2 ± 38.0* |
| DAY 15 | MEAN±S.D. | 98.4 ± 3.7 | 88.2 ± 25.6 | 76.1 ± 37.8 | 73.4 ± 42.4 |
| DAY 16 | MEAN±S.D. | 100.0 ± 0.0 | 99.2 ± 3.3 | 91.1 ± 22.7 | 99.2 ± 2.5 |
| DAY 17 | MEAN±S.D. | 100.0 ± 0.0 | 100.0 ± 0.0 | 100.0 ± 0.0 | 100.0 ± 0.0 |
| CRITERION DAY c | MEAN±S.D. | 13.8 ± 0.7 | 14.2 ± 0.8 | 14.9 ± 1.1** | 14.5 ± 1.0 |

DAY = DAY POSTPARTUM
a. Dosage occurred on days 6 through 18 of gestation.
b. Excludes values for litters that had no surviving pups at time of testing.
c. The average day postpartum that at least 50% of the pups had the developmental measure present.
* Significantly different from the control group value ($p \leq 0.05$).
** Significantly different from the control group value ($p \leq 0.01$).

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| LITTERS EVALUATED | N | 19 | 19 | 19 | 17 |
| TOTAL PUPS STILLBORN OR FOUND DEAD a,b | N | 3 | 1 | 9 | 32 |
| STILLBORN | N | 3 | 0 | 4 | 10 |
| FOUND DEAD | N | 0 | 1 | 5 | 22 |
| NO MILK IN STOMACH c | N(%) | | 0( 0.0) | 0( 0.0) | 11( 50.0) |
| APPEARED NORMAL | N(%) | 3(100.0) | 1(100.0) | 9(100.0) | 21( 65.6) |
| PUPS SACRIFICED AND NECROPSIED ON DAY 20 POSTPARTUM | | | | | |
| LITTERS EVALUATED | N | 18 | 19 | 17 | 11 |
| PUPS EVALUATED | N | 174 | 173 | 158 | 69 |
| APPEARED NORMAL | | | | | |
| LITTER INCIDENCE | N(%) | 18(100.0) | 19(100.0) | 17(100.0) | 11(100.0) |
| PUP INCIDENCE | N(%) | 174(100.0) | 173(100.0) | 158(100.0) | 69(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. Excludes mortality of pups that remained on study after dam was found dead.
c. Analysis restricted to pups found dead and necropsied.

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MAXIMUM POSSIBLE INCIDENCE | 420/ 20 | 420/ 20 | 402/ 20 | 420/ 20 |
| FOUND DEAD | 0 | 0 | 1a | 0 |
| TIP OF TAIL: CONSTRICTED | 0/ 0 | 0/ 0 | 0/ 0 | 14/ 1 |
| TAIL BENT | 0/ 0 | 0/ 0 | 0/ 0 | 4/ 1 |
| TIP OF TAIL MISSING | 0/ 0 | 0/ 0 | 0/ 0 | 4/ 1 |
| TIP OF TAIL: PURPLE | 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
a. Mouse 9049 was found dead on day 23 postpartum.

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MAXIMUM POSSIBLE INCIDENCE | 420/ 20 | 420/ 20 | 420/ 20 | 420/ 20 |
| MORTALITY | 0 | 0 | 0 | 0 |
| TAIL BENT | 21/ 1 | 0/ 0 | 0/ 0 | 0/ 0 |

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 20005045: 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 | 100 | 350 | 500 |
| MICE TESTED | N | 20 | 20 | 20 | 20 |
| BODY WEIGHT (G) | | | | | |
| DAY 21 | MEAN±S.D. | 12.5 ± 2.7 | 10.6 ± 2.2* | 10.3 ± 2.8* | 10.8 ± 2.4 |
| DAY 28 | MEAN±S.D. | 22.8 ± 3.4 | 20.6 ± 3.4 | 20.6 ± 3.8 [ 19]a | 20.9 ± 3.7 |
| DAY 35 | MEAN±S.D. | 29.0 ± 2.7 | 27.9 ± 2.8 | 28.0 ± 2.6 [ 19]a | 27.6 ± 2.7 |
| DAY 41 | MEAN±S.D. | 32.1 ± 3.0 | 31.3 ± 2.6 | 31.0 ± 2.5 [ 19]a | 30.9 ± 2.7 |

DAY = DAY POSTPARTUM
[ ] = NUMBER OF VALUES AVERAGED
a. Excludes values for mouse 9049, which was found dead on day 23 postpartum.
* Significantly different from the control group value (p≤0.05).

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MICE TESTED | N | 20 | 20 | 20 | 20 |
| BODY WEIGHT CHANGE (G) | | | | | |
| DAYS 21 - 28 | MEAN±S.D. | +10.4 ± 1.8 | +10.0 ± 1.3 | +10.1 ± 1.3 [ 19]a | +10.1 ± 1.3 |
| DAYS 28 - 35 | MEAN±S.D. | +6.1 ± 1.6 | +7.2 ± 1.2* | +7.4 ± 1.7** [ 19]a | +6.7 ± 1.4 |
| DAYS 35 - 41 | MEAN±S.D. | +3.1 ± 1.4 | +3.4 ± 1.1 | +3.0 ± 0.8 [ 19]a | +3.3 ± 1.3 |
| DAYS 21 - 41 | MEAN±S.D. | +19.6 ± 2.3 | +20.7 ± 1.6 | +20.5 ± 1.7 [ 19]a | +20.1 ± 1.6 |

DAYS = DAYS POSTPARTUM
[ ] = NUMBER OF VALUES AVERAGED
a. Excludes values for mouse 9049, which was found dead on day 23 postpartum.
* Significantly different from the control group value ($p \leq 0.05$).
** Significantly different from the control group value ($p \leq 0.01$).

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MICE TESTED | N | 20 | 20 | 20 | 20 |
| BODY WEIGHT (G) | | | | | |
| DAY 21 | MEAN±S.D. | 11.8 ± 2.4 | 10.1 ± 2.2* | 9.8 ± 1.6** | 10.8 ± 1.8 |
| DAY 28 | MEAN±S.D. | 19.5 ± 2.4 | 17.7 ± 2.6* | 16.4 ± 3.1** | 18.1 ± 2.3 |
| DAY 35 | MEAN±S.D. | 24.2 ± 1.8 | 23.2 ± 2.5 | 21.7 ± 2.8** | 22.4 ± 1.5* |
| DAY 41 | MEAN±S.D. | 25.6 ± 2.0 | 24.7 ± 1.9 | 23.6 ± 2.0** | 24.6 ± 1.7 |

DAY = DAY POSTPARTUM
* Significantly different from the control group value ($p \leq 0.05$).
** Significantly different from the control group value ($p \leq 0.01$).

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MICE TESTED | N | 20 | 20 | 20 | 20 |
| BODY WEIGHT CHANGE (G) | | | | | |
| DAYS 21 - 28 | MEAN±S.D. | +7.7 ± 1.4 | +7.6 ± 0.8 | +6.7 ± 2.3 | +7.3 ± 0.9 |
| DAYS 28 - 35 | MEAN±S.D. | +4.7 ± 1.3 | +5.5 ± 1.2 | +5.3 ± 1.2 | +4.3 ± 1.3 |
| DAYS 35 - 41 | MEAN±S.D. | +1.4 ± 0.9 | +1.5 ± 1.0 | +1.9 ± 1.4 | +2.2 ± 0.7 |
| DAYS 21 - 41 | MEAN±S.D. | +13.8 ± 1.2 | +14.6 ± 1.6 | +13.8 ± 1.6 | +13.8 ± 1.5 |

DAYS = DAYS POSTPARTUM

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MALE MICE | N | 20 | 20 | 19a | 20 |
| PREPUTIAL SEPARATION b | MEAN±S.D. | 29.4 ± 1.9 [ 18]c | 29.8 ± 2.2 | 29.3 ± 2.3 | 29.4 ± 1.7 |
| BODY WEIGHT AT SEPARATION (G)d | MEAN±S.D. | 24.49 ± 3.03 [ 18]c | 23.22 ± 2.11 | 22.40 ± 2.27 | 22.80 ± 2.68 |
| FEMALE MICE | N | 20 | 20 | 20 | 20 |
| VAGINAL PATENCY e | MEAN±S.D. | 26.8 ± 2.0 [ 19]c | 27.5 ± 1.1 [ 19]c | 27.6 ± 2.0 [ 18]c,f | 27.5 ± 2.1 |
| BODY WEIGHT AT VAGINAL PATENCY (G)g | MEAN±S.D. | 18.08 ± 1.44 [ 19]c | 17.38 ± 2.82 [ 19]c | 16.31 ± 1.70 [ 18]c,f | 17.57 ± 2.20 |

[ ] = NUMBER OF VALUES AVERAGED
a. Excludes values for mouse 9049, which was found dead on day 23 postpartum.
b. Average day postpartum that the prepuce was observed to be separated.
c. Excludes mice for which the exact day of maturity could not be determined.
d. Average body weight on day prepuce was first observed to be separated.
e. Average day postpartum that the vagina was observed to be patent.
f. Excludes mouse 9130, which had not reached sexual maturity by day 41 postpartum, the day of scheduled sacrifice.
g. Average body weight on day vagina was first observed to be patent.

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MICE EXAMINED a | N | 20 | 20 | 20 | 20 |
| FOUND DEAD | N | 0 | 0 | 1b | 0 |
| APPEARED NORMAL | N | 20 | 20 | 20 | 20 |

a. Refer to the individual clinical observations table (Table 36) for external observations confirmed at necropsy.
b. Mouse 9049 was found dead on day 23 postpartum.

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MICE EXAMINED a | N | 20 | 20 | 20 | 20 |
| MORTALITY | N | 0 | 0 | 0 | 0 |
| APPEARED NORMAL | N | 20 | 19 | 20 | 20 |
| KIDNEYS: | | | | | |
| LEFT SMALL | N | 0 | 1 | 0 | 0 |

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

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MICE TESTED | N | 5 | 5 | 6 | 5 |
| INCLUDED IN ANALYSES | N | 5 | 5 | 5a | 5 |
| TERMINAL BODY WEIGHT | MEAN±S.D. | 30.9 ± 2.3 | 31.3 ± 3.4 | 30.9 ± 1.1 | 30.1 ± 2.0 |
| LIVER | MEAN±S.D. | 2.110 ± 0.140 | 2.121 ± 0.254 | 2.220 ± 0.126 | 1.930 ± 0.155 |
| LIVER (%) | MEAN±S.D. | 6.830 ± 0.341 | 6.782 ± 0.277 | 7.192 ± 0.251 | 6.412 ± 0.267* |

ALL WEIGHTS WERE RECORDED IN GRAMS (G). RATIOS (%) = (LIVER WEIGHT/TERMINAL BODY WEIGHT) X 100.

a. Excludes values for mouse 9049, which was found dead on day 23 postpartum.

* Significantly different from the control group value ($p \leq 0.05$).

PROTOCOL 20005045: 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 | 100 | 350 | 500 |
| MICE TESTED | N | 5 | 5 | 5 | 5 |
| TERMINAL BODY WEIGHT | MEAN±S.D. | 25.4 ± 1.4 | 26.1 ± 1.9 | 22.8 ± 1.2* | 25.4 ± 1.4 |
| LIVER | MEAN±S.D. | 1.536 ± 0.104 | 1.549 ± 0.168 | 1.457 ± 0.174 | 1.569 ± 0.080 |
| LIVER (%) | MEAN±S.D. | 6.056 ± 0.232 | 5.928 ± 0.239 | 6.392 ± 0.522 | 6.180 ± 0.395 |

ALL WEIGHTS WERE RECORDED IN GRAMS (G). RATIOS (%) = (LIVER WEIGHT/TERMINAL BODY WEIGHT) X 100.
* Significantly different from the control group value ($p \leq 0.05$).

PROTOCOL 20005045: 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 | CONTROL | 0 MG/KG/DAY |
|---|---|---|
| MOUSE # | DESCRIPTION | |
| 8311 | DL( 16- 19) | ABDOMINAL AREA: PURPLE |
| 8312 | DL( 18- 19) | ABDOMINAL AREA: PURPLE |
| 8313 | | NO ADVERSE FINDINGS |
| 8314 | DL( 16 ) | FOUND DEAD |
| 8315 | | NO ADVERSE FINDINGS |
| 8316 | DL( 16 ) | FOUND DEAD |
| 8317 | | NO ADVERSE FINDINGS |
| 8318 | | NO ADVERSE FINDINGS |
| 8319 | DL( 16- 19) | ABDOMINAL AREA: PURPLE |
| 8320 | | NO ADVERSE FINDINGS |
| 8321 | | NO ADVERSE FINDINGS |
| 8322 | DL( 18- 19) | ABDOMINAL AREA: PURPLE |
| 8323 | DL( 16 ) | SOFT OR LIQUID FECES |
| | DL( 17- 18) | ABDOMINAL AREA: PURPLE |
| | DL( 19 ) | DEHYDRATION - MILD |
| | DL( 19 ) | ABDOMINAL DISTENTION - SLIGHT |
| 8324 | DL( 16- 18) | ABDOMINAL AREA: PURPLE |
| | DL( 19 ) | ABDOMINAL DISTENTION - SLIGHT |
| 8325 | DL( 16- 18) | ABDOMINAL AREA: PURPLE |
| 8326 | DL( 14- 17) | ABDOMINAL AREA: PURPLE |
| 8327 | DL( 15- 16) | HYPERPNEA |
| | DL( 15- 17) | ABDOMINAL AREA: PURPLE |
| | DL( 15- 20) | ABDOMINAL DISTENTION - MODERATE |
| 8328 | DL( 14 ) | FOUND DEAD |
| 8329 | DL( 3 ) | SACRIFICED DUE TO NO SURVIVING PUPS |
| 8330 | DL( 13- 15) | ABDOMINAL AREA: PURPLE |

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE
DG = DAY OF PRESUMED GESTATION DL = DAY OF LACTATION

PROTOCOL 20005045: 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 | 100 MG/KG/DAY |
|---|---|---|---|
| MOUSE # | | DESCRIPTION | |
| 8331 | DL( 16- 19) | ABDOMINAL AREA: PURPLE | |
| | DL( 17- 20) | ABDOMINAL DISTENTION - SLIGHT | |
| | DL( 19- 20) | HYPERPNEA | |
| 8332 | DL( 18- 19) | ABDOMINAL AREA: PURPLE | |
| 8333 | DL( 16 ) | FOUND DEAD | |
| 8334 | DL( 17- 19) | ABDOMINAL AREA: PURPLE | |
| 8335 | DL( 16- 19) | ABDOMINAL AREA: PURPLE | |
| 8336 | DL( 16- 19) | ABDOMINAL AREA: PURPLE | |
| | DL( 17- 20) | ABDOMINAL DISTENTION - SLIGHT | |
| 8337 | | NO ADVERSE FINDINGS | |
| 8338 | DL( 17- 19) | ABDOMINAL AREA: PURPLE | |
| 8339 | DL( 15- 18) | ABDOMINAL AREA: PURPLE | |
| 8340 | DL( 15- 18) | ABDOMINAL AREA: PURPLE | |
| | DL( 19 ) | ABDOMINAL DISTENTION - SLIGHT | |
| 8341 | DL( 16- 18) | ABDOMINAL AREA: PURPLE | |
| 8342 | DL( 17 ) | ABDOMINAL AREA: PURPLE | |
| 8343 | DL( 13 ) | FOUND DEAD | |
| 8344 | DL( 13 ) | DECREASED MOTOR ACTIVITY | |
| | DL( 13 ) | PTOSIS | |
| | DL( 13 ) | DEHYDRATION - MILD | |
| | DL( 13 ) | BOTH EARS: PALE | |
| | DL( 13 ) | PALE EXTREMITIES - FORELIMBS, HINDLIMBS AND TAIL | |
| | DL( 13 ) | DEHYDRATION - MODERATE a | |
| | DL( 14 ) | FOUND DEAD | |
| 8345 | | NO ADVERSE FINDINGS | |
| 8346 | DL( 13 ) | FOUND DEAD | |
| 8347 | DL( 13 ) | FOUND DEAD | |
| 8348 | DL( 12 ) | SOFT OR LIQUID FECES | |
| | DL( 13 ) | FOUND DEAD | |
| 8349 | DL( 13- 15) | ABDOMINAL AREA: PURPLE | |
| 8350 | DL( 11- 12) | BOTH EARS: PALE | |
| | DL( 12- 15) | ABDOMINAL AREA: PURPLE | |

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE
DG = DAY OF PRESUMED GESTATION DL = DAY OF LACTATION
a. Observation confirmed at necropsy.

PROTOCOL 20005045: 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 | 350 MG/KG/DAY |
|---|---|---|---|
| MOUSE # | | DESCRIPTION | |
| 8351 | DL( 18- 19) | ABDOMINAL AREA: PURPLE | |
| 8352 | DL( 17- 19) | ABDOMINAL AREA: PURPLE | |
| 8353 | | NO ADVERSE FINDINGS | |
| 8354 | DG( 17 ) | EXCESS SALIVATION - SLIGHT | |
| | DL( 1 ) | SACRIFICED DUE TO NO SURVIVING PUPS | |
| 8355 | DL( 16- 18) | ABDOMINAL AREA: PURPLE | |
| 8356 | DL( 15- 18) | ABDOMINAL AREA: PURPLE | |
| 8357 | | NO ADVERSE FINDINGS | |
| 8358 | DL( 1 ) | SACRIFICED DUE TO NO SURVIVING PUPS | |
| 8359 | DL( 15- 18) | ABDOMINAL AREA: PURPLE | |
| 8360 | DL( 15- 18) | ABDOMINAL AREA: PURPLE | |
| 8361 | DG( 11- 12) | DYSPNEA | |
| | DG( 12 ) | DECREASED MOTOR ACTIVITY | |
| | DG( 12 ) | TREMORS | |
| | DG( 12 ) | PTOSIS | |
| | DG( 12 ) | DEHYDRATION - MILD | |
| | DG( 12 ) | COLD TO TOUCH | |
| | DG( 12 ) | BOTH EARS: PALE | |
| | DG( 12 ) | DEHYDRATION - MODERATE a | |
| | DG( 12 ) | RED PERIVAGINAL SUBSTANCE a | |
| | DG( 12 ) | PALE EXTREMITIES | |
| | DG( 12 ) | SCANT FECES | |
| | DG( 13 ) | FOUND DEAD | |
| 8362 | DG( 13 ) | GASPING | |
| | DG( 13 ) | RALES | |
| | DL( 16- 19) | ABDOMINAL AREA: PURPLE | |
| 8363 | | NO ADVERSE FINDINGS | |
| 8364 | | NO ADVERSE FINDINGS | |
| 8365 | DG( 18 ) | EXCESS SALIVATION - SLIGHT | |
| | DL( 14 ) | SOFT OR LIQUID FECES | |
| | DL( 15- 17) | ABDOMINAL AREA: PURPLE | |
| 8366 | DL( 13- 17) | ABDOMINAL AREA: PURPLE | |
| 8367 | DG( 8 ) | GASPING (IMMEDIATELY AFTER DOSAGE ADMINISTRATION) | |
| | DL( 14- 17) | ABDOMINAL AREA: PURPLE | |
| 8368 | DG( 15 ) | EXCESS SALIVATION - SLIGHT | |
| | DL( 16- 17) | ABDOMINAL AREA: PURPLE | |
| 8369 | DL( 13- 16) | ABDOMINAL AREA: PURPLE | |
| 8370 | DL( 12- 15) | ABDOMINAL AREA: PURPLE | |

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE
DG = DAY OF PRESUMED GESTATION DL = DAY OF LACTATION
a. Observation confirmed at necropsy.

PROTOCOL 20005045: 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 | 500 MG/KG/DAY |
|---|---|---|---|
| MOUSE # | | DESCRIPTION | |
| 8371 | DL( 16- 19) | ABDOMINAL AREA: PURPLE | |
| 8372 | | NO ADVERSE FINDINGS | |
| 8373 | DL( 17- 19) | ABDOMINAL AREA: PURPLE | |
| 8374 | DL( 16- 19) | ABDOMINAL AREA: PURPLE | |
| 8375 | DG( 14 ) | DEHYDRATION - MILD | |
| | DG( 14 ) | RED PERIVAGINAL SUBSTANCE | |
| | DG( 14- 15) | DECREASED MOTOR ACTIVITY | |
| | DG( 14- 15) | PTOSIS | |
| | DG( 14- 16) | DYSPNEA | |
| | DG( 15 ) | DRIED RED PERIVAGINAL SUBSTANCE | |
| | DG( 15 ) | SCANT FECES | |
| | DG( 15- 17) | DEHYDRATION - SLIGHT | |
| | DG( 17 ) | EXCESS SALIVATION - MODERATE | |
| | DG( 17 ) | TACHYPNEA | |
| | DG( 20- 21) | HYPERPNEA | |
| | DL( 0 ) | SACRIFICED DUE TO NO SURVIVING PUPS | |
| 8376 | DL( 18- 19) | ABDOMINAL AREA: PURPLE | |
| 8377 | DG( 12 ) | EXCESS SALIVATION - SLIGHT | |
| | DL( 18- 19) | ABDOMINAL AREA: PURPLE | |
| 8378 | DL( 0 ) | SACRIFICED DUE TO NO SURVIVING PUPS | |
| 8379 | DG( 16 ) | EXCESS SALIVATION - SLIGHT | |
| | DG( 18 ) | EXCESS SALIVATION - SLIGHT | |
| | DL( 15- 18) | ABDOMINAL AREA: PURPLE | |
| 8380 | DL( 12- 15) | ABDOMINAL AREA: PURPLE | |
| 8381 | DL( 1 ) | SACRIFICED DUE TO NO SURVIVING PUPS | |
| 8382 | DL( 13- 17) | ABDOMINAL AREA: PURPLE | |
| 8383 | DG( 15 ) | EXCESS SALIVATION - SLIGHT | |
| | DL( 0 ) | SACRIFICED DUE TO NO SURVIVING PUPS | |
| 8384 | | NO ADVERSE FINDINGS | |
| 8385 | DL( 0 ) | SACRIFICED DUE TO NO SURVIVING PUPS | |
| 8386 | DG( 8 ) | FOUND DEAD | |
| 8387 | DG( 15 ) | TACHYPNEA | |
| | DL( 13 ) | FOUND DEAD | |
| 8388 | DL( 13 ) | FOUND DEAD | |
| 8389 | DG( 15 ) | EXCESS SALIVATION - SLIGHT | |
| | DL( 1 ) | SACRIFICED DUE TO NO SURVIVING PUPS | |
| 8390 | DG( 10- 13) | DEHYDRATION - MILD | |
| | DG( 12 ) | DYSPNEA | |
| | DG( 15 ) | EXCESS SALIVATION - SLIGHT | |
| | DL( 12- 15) | ABDOMINAL AREA: PURPLE | |

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE
DG = DAY OF PRESUMED GESTATION DL = DAY OF LACTATION

PROTOCOL 20005045: 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 | | | | CONTROL | | | | 0 MG/KG/DAY | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PREGNANCY STATUS | DAY 0 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
| 8311 P | 28.4 | 30.7 | 31.4 | 32.2 | 33.4 | 35.1 | 37.8 | 39.6 | 42.7 | 44.7 | 50.3 | 55.3 | 59.7 |
| 8312 P | 28.0 | 29.0 | 29.8 | 31.6 | 32.0 | 33.2 | 35.7 | 38.0 | 39.8 | 42.5 | 46.2 | 50.2 | 54.5 |
| 8313 NP | 27.4 | 29.0 | 28.8 | 28.9 | 28.9 | 28.2 | 27.4 | 27.2 | 27.4 | 27.9 | 28.3 | 27.9 | 27.3 |
| 8314 P | 29.7 | 32.0 | 33.5 | 34.2 | 35.2 | 36.4 | 37.6 | 39.7 | 40.7 | 42.3 | 45.6 | 48.3 | 51.3 |
| 8315 P | 28.7 | 30.9 | 31.9 | 32.8 | 33.2 | 34.7 | 37.1 | 38.9 | 40.4 | 43.5 | 47.1 | 51.5 | 55.5 |
| 8316 P | 27.3 | 30.0 | 31.0 | 31.9 | 32.2 | 34.2 | 35.7 | 38.3 | 40.6 | 43.3 | 46.5 | 51.3 | 55.2 |
| 8317 P | 28.9 | 31.6 | 32.5 | 33.5 | 35.0 | 36.1 | 38.5 | 39.7 | 42.0 | 44.5 | 47.5 | 51.7 | 55.7 |
| 8318 P | 26.8 | 29.5 | 29.7 | 30.0 | 31.0 | 31.5 | 32.6 | 34.5 | 35.3 | 35.6 | 36.6 | 38.0 | 39.6 |
| 8319 P | 26.8 | 29.1 | 30.2 | 31.2 | 32.6 | 34.1 | 36.9 | 39.8 | 41.5 | 44.0 | 47.0 | 50.3 | 54.0 |
| 8320 P | 27.7 | 30.0 | 30.2 | 30.6 | 31.5 | 32.0 | 32.8 | 34.3 | 34.4 | 36.5 | 37.8 | 39.7 | 40.7 |
| 8321 P | 29.3 | 31.3 | 32.9 | 33.5 | 34.3 | 35.8 | 38.2 | 39.7 | 42.3 | 45.0 | 48.6 | 52.7 | 57.5 |
| 8322 P | 26.1 | 30.1 | 30.7 | 32.1 | 33.2 | 35.0 | 37.4 | 40.6 | 42.7 | 45.9 | 50.0 | 54.0 | 56.6 |
| 8323 P | 27.5 | 29.4 | 29.4 | 29.7 | 30.4 | 32.2 | 34.8 | 36.2 | 38.1 | 40.7 | 44.3 | 48.5 | 51.7 |
| 8324 P | 27.9 | 30.6 | 31.6 | 33.0 | 34.3 | 35.2 | 37.7 | 39.4 | 42.4 | 45.6 | 49.0 | 52.1 | 55.4 |
| 8325 P | 28.2 | 30.2 | 31.2 | 32.0 | 33.2 | 34.2 | 36.2 | 38.5 | 40.9 | 43.9 | 47.6 | 51.8 | 55.0 |
| 8326 P | 27.0 | 30.4 | 31.2 | 31.8 | 33.1 | 35.4 | 37.1 | 39.6 | 42.2 | 45.2 | 49.8 | 53.6 | 57.2 |
| 8327 P | 28.2 | 30.4 | 31.4 | 31.9 | 32.0 | 33.2 | 34.8 | 36.2 | 37.9 | 39.9 | 43.9 | 46.5 | 49.3 |
| 8328 P | 28.1 | 29.4 | 29.8 | 31.0 | 31.5 | 32.5 | 34.3 | 37.8 | 40.3 | 43.3 | 46.1 | 50.3 | 53.2 |
| 8329 P | 28.5 | 30.6 | 30.7 | 31.0 | 30.7 | 30.6 | 31.5 | 31.6 | 31.5 | 31.9 | 32.2 | 32.4 | 33.2 |
| 8330 P | 28.8 | 32.7 | 34.1 | 34.9 | 36.1 | 37.4 | 39.5 | 41.3 | 43.4 | 45.3 | 48.7 | 52.5 | 55.4 |

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)
DAY = DAY OF PRESUMED GESTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 20005045: 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 I | CONTROL | 0 MG/KG/DAY | | | |
|---|---|---|---|---|---|---|
| PREGNANCY STATUS | DAY 18 | 19 | 20 | 21 | 22 | 23 |
| 8311 P | 63.1 | | | | | |
| 8312 P | 58.4 | | | | | |
| 8313 NP | 27.3 | 27.1 | 27.6 | 26.7 | 27.4 | 29.0 |
| 8314 P | 54.5 | | | | | |
| 8315 P | 58.8 | | | | | |
| 8316 P | 58.8 | | | | | |
| 8317 P | 58.1 | | | | | |
| 8318 P | 40.7 | | | | | |
| 8319 P | 56.6 | | | | | |
| 8320 P | 42.4 | | | | | |
| 8321 P | 61.7 | 65.2 | 63.6 | | | |
| 8322 P | | | | | | |
| 8323 P | 55.0 | | | | | |
| 8324 P | 59.5 | | | | | |
| 8325 P | 58.6 | | | | | |
| 8326 P | 60.6 | | | | | |
| 8327 P | 52.8 | | | | | |
| 8328 P | 55.6 | | | | | |
| 8329 P | 33.5 | | | | | |
| 8330 P | 58.5 | | | | | |

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)
DAY = DAY OF PRESUMED GESTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 20005045: 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 II | | | LOW DOSAGE | | | | 100 MG/KG/DAY | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PREGNANCY STATUS DAY | 0 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
| 8331 P | 26.6 | 30.5 | 31.3 | 32.6 | 33.7 | 35.6 | 37.8 | 39.1 | 41.5 | 45.1 | 49.0 | 51.9 | 56.4 |
| 8332 P | 27.2 | 29.5 | 30.4 | 30.7 | 31.3 | 32.3 | 34.5 | 36.5 | 38.7 | 41.1 | 44.0 | 47.4 | 51.0 |
| 8333 P | 26.9 | 28.8 | 29.6 | 30.5 | 31.4 | 32.8 | 34.8 | 36.8 | 38.0 | 40.7 | 44.4 | 48.4 | 52.3 |
| 8334 P | 28.6 | 31.1 | 32.5 | 34.6 | 35.2 | 36.8 | 38.1 | 40.5 | 41.4 | 44.5 | 47.9 | 50.8 | 54.2 |
| 8335 P | 27.5 | 30.1 | 31.5 | 32.7 | 32.5 | 34.4 | 35.7 | 38.4 | 40.0 | 43.1 | 47.1 | 50.8 | 55.3 |
| 8336 P | 28.8 | 31.1 | 31.8 | 33.2 | 33.8 | 35.2 | 37.1 | 39.1 | 41.9 | 44.2 | 48.0 | 52.4 | 56.9 |
| 8337 P | 27.4 | 30.3 | 30.6 | 31.7 | 33.2 | 34.6 | 36.3 | 38.6 | 39.3 | 42.0 | 44.6 | 47.8 | 50.7 |
| 8338 P | 28.4 | 30.2 | 31.0 | 31.2 | 31.5 | 32.7 | 35.4 | 36.7 | 39.3 | 41.8 | 45.6 | 49.7 | 51.9 |
| 8339 P | 27.8 | 30.0 | 30.3 | 30.9 | 31.4 | 33.2 | 35.5 | 37.5 | 38.9 | 42.0 | 45.3 | 49.1 | 52.1 |
| 8340 P | 29.0 | 32.0 | 33.1 | 33.7 | 34.8 | 36.1 | 37.7 | 39.5 | 40.5 | 43.8 | 46.7 | 50.3 | 54.5 |
| 8341 P | 26.5 | 28.6 | 29.2 | 29.3 | 29.7 | 30.6 | 32.8 | 34.7 | 36.9 | 39.1 | 42.5 | 46.2 | 49.1 |
| 8342 P | 28.2 | 30.7 | 31.2 | 32.5 | 33.4 | 34.2 | 37.4 | 39.2 | 41.0 | 43.5 | 47.2 | 51.5 | 55.3 |
| 8343 P | 28.3 | 29.6 | 29.8 | 29.9 | 30.7 | 31.5 | 33.5 | 35.6 | 37.7 | 40.1 | 43.2 | 45.9 | 48.8 |
| 8344 P | 28.0 | 30.7 | 31.4 | 32.4 | 32.8 | 34.8 | 36.8 | 39.5 | 41.9 | 44.1 | 48.4 | 52.2 | 54.8 |
| 8345 NP | 27.7 | 29.2 | 29.5 | 29.3 | 29.0 | 28.6 | 28.1 | 28.8 | 29.9 | 30.1 | 30.2 | 29.7 | 29.4 |
| 8346 P | 28.8 | 31.9 | 32.6 | 32.8 | 33.2 | 35.4 | 37.3 | 40.2 | 42.2 | 45.0 | 49.9 | 53.7 | 57.3 |
| 8347 P | 28.1 | 32.3 | 33.3 | 34.6 | 36.1 | 37.9 | 40.3 | 43.7 | 46.7 | 50.0 | 53.5 | 59.0 | 63.6 |
| 8348 P | 30.0 | 32.3 | 32.7 | 33.0 | 34.0 | 35.8 | 37.9 | 39.9 | 42.6 | 45.9 | 49.9 | 53.6 | 57.8 |
| 8349 P | 29.6 | 32.7 | 33.2 | 34.9 | 35.7 | 36.8 | 38.8 | 41.4 | 44.4 | 46.2 | 50.0 | 53.1 | 57.8 |
| 8350 P | 26.8 | 30.3 | 30.5 | 31.4 | 31.8 | 32.9 | 35.4 | 37.1 | 39.6 | 42.2 | 44.8 | 49.1 | 51.9 |

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)
DAY = DAY OF PRESUMED GESTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 20005045: 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 II | LOW DOSAGE | 100 MG/KG/DAY | | | |
|---|---|---|---|---|---|---|
| PREGNANCY STATUS | DAY 18 | 19 | 20 | 21 | 22 | 23 |
| 8331 P | 59.0 | | | | | |
| 8332 P | 54.6 | | | | | |
| 8333 P | 55.6 | | | | | |
| 8334 P | 57.7 | | | | | |
| 8335 P | 59.0 | | | | | |
| 8336 P | 60.3 | | | | | |
| 8337 P | | | | | | |
| 8338 P | 54.5 | | | | | |
| 8339 P | 54.7 | | | | | |
| 8340 P | 56.7 | | | | | |
| 8341 P | 51.4 | | | | | |
| 8342 P | 59.7 | | | | | |
| 8343 P | 51.0 | | | | | |
| 8344 P | 58.7 | | | | | |
| 8345 NP | 30.4 | 29.5 | 30.5 | 30.4 | 29.9 | 31.2 |
| 8346 P | 60.3 | | | | | |
| 8347 P | 67.5 | | | | | |
| 8348 P | 61.0 | | | | | |
| 8349 P | 60.3 | | | | | |
| 8350 P | 55.5 | | | | | |

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)
DAY = DAY OF PRESUMED GESTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 20005045: 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 5): MATERNAL BODY WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

| MOUSE # | DOSAGE GROUP III | | | MIDDLE DOSAGE | | | | 350 MG/KG/DAY | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PREGNANCY STATUS DAY | 0 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
| 8351 P | 27.9 | 31.4 | 32.2 | 33.3 | 34.6 | 36.7 | 39.8 | 42.6 | 44.9 | 49.0 | 53.9 | 58.9 | 63.5 |
| 8352 P | 26.9 | 30.8 | 31.6 | 32.7 | 33.4 | 35.1 | 36.2 | 37.6 | 39.2 | 41.8 | 45.7 | 48.6 | 51.8 |
| 8353 P | 26.7 | 29.1 | 30.0 | 30.8 | 32.6 | 34.0 | 36.5 | 39.1 | 41.4 | 45.0 | 49.4 | 53.8 | 57.8 |
| 8354 P | 29.5 | 32.4 | 32.9 | 33.7 | 35.5 | 37.6 | 41.0 | 44.2 | 46.8 | 50.4 | 56.1 | 60.5 | 62.8 |
| 8355 P | 27.0 | 29.3 | 30.0 | 30.8 | 32.1 | 33.0 | 35.4 | 38.2 | 39.8 | 42.2 | 45.8 | 48.9 | 52.9 |
| 8356 P | 28.2 | 30.3 | 31.6 | 33.1 | 33.9 | 32.6 | 35.3 | 37.7 | 38.6 | 42.4 | 45.0 | 47.5 | 51.3 |
| 8357 P | 27.5 | 30.0 | 30.8 | 31.9 | 32.7 | 33.5 | 35.3 | 37.5 | 37.0 | 39.2 | 41.8 | 44.9 | 46.9 |
| 8358 P | 28.6 | 29.7 | 30.6 | 31.0 | 32.8 | 33.7 | 35.8 | 38.1 | 39.5 | 42.3 | 44.9 | 48.1 | 51.0 |
| 8359 P | 28.6 | 31.3 | 31.8 | 32.2 | 33.5 | 35.3 | 37.9 | 39.8 | 42.6 | 45.4 | 48.0 | 51.3 | 54.8 |
| 8360 P | 27.6 | 29.7 | 30.6 | 31.2 | 32.3 | 34.1 | 37.1 | 37.9 | 39.6 | 43.5 | 47.9 | 50.8 | 53.5 |
| 8361 P | 28.5 | 33.7 | 34.2 | 35.7 | 37.8 | 39.1 | 36.5 | 34.7 | FOUND DEAD ON DAY 13 OF GESTATION | | | | |
| 8362 P | 28.1 | 30.1 | 30.9 | 31.0 | 32.0 | 33.4 | 36.0 | 37.4 | 40.0 | 42.6 | 47.2 | 49.6 | 51.1 |
| 8363 P | 26.3 | 27.1 | 27.2 | 27.7 | 27.6 | 27.6 | 28.1 | 28.6 | 30.7 | 29.7 | 30.6 | 32.1 | 33.9 |
| 8364 P | 27.5 | 30.1 | 30.8 | 27.9 | 29.8 | 31.1 | 33.6 | 36.1 | 38.5 | 41.8 | 45.7 | 49.5 | 52.9 |
| 8365 P | 27.8 | 31.2 | 32.0 | 30.4 | 31.4 | 33.4 | 35.2 | 37.9 | 40.3 | 43.2 | 46.0 | 49.3 | 52.4 |
| 8366 P | 28.2 | 31.3 | 32.1 | 32.9 | 32.9 | 34.7 | 37.0 | 39.2 | 41.3 | 43.8 | 46.2 | 49.5 | 53.2 |
| 8367 P | 29.7 | 31.1 | 32.1 | 33.1 | 31.2 | 31.9 | 33.0 | 34.5 | 36.3 | 39.3 | 40.9 | 44.7 | 47.6 |
| 8368 P | 27.2 | 29.7 | 30.7 | 31.4 | 32.8 | 34.8 | 36.2 | 38.8 | 41.6 | 44.4 | 47.2 | 51.3 | 54.0 |
| 8369 P | 28.8 | 30.9 | 31.5 | 31.4 | 33.1 | 34.8 | 36.3 | 39.1 | 42.5 | 45.1 | 49.1 | 53.4 | 56.7 |
| 8370 P | 29.3 | 31.3 | 32.1 | 32.7 | 33.3 | 34.6 | 37.0 | 39.8 | 42.3 | 45.3 | 49.6 | 53.2 | 57.6 |

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)
DAY = DAY OF PRESUMED GESTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 20005045: 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 6): MATERNAL BODY WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

| MOUSE # | DOSAGE GROUP III | MIDDLE DOSAGE | 350 MG/KG/DAY |
|---|---|---|---|

| MOUSE # | PREGNANCY STATUS | DAY 18 | 19 | 20 | 21 | 22 | 23 |
|---|---|---|---|---|---|---|---|
| 8351 | P | | | | | | |
| 8352 | P | 53.3 | | | | | |
| 8353 | P | | | | | | |
| 8354 | P | 64.6 | | | | | |
| 8355 | P | 55.0 | | | | | |
| 8356 | P | 53.3 | | | | | |
| 8357 | P | 48.8 | | | | | |
| 8358 | P | | | | | | |
| 8359 | P | 56.4 | | | | | |
| 8360 | P | 56.1 | | | | | |
| 8361 | P | FOUND DEAD ON DAY 13 OF GESTATION | | | | | |
| 8362 | P | | | | | | |
| 8363 | P | 34.9 | 35.3 | 36.2 | | | |
| 8364 | P | 56.5 | | | | | |
| 8365 | P | 54.8 | | | | | |
| 8366 | P | 56.2 | | | | | |
| 8367 | P | 46.0 | | | | | |
| 8368 | P | 57.3 | | | | | |
| 8369 | P | 59.6 | | | | | |
| 8370 | P | 60.7 | | | | | |

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)
DAY = DAY OF PRESUMED GESTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 20005045: 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 7): MATERNAL BODY WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

| MOUSE # | DOSAGE GROUP IV | | | HIGH DOSAGE | | | | 500 MG/KG/DAY | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PREGNANCY STATUS | DAY 0 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
| 8371 P | 26.7 | 29.6 | 31.0 | 31.4 | 32.8 | 34.2 | 36.0 | 39.6 | 41.8 | 43.9 | 47.5 | 50.6 | 55.1 |
| 8372 NP | 27.4 | 29.5 | 29.8 | 30.2 | 29.5 | 29.5 | 29.7 | 29.5 | 29.1 | 29.3 | 28.7 | 29.7 | 30.4 |
| 8373 P | 26.2 | 29.9 | 30.8 | 31.3 | 33.4 | 35.9 | 38.3 | 41.6 | 44.8 | 47.8 | 51.4 | 55.8 | 54.4 |
| 8374 P | 27.1 | 29.6 | 29.8 | 30.3 | 31.3 | 34.1 | 36.0 | 37.8 | 39.5 | 41.6 | 44.7 | 48.7 | 51.3 |
| 8375 P | 27.8 | 29.7 | 30.6 | 31.2 | 32.3 | 34.2 | 35.8 | 37.3 | 35.8 | 31.7 | 29.1 | 32.0 | 35.9 |
| 8376 P | 27.0 | 28.3 | 29.4 | 30.5 | 28.9 | 31.0 | 33.3 | 35.8 | 37.7 | 40.8 | 44.3 | 47.5 | 50.7 |
| 8377 P | 27.9 | 30.9 | 30.7 | 31.8 | 33.0 | 34.8 | 36.3 | 38.0 | 38.7 | 41.3 | 44.5 | 45.8 | 49.4 |
| 8378 P | 28.3 | 31.1 | 31.7 | 32.5 | 33.6 | 34.1 | 35.8 | 37.8 | 40.4 | 43.0 | 46.6 | 50.7 | 48.4 |
| 8379 P | 28.2 | 30.8 | 31.4 | 32.4 | 34.7 | 35.5 | 39.1 | 43.0 | 46.4 | 50.1 | 54.6 | 58.3 | 62.2 |
| 8380 P | 27.9 | 30.6 | 30.8 | 31.9 | 31.1 | 32.1 | 33.1 | 35.1 | 36.6 | 38.5 | 40.3 | 42.1 | 44.4 |
| 8381 P | 28.2 | 31.3 | 31.3 | 31.9 | 32.8 | 33.7 | 35.7 | 37.9 | 40.3 | 43.5 | 46.9 | 50.4 | 55.0 |
| 8382 P | 29.6 | 31.3 | 32.4 | 32.9 | 33.4 | 35.6 | 37.2 | 40.5 | 42.3 | 46.5 | 50.4 | 54.2 | 56.2 |
| 8383 P | 28.8 | 32.0 | 32.9 | 33.7 | 34.6 | 36.6 | 38.7 | 41.9 | 44.8 | 48.2 | 52.5 | 51.5 | 53.8 |
| 8384 NP | 27.6 | 27.7 | 28.2 | 28.4 | 28.4 | 29.0 | 29.1 | 29.7 | 29.5 | 30.4 | 29.3 | 29.5 | 29.5 |
| 8385 P | 28.5 | 29.8 | 30.7 | 31.4 | 32.2 | 34.6 | 35.6 | 39.0 | 40.7 | 44.1 | 48.2 | 52.7 | 56.1 |
| 8386 P | 28.9 | 33.0 | 31.4 | FOUND DEAD ON DAY 8 OF GESTATION | | | | | | | | | |
| 8387 P | 28.7 | 32.2 | 31.1 | 32.0 | 35.0 | 35.9 | 39.5 | 42.6 | 45.3 | 47.2 | 48.0 | 54.6 | 57.0 |
| 8388 P | 26.8 | 29.2 | 30.1 | 30.7 | 31.4 | 33.5 | 35.0 | 37.3 | 39.4 | 42.5 | 46.2 | 49.6 | 52.8 |
| 8389 P | 30.0 | 34.0 | 34.8 | 36.0 | 36.3 | 39.4 | 42.0 | 45.2 | 46.6 | 49.8 | 54.1 | 54.5 | 53.5 |
| 8390 P | 28.0 | 29.8 | 31.0 | 32.4 | 33.1 | 27.9 | 33.2 | 36.9 | 39.0 | 43.3 | 46.4 | 50.8 | 54.5 |

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)
DAY = DAY OF PRESUMED GESTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 20005045: 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 8): MATERNAL BODY WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

| MOUSE # | DOSAGE GROUP IV | HIGH DOSAGE | 500 MG/KG/DAY | | | |
|---|---|---|---|---|---|---|
| PREGNANCY STATUS | DAY 18 | 19 | 20 | 21 | 22 | 23 |
| 8371 P | 58.5 | | | | | |
| 8372 NP | 30.7 | 29.5 | 29.5 | 28.3 | 29.1 | 29.0 |
| 8373 P | 58.2 | | | | | |
| 8374 P | 52.5 | | | | | |
| 8375 P | 35.4 | 32.9 | 36.1 | 33.3 | | |
| 8376 P | | | | | | |
| 8377 P | | | | | | |
| 8378 P | 42.6 | | | | | |
| 8379 P | 65.9 | | | | | |
| 8380 P | 47.0 | 48.8 | 50.4 | | | |
| 8381 P | 52.8 | | | | | |
| 8382 P | 58.3 | | | | | |
| 8383 P | 58.6 | 58.7 | 58.3 | | | |
| 8384 NP | 29.4 | 28.9 | 29.5 | 29.3 | 29.1 | 31.2 |
| 8385 P | 59.4 | | | | | |
| 8386 P | FOUND DEAD ON DAY 8 OF GESTATION | | | | | |
| 8387 P | 58.8 | | | | | |
| 8388 P | 54.6 | | | | | |
| 8389 P | 59.6 | | | | | |
| 8390 P | 57.3 | 61.7 | | | | |

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)
DAY = DAY OF PRESUMED GESTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 20005045: 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

| DAY | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE # | DOSAGE GROUP I | | | | CONTROL | | | | 0 MG/KG/DAY | | | | |
| 8311 | 35.8 | 37.4 | 38.8 | 42.2 | 41.8 | 42.7 | 40.8 | 44.7 | 48.9 | 45.7 | 45.6 | 44.6 | 49.6 |
| 8312 | 33.1 | 33.8 | 37.0 | 38.3 | 39.8 | 39.3 | 39.1 | 42.4 | 46.8 | 46.6 | 45.4 | 45.2 | 47.1 |
| 8313 | NOT PREGNANT | | | | | | | | | | | | |
| 8314 | 34.4 | 37.0 | 38.2 | 40.9 | 40.6 | 42.4 | 43.1 | 43.0 | 49.2 | 47.8 | 48.6 | 45.7 | 49.5 |
| 8315 | 34.2 | 34.9 | 34.8 | 37.5 | 38.2 | 40.6 | 39.4 | 42.8 | 43.1 | 43.9 | 45.2 | 41.3 | 47.2 |
| 8316 | 33.8 | 35.2 | 36.3 | 37.4 | 40.7 | 39.8 | 41.0 | 41.1 | 44.8 | 43.4 | 46.1 | 44.6 | 48.1 |
| 8317 | 35.4 | 37.9 | 38.7 | 41.3 | 42.3 | 42.3 | 41.8 | 44.8 | 49.4 | 47.9 | 48.2 | 47.8 | 51.7 |
| 8318 | 31.6 | 30.8 | 30.5 | 33.0 | 34.1 | 34.8 | 33.8 | 34.7 | 37.6 | 36.1 | 36.1 | 37.0 | 39.1 |
| 8319 | 35.3 | 35.3 | 37.5 | 39.5 | 42.0 | 42.8 | 45.8 | 46.0 | 48.8 | 48.9 | 48.5 | 48.0 | 51.8 |
| 8320 | 30.4 | 31.9 | 32.5 | 32.6 | 33.7 | 34.0 | 34.3 | 34.9 | 38.5 | 38.0 | 37.3 | 36.3 | 38.9 |
| 8321 | 36.5 | 35.6 | 36.9 | 36.8 | 37.0 | 38.1 | 40.8 | 41.8 | 41.4 | 41.7 | 44.4 | 46.7 | 43.3 |
| 8322 | 34.4 | 35.6 | 37.3 | 37.7 | 40.3 | 42.4 | 42.5 | 43.3 | 43.8 | 49.4 | 48.4 | 49.2 | 48.6 |
| 8323 | 32.5 | 33.8 | 36.1 | 37.3 | 38.9 | 41.1 | 41.8 | 45.0 | 43.3 | 45.1 | 41.7 | 47.4 | 47.4 |
| 8324 | 36.0 | 37.6 | 39.7 | 42.4 | 44.7 | 43.5 | 46.7 | 49.4 | 49.1 | 47.8 | 47.8 | 50.7 | 52.4 |
| 8325 | 34.6 | 36.6 | 39.5 | 40.0 | 40.2 | 41.7 | 42.0 | 46.6 | 45.8 | 45.0 | 45.0 | 48.8 | 49.0 |
| 8326 | 35.5 | 39.7 | 42.4 | 41.6 | 42.5 | 44.2 | 47.6 | 46.7 | 48.1 | 44.5 | 50.0 | 52.0 | 46.9 |
| 8327 | 31.4 | 34.8 | 35.8 | 37.5 | 36.5 | 39.9 | 43.3 | 41.8 | 41.9 | 41.3 | 44.9 | 44.9 | 45.2 |
| 8328 | 32.9 | 35.6 | 37.8 | 38.1 | 37.3 | 39.7 | 43.7 | 42.0 | 42.5 | 42.1 | 45.3 | 47.0 | 42.8 |
| 8329 | 31.4 | 30.0 | 29.3 | 29.3 | SACRIFICED ON DAY 3 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | | |
| 8330 | 35.9 | 36.7 | 37.2 | 39.7 | 45.0 | 42.9 | 42.4 | 43.4 | 45.4 | 47.9 | 43.8 | 47.1 | 47.7 |

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

PROTOCOL 20005045: 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

| | DAY 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
|---|---|---|---|---|---|---|---|---|
| MOUSE # | DOSAGE GROUP I | | | | CONTROL | | | 0 MG/KG/DAY |
| 8311 | 51.8 | 48.7 | 49.2 | 50.3 | 50.5 | 48.7 | 48.8 | 47.7 |
| 8312 | 50.2 | 45.8 | 49.2 | 46.1 | 46.8 | 44.9 | 44.3 | 43.5 |
| 8313 | NOT PREGNANT | | | | | | | |
| 8314 | 50.9 | 48.9 | 51.4 | FOUND DEAD ON DAY 16 OF LACTATION | | | | |
| 8315 | 45.9 | 41.3 | 47.1 | 45.2 | 43.1 | 44.9 | 42.7 | 44.0 |
| 8316 | 48.7 | 47.0 | 49.5 | FOUND DEAD ON DAY 16 OF LACTATION | | | | |
| 8317 | 52.0 | 46.9 | 50.4 | 48.9 | 48.1 | 48.7 | 43.5 | 44.0 |
| 8318 | 39.3 | 38.4 | 38.2 | 38.4 | 37.8 | 39.1 | 37.2 | 39.9 |
| 8319 | 52.9 | 50.4 | 51.5 | 49.4 | 49.3 | 48.8 | 45.0 | 47.1 |
| 8320 | 39.9 | 39.2 | 37.9 | 38.1 | 38.3 | 38.2 | 34.0 | 34.8 |
| 8321 | 46.0 | 44.6 | 43.0 | 44.5 | 40.6 | 41.1 | 43.3 | 44.1 |
| 8322 | 50.1 | 51.7 | 48.3 | 48.6 | 48.6 | 47.5 | 47.6 | 42.6 |
| 8323 | 43.3 | 47.0 | 44.2 | 47.2 | 48.6 | 42.2 | 40.9 | 40.2 |
| 8324 | 47.2 | 51.4 | 45.1 | 51.4 | 50.0 | 43.0 | 40.3 | 37.9 |
| 8325 | 44.3 | 46.6 | 46.1 | 43.6 | 45.5 | 42.6 | 42.9 | 42.3 |
| 8326 | 48.5 | 51.4 | 50.9 | 53.6 | 50.3 | 52.3 | 51.3 | 46.4 |
| 8327 | 43.7 | 35.4 | 45.4 | 44.4 | 44.7 | 42.6 | 42.7 | 40.9 |
| 8328 | 46.8 | FOUND DEAD ON DAY 14 OF LACTATION | | | | | | |
| 8329 | SACRIFICED ON DAY 3 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | |
| 8330 | 45.7 | 47.4 | 45.3 | 48.9 | 50.2 | 47.2 | 49.6 | 47.3 |

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

PROTOCOL 20005045: 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

| DAY | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE # | DOSAGE GROUP II | | | | LOW DOSAGE | | | | 100 MG/KG/DAY | | | | |
| 8331 | 34.7 | 37.7 | 38.4 | 41.7 | 42.3 | 42.5 | 42.7 | 44.4 | 47.0 | 49.1 | 49.1 | 47.9 | 51.6 |
| 8332 | 31.4 | 32.9 | 33.6 | 36.0 | 36.6 | 36.3 | 37.6 | 38.1 | 41.7 | 40.3 | 40.3 | 37.8 | 42.6 |
| 8333 | 33.8 | 35.4 | 36.4 | 38.6 | 40.5 | 39.5 | 41.5 | 41.1 | 43.5 | 43.2 | 42.9 | 43.5 | 45.4 |
| 8334 | 33.7 | 35.5 | 37.2 | 38.3 | 38.6 | 40.1 | 41.2 | 41.9 | 46.6 | 45.2 | 44.8 | 44.1 | 49.7 |
| 8335 | 35.1 | 36.5 | 36.5 | 41.1 | 41.6 | 42.7 | 40.8 | 42.8 | 46.1 | 46.3 | 45.4 | 44.5 | 48.2 |
| 8336 | 37.5 | 37.4 | 37.3 | 40.4 | 41.2 | 43.9 | 43.6 | 46.3 | 49.7 | 47.9 | 46.5 | 44.2 | 51.2 |
| 8337 | 35.1 | 34.4 | 35.5 | 35.2 | 36.6 | 38.6 | 38.5 | 39.7 | 40.8 | 43.2 | 42.6 | 43.6 | 42.3 |
| 8338 | 34.7 | 36.9 | 37.3 | 41.3 | 41.4 | 42.0 | 43.0 | 45.6 | 50.2 | 47.5 | 48.0 | 44.8 | 51.5 |
| 8339 | 33.9 | 34.2 | 37.5 | 38.1 | 38.8 | 38.1 | 41.5 | 44.9 | 43.7 | 44.0 | 44.1 | 49.4 | 49.7 |
| 8340 | 36.1 | 36.1 | 40.5 | 41.2 | 40.6 | 43.0 | 45.4 | 46.6 | 47.6 | 47.7 | 47.3 | 49.4 | 52.7 |
| 8341 | 31.5 | 32.1 | 35.1 | 36.2 | 36.3 | 36.8 | 39.6 | 42.1 | 42.0 | 43.2 | 41.8 | 44.7 | 41.2 |
| 8342 | 35.4 | 36.6 | 39.5 | 41.8 | 42.7 | 44.7 | 46.2 | 49.7 | 48.6 | 48.5 | 46.3 | 50.4 | 53.2 |
| 8343 | 32.1 | 34.5 | 37.3 | 35.3 | 35.1 | 38.3 | 40.9 | 38.0 | 41.0 | 39.0 | 40.7 | 43.2 | 39.8 |
| 8344 | 33.5 | 36.4 | 38.1 | 39.7 | 40.4 | 40.7 | 46.7 | 45.0 | 45.6 | 44.3 | 47.0 | 49.9 | 45.9 |
| 8345 | NOT PREGNANT | | | | | | | | | | | | |
| 8346 | 38.0 | 39.1 | 39.9 | 43.2 | 40.6 | 43.8 | 47.7 | 45.5 | 46.2 | 47.7 | 49.0 | 51.4 | 44.3 |
| 8347 | 37.8 | 39.4 | 42.1 | 43.1 | 45.3 | 45.9 | 51.5 | 49.4 | 50.1 | 49.5 | 53.6 | 54.9 | 51.0 |
| 8348 | 36.2 | 38.1 | 39.8 | 39.9 | 41.4 | 41.5 | 45.7 | 44.8 | 44.7 | 44.4 | 50.0 | 50.4 | 41.7 |
| 8349 | 38.6 | 40.8 | 41.4 | 42.2 | 45.7 | 49.9 | 48.9 | 50.0 | 47.7 | 53.9 | 55.0 | 51.6 | 54.5 |
| 8350 | 34.8 | 34.8 | 34.8 | 37.1 | 40.2 | 39.8 | 41.8 | 42.0 | 43.0 | 45.9 | 44.0 | 45.5 | 45.2 |

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

PROTOCOL 20005045: 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

| | DAY 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
|---|---|---|---|---|---|---|---|---|
| MOUSE # | DOSAGE GROUP II | | | | LOW DOSAGE | | | 100 MG/KG/DAY |
| 8331 | 49.0 | 46.4 | 50.4 | 46.0 | 47.4 | 47.5 | 44.4 | 45.9 |
| 8332 | 42.7 | 39.1 | 43.3 | 40.5 | 40.4 | 40.8 | 38.0 | 37.8 |
| 8333 | 46.7 | 43.9 | 43.3 | FOUND DEAD ON DAY 16 OF LACTATION | | | | |
| 8334 | 49.8 | 47.5 | 49.7 | 48.7 | 48.9 | 46.7 | 43.9 | 44.7 |
| 8335 | 48.8 | 46.0 | 47.4 | 45.6 | 47.0 | 46.5 | 41.3 | 43.2 |
| 8336 | 51.0 | 48.2 | 50.5 | 45.9 | 45.1 | 46.6 | 44.9 | 43.7 |
| 8337 | 44.4 | 45.1 | 43.7 | 46.6 | 46.2 | 46.0 | 44.5 | 41.3 |
| 8338 | 53.0 | 47.6 | 50.6 | 48.2 | 48.7 | 48.6 | 43.2 | 42.5 |
| 8339 | 48.8 | 48.3 | 46.8 | 47.3 | 47.4 | 43.8 | 40.7 | 40.7 |
| 8340 | 47.0 | 49.7 | 49.0 | 49.0 | 51.8 | 47.1 | 45.8 | 44.7 |
| 8341 | 43.2 | 44.5 | 45.1 | 44.1 | 43.9 | 41.6 | 41.6 | 39.4 |
| 8342 | 52.1 | 53.6 | 49.7 | 53.7 | 52.2 | 49.6 | 48.0 | 45.8 |
| 8343 | FOUND DEAD ON DAY 13 OF LACTATION | | | | | | | |
| 8344 | 40.5 | FOUND DEAD ON DAY 14 OF LACTATION | | | | | | |
| 8345 | NOT PREGNANT | | | | | | | |
| 8346 | FOUND DEAD ON DAY 13 OF LACTATION | | | | | | | |
| 8347 | FOUND DEAD ON DAY 13 OF LACTATION | | | | | | | |
| 8348 | FOUND DEAD ON DAY 13 OF LACTATION | | | | | | | |
| 8349 | 52.2 | 53.0 | 54.9 | 51.3 | 51.0 | 53.0 | 49.3 | 47.7 |
| 8350 | 47.7 | 48.7 | 45.1 | 44.9 | 49.2 | 48.4 | 49.8 | 45.7 |

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

PROTOCOL 20005045: 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

| DAY | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE # | DOSAGE GROUP III | | | | MIDDLE DOSAGE | | | | 350 MG/KG/DAY | | | | |
| 8351 | 36.3 | 37.5 | 39.4 | 41.0 | 44.8 | 43.6 | 43.7 | 43.2 | 47.1 | 51.0 | 50.7 | 51.3 | 50.4 |
| 8352 | 34.4 | 38.0 | 38.0 | 39.9 | 38.9 | 40.7 | 41.6 | 44.0 | 47.4 | 45.3 | 43.6 | 41.9 | 45.5 |
| 8353 | 39.2 | 33.5 | 34.0 | 36.7 | 37.4 | 37.4 | 37.0 | 38.8 | 40.3 | 44.3 | 42.7 | 42.6 | 41.0 |
| 8354 | 37.8 | 36.2 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | | | | |
| 8355 | 33.0 | 35.1 | 36.0 | 36.3 | 36.7 | 37.2 | 38.5 | 42.4 | 42.2 | 42.5 | 43.4 | 44.2 | 46.4 |
| 8356 | 32.4 | 36.2 | 36.6 | 39.1 | 37.3 | 39.4 | 40.0 | 44.1 | 44.3 | 45.5 | 44.5 | 49.8 | 50.2 |
| 8357 | 31.7 | 31.2 | 35.9 | 36.1 | 35.1 | 34.8 | 38.3 | 40.1 | 38.9 | 39.1 | 38.8 | 41.2 | 42.5 |
| 8358 | 36.3 | 34.3 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | | | | |
| 8359 | 32.6 | 35.0 | 36.9 | 38.3 | 39.2 | 39.3 | 41.4 | 45.0 | 42.6 | 44.2 | 42.9 | 46.0 | 47.1 |
| 8360 | 31.6 | 34.7 | 35.7 | 37.9 | 37.5 | 35.5 | 40.3 | 41.1 | 42.7 | 44.8 | 42.5 | 47.1 | 46.4 |
| 8361 | FOUND DEAD ON DAY 13 OF GESTATION | | | | | | | | | | | | |
| 8362 | 32.9 | 32.6 | 34.2 | 36.2 | 39.7 | 37.6 | 38.6 | 40.4 | 44.9 | 42.5 | 43.0 | 43.9 | 45.9 |
| 8363 | 31.1 | 29.3 | 28.5 | 28.3 | 29.9 | 32.9 | 32.2 | 32.1 | 32.5 | 33.9 | 33.9 | 33.1 | 33.7 |
| 8364 | 34.4 | 35.2 | 37.2 | 35.6 | 37.2 | 36.8 | 38.0 | 42.7 | 41.0 | 42.7 | 43.4 | 47.0 | 46.6 |
| 8365 | 36.4 | 37.1 | 37.4 | 38.6 | 38.7 | 38.7 | 43.2 | 43.0 | 42.4 | 42.0 | 46.6 | 47.2 | 45.6 |
| 8366 | 34.8 | 37.0 | 39.0 | 38.0 | 39.9 | 40.1 | 44.9 | 42.5 | 44.1 | 45.2 | 48.1 | 48.0 | 48.1 |
| 8367 | 27.9 | 31.9 | 35.2 | 34.3 | 32.4 | 36.6 | 39.5 | 40.0 | 41.7 | 38.5 | 43.6 | 46.1 | 43.5 |
| 8368 | 34.3 | 36.4 | 39.2 | 38.0 | 37.5 | 40.0 | 44.5 | 43.5 | 43.1 | 42.5 | 44.9 | 47.7 | 45.4 |
| 8369 | 39.4 | 38.0 | 38.4 | 38.6 | 41.0 | 42.3 | 44.3 | 45.5 | 43.8 | 48.6 | 48.0 | 46.6 | 42.6 |
| 8370 | 38.5 | 36.2 | 39.4 | 39.4 | 41.7 | 41.9 | 42.4 | 42.8 | 45.2 | 46.8 | 44.7 | 46.1 | 45.9 |

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

PROTOCOL 20005045: 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

| | DAY 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
|---|---|---|---|---|---|---|---|---|
| MOUSE # | DOSAGE GROUP III | | | | MIDDLE DOSAGE | | | 350 MG/KG/DAY |
| 8351 | 55.1 | 52.2 | 50.6 | 52.3 | 52.0 | 51.1 | 53.3 | 52.6 |
| 8352 | 49.4 | 44.6 | 45.5 | 45.2 | 47.2 | 45.8 | 46.1 | 44.4 |
| 8353 | 45.5 | 46.7 | 45.7 | 47.3 | 45.1 | 47.1 | 45.7 | 44.2 |
| 8354 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | |
| 8355 | 44.5 | 47.2 | 45.5 | 44.2 | 43.4 | 44.3 | 42.9 | 40.7 |
| 8356 | 47.1 | 48.5 | 51.0 | 50.0 | 53.2 | 50.2 | 46.4 | 46.5 |
| 8357 | 40.9 | 42.6 | 42.0 | 41.8 | 41.6 | 37.2 | 35.1 | 37.5 |
| 8358 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | |
| 8359 | 43.8 | 44.8 | 44.0 | 44.7 | 47.0 | 44.8 | 44.3 | 44.1 |
| 8360 | 44.4 | 47.2 | 45.1 | 46.1 | 46.8 | 44.0 | 44.3 | 42.7 |
| 8361 | FOUND DEAD ON DAY 13 OF GESTATION | | | | | | | |
| 8362 | 46.6 | 44.0 | 47.5 | 45.0 | 44.7 | 48.2 | 43.3 | 44.0 |
| 8363 | 33.5 | 33.7 | 33.7 | 32.5 | 33.9 | 35.0 | 35.7 | 36.3 |
| 8364 | 42.3 | 45.7 | 46.4 | 47.2 | 49.3 | 49.8 | 47.6 | 51.9 |
| 8365 | 48.1 | 42.6 | 46.3 | 48.1 | 46.8 | 42.9 | 39.9 | 39.5 |
| 8366 | 45.4 | 47.6 | 48.8 | 50.6 | 47.6 | 43.5 | 40.7 | 38.9 |
| 8367 | 43.1 | 45.5 | 45.5 | 48.2 | 47.0 | 46.2 | 47.4 | 47.1 |
| 8368 | 44.6 | 43.6 | 45.4 | 46.1 | 42.9 | 42.0 | 43.5 | 41.4 |
| 8369 | 46.3 | 46.9 | 50.1 | 49.1 | 49.5 | 49.5 | 47.9 | 46.2 |
| 8370 | 44.1 | 51.1 | 49.7 | 51.2 | 50.5 | 54.4 | 49.9 | 46.3 |

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

PROTOCOL 20005045: 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

| DAY | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE # | DOSAGE GROUP IV | | | | HIGH DOSAGE | | | | 500 MG/KG/DAY | | | | |
| 8371 | 34.5 | 33.9 | 33.3 | 36.4 | 36.1 | 34.8 | 34.7 | 36.9 | 39.6 | 39.8 | 41.1 | 41.1 | 43.8 |
| 8372 | NOT PREGNANT | | | | | | | | | | | | |
| 8373 | 39.4 | 39.2 | 39.0 | 38.7 | 41.1 | 41.1 | 41.5 | 44.7 | 47.6 | 47.1 | 48.5 | 45.3 | 49.5 |
| 8374 | 33.2 | 34.7 | 36.1 | 37.0 | 38.2 | 37.6 | 38.2 | 38.9 | 42.4 | 42.1 | 44.4 | 42.6 | 47.1 |
| 8375 | 28.9 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | | | | | |
| 8376 | 33.5 | 33.0 | 34.6 | 34.6 | 38.1 | 39.3 | 39.0 | 38.6 | 41.8 | 46.1 | 43.7 | 44.8 | 42.7 |
| 8377 | 32.5 | 33.4 | 36.5 | 35.5 | 37.3 | 37.0 | 38.1 | 37.7 | 42.6 | 40.7 | 40.4 | 41.1 | 44.3 |
| 8378 | 30.0 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | | | | | |
| 8379 | 37.5 | 39.4 | 42.6 | 42.6 | 42.1 | 44.0 | 46.5 | 47.2 | 48.0 | 48.5 | 47.9 | 51.5 | 49.6 |
| 8380 | 35.6 | 34.6 | 36.0 | 37.1 | 40.0 | 39.1 | 40.1 | 41.5 | 42.9 | 44.5 | 42.5 | 44.7 | 43.7 |
| 8381 | 34.2 | 34.2 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | | | | |
| 8382 | 36.9 | 39.9 | 39.3 | 39.4 | 40.1 | 39.8 | 44.4 | 43.2 | 43.9 | 44.4 | 46.7 | 47.7 | 48.1 |
| 8383 | 38.9 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | | | | | |
| 8384 | NOT PREGNANT | | | | | | | | | | | | |
| 8385 | 38.9 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | | | | | |
| 8386 | FOUND DEAD ON DAY 8 OF GESTATION | | | | | | | | | | | | |
| 8387 | 36.7 | 36.4 | 37.2 | 37.3 | 37.4 | 39.4 | 44.1 | 41.9 | 45.0 | 44.6 | 46.2 | 48.7 | 42.4 |
| 8388 | 35.1 | 35.4 | 35.8 | 35.4 | 34.2 | 36.7 | 39.4 | 39.7 | 39.6 | 39.4 | 43.2 | 45.5 | 40.1 |
| 8389 | 37.4 | 37.9 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | | | | |
| 8390 | 36.7 | 33.8 | 34.8 | 35.3 | 38.3 | 37.6 | 39.5 | 39.3 | 41.2 | 42.2 | 42.7 | 43.7 | 44.9 |

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

PROTOCOL 20005045: 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

| | DAY 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
|---|---|---|---|---|---|---|---|---|
| MOUSE # | DOSAGE GROUP IV | | | | HIGH DOSAGE | | | 500 MG/KG/DAY |
| 8371 | 44.7 | 42.2 | 42.5 | 43.0 | 43.6 | 45.8 | 42.6 | 44.2 |
| 8372 | NOT PREGNANT | | | | | | | |
| 8373 | 47.7 | 48.7 | 47.6 | 47.2 | 47.9 | 46.3 | 41.4 | 38.7 |
| 8374 | 45.4 | 44.7 | 46.8 | 44.8 | 43.5 | 46.2 | 43.0 | 43.9 |
| 8375 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | |
| 8376 | 45.8 | 47.5 | 46.3 | 44.9 | 46.9 | 45.1 | 44.2 | 37.3 |
| 8377 | 45.0 | 42.8 | 41.7 | 42.7 | 42.8 | 43.0 | 38.9 | 36.6 |
| 8378 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | |
| 8379 | 48.1 | 50.0 | 52.1 | 53.0 | 52.1 | 48.2 | 44.5 | 42.3 |
| 8380 | 45.3 | 45.8 | 44.7 | 43.0 | 42.9 | 37.7 | 38.6 | 40.7 |
| 8381 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | |
| 8382 | 50.7 | 48.2 | 49.1 | 48.4 | 50.1 | 50.0 | 50.7 | 48.1 |
| 8383 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | |
| 8384 | NOT PREGNANT | | | | | | | |
| 8385 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | |
| 8386 | FOUND DEAD ON DAY 8 OF GESTATION | | | | | | | |
| 8387 | FOUND DEAD ON DAY 13 OF LACTATION | | | | | | | |
| 8388 | FOUND DEAD ON DAY 13 OF LACTATION | | | | | | | |
| 8389 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS | | | | | | | |
| 8390 | 44.7 | 45.9 | 44.3 | 46.0 | 46.6 | 45.5 | 41.5 | 38.1 |

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

PROTOCOL 20005045: 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 CONTROL 0 MG/KG/DAY

| MOUSE/ LITTER NUMBER | DURATION OF GESTATION (DAYS) N | LITTER DELIVERED LIVE BORN N | STILL-BORN N | TOTAL BORN N | NUMBER OF LIVE PUPS AT COMPLETION OF DAY POSTPARTUM 0 M | 0 F | 4 M | 4 F | 7 M | 7 F | 14 M | 14 F | 20 M | 20 F | TOTAL IMPLAN-TATIONS N |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 8311 | 20 | 16 | 0 | 16 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 16 |
| 8312 | 20 | 15 | 0 | 15 | 6 | 9 | 6 | 8 | 6 | 8 | 6 | 8 | 6 | 8 | 15 |
| 8313 | NOT PREGNANT | | | | | | | | | | | | | | |
| 8314a | 20 | 11 | 0 | 11 | 6 | 5 | 6 | 5 | 6 | 5 | 6 | 5 | 6 | 5 | 13 |
| 8315 | 20 | 13 | 0 | 13 | 12 | 1 | 12 | 1 | 12 | 1 | 12 | 1 | 12 | 1 | 14 |
| 8316a | 20 | 14 | 0 | 14 | 6 | 8 | 6 | 8 | 6 | 8 | 6 | 8 | 6 | 8 | 15 |
| 8317 | 20 | 11 | 1 | 12 | 5 | 6 | 5 | 6 | 5 | 6 | 5 | 6 | 5 | 6 | 15 |
| 8318 | 20 | 4 | 0 | 4 | 1 | 3 | 1 | 3 | 1 | 3 | 1 | 3 | 1 | 3 | 5 |
| 8319 | 20 | 13 | 0 | 13 | 5 | 8 | 5 | 8 | 5 | 8 | 5 | 8 | 5 | 8 | 13 |
| 8320 | 20 | 5 | 0 | 5 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 5 |
| 8321 | 22 | 4 | 3 | 7 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 16 |
| 8322 | 19 | 14 | 0 | 14 | 5 | 9 | 5 | 9 | 5 | 9 | 5 | 9 | 5 | 9 | 14 |
| 8323 | 20 | 16 | 0 | 16 | 9 | 7 | 9 | 7 | 9 | 7 | 9 | 7 | 9 | 7 | 16 |
| 8324 | 19 | 12 | 0 | 12 | 7 | 5 | 7 | 5 | 7 | 5 | 7 | 5 | 7 | 5 | 15 |
| 8325 | 20 | 14 | 0 | 14 | 6 | 8 | 6 | 8 | 6 | 8 | 6 | 8 | 6 | 8 | 15 |
| 8326 | 19 | 15 | 0 | 15 | 10 | 5 | 10 | 5 | 10 | 5 | 10 | 5 | 10 | 5 | 15 |
| 8327 | 20 | 12 | 0 | 12 | 7 | 5 | 7 | 5 | 7 | 5 | 7 | 5 | 7 | 5 | 12 |
| 8328b | 20 | 13 | 0 | 13 | 6 | 7 | 6 | 7 | 5 | 7 | 5 | 7 | 5 | 7 | 14 |
| 8329 | 20 | 1 | 0 | 1 | - | 1 | - | - | - | - | - | - | - | - | 1 |
| 8330 | 20 | 14 | 0 | 14 | 4 | 10 | 4 | 10 | 4 | 10 | 4 | 10 | 4 | 10 | 16 |

M = MALE F = FEMALE

a. Mouse was found dead on day 16 of lactation; pups remained on study to day 20 postpartum.

b. Mouse was found dead on day 14 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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 | | | 100 MG/KG/DAY | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | DURATION OF | LITTER DELIVERED | | | NUMBER OF LIVE PUPS AT COMPLETION OF DAY POSTPARTUM | | | | | | | | | | TOTAL |
| MOUSE/ | GESTATION | LIVE | STILL- | TOTAL | 0 | | 4 | | 7 | | 14 | | 20 | | IMPLAN- |
| LITTER | (DAYS) | BORN | BORN | BORN | | | | | | | | | | | TATIONS |
| NUMBER | N | N | N | N | M | F | M | F | M | F | M | F | M | F | N |
| 8331 | 20 | 15 | 0 | 15 | 8 | 7 | 8 | 7 | 8 | 7 | 8 | 7 | 8 | 6 | 17 |
| 8332 | 20 | 13 | 0 | 13 | 7 | 6 | 7 | 5 | 7 | 5 | 7 | 5 | 7 | 5 | 14 |
| 8333a | 20 | 14 | 0 | 14 | 6 | 8 | 6 | 8 | 6 | 8 | 6 | 8 | 6 | 8 | 17 |
| 8334 | 20 | 12 | 0 | 12 | 8 | 4 | 8 | 4 | 8 | 4 | 8 | 3 | 8 | 3 | 14 |
| 8335 | 20 | 13 | 0 | 13 | 7 | 6 | 7 | 6 | 7 | 6 | 7 | 6 | 7 | 6 | 13 |
| 8336 | 20 | 12 | 0 | 12 | 7 | 5 | 7 | 4 | 7 | 4 | 7 | 4 | 7 | 4 | 12 |
| 8337 | 19 | 10 | 0 | 10 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 12 |
| 8338 | 20 | 13 | 0 | 13 | 6 | 7 | 6 | 7 | 6 | 7 | 6 | 7 | 6 | 7 | 14 |
| 8339 | 20 | 14 | 0 | 14 | 7 | 7 | 7 | 6 | 7 | 6 | 7 | 6 | 7 | 6 | 16 |
| 8340 | 20 | 12 | 0 | 12 | 5 | 7 | 5 | 7 | 5 | 7 | 5 | 7 | 5 | 7 | 14 |
| 8341 | 20 | 13 | 0 | 13 | 7 | 6 | 7 | 6 | 7 | 6 | 7 | 6 | 7 | 5 | 13 |
| 8342 | 20 | 12 | 0 | 12 | 4 | 8 | 4 | 8 | 4 | 8 | 4 | 8 | 4 | 8 | 14 |
| 8343b | 20 | 11 | 0 | 11 | 5 | 6 | 5 | 6 | 5 | 6 | 5 | 6 | 5 | 6 | 14 |
| 8344c | 20 | 15 | 0 | 15 | 3 | 12 | 3 | 12 | 2 | 12 | 2 | 12 | 2 | 9 | 16 |
| 8345 | NOT PREGNANT | | | | | | | | | | | | | | |
| 8346b | 20 | 13 | 0 | 13 | 5 | 8 | 5 | 8 | 5 | 8 | 4 | 8 | 3 | 3 | 14 |
| 8347b | 20 | 17 | 0 | 17 | 9 | 8 | 9 | 8 | 9 | 8 | 8 | 8 | 2 | 2 | 17 |
| 8348b | 20 | 15 | 0 | 15 | 9 | 6 | 9 | 6 | 9 | 6 | 9 | 6 | 6 | 2 | 18 |
| 8349 | 20 | 12 | 0 | 12 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 13 |
| 8350 | 20 | 14 | 0 | 14 | 8 | 6 | 8 | 6 | 8 | 6 | 8 | 6 | 8 | 6 | 14 |

M = MALE F = FEMALE

a. Mouse was found dead on day 16 of lactation; pups remained on study to day 20 postpartum.

b. Mouse was found dead on day 13 of lactation; pups remained on study to day 20 postpartum.

c. Mouse was found dead on day 14 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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 350 MG/KG/DAY

| MOUSE/ LITTER NUMBER | DURATION OF GESTATION (DAYS) N | LITTER DELIVERED LIVE BORN N | STILL-BORN N | TOTAL BORN N | NUMBER OF LIVE PUPS AT COMPLETION OF DAY POSTPARTUM 0 M | 0 F | 4 M | 4 F | 7 M | 7 F | 14 M | 14 F | 20 M | 20 F | TOTAL IMPLANTATIONS N |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 8351 | 19 | 18 | 0 | 18 | 11 | 7 | 11 | 7 | 11 | 7 | 11 | 7 | 11 | 7 | 18 |
| 8352 | 20 | 11 | 0 | 11 | 7 | 4 | 7 | 4 | 7 | 4 | 7 | 4 | 7 | 4 | 13 |
| 8353 | 19 | 15 | 1 | 16 | 7 | 8 | 7 | 8 | 7 | 7 | 6 | 7 | 6 | 7 | 16 |
| 8354 | 20 | 13(2) | 0 | 19[6] | 7 | 4 | - | - | - | - | - | - | - | - | 19 |
| 8355 | 20 | 14 | 0 | 14 | 8 | 6 | 8 | 6 | 7 | 6 | 6 | 6 | 6 | 6 | 15 |
| 8356 | 20 | 11 | 0 | 12[1] | 6 | 5 | 6 | 5 | 6 | 5 | 6 | 5 | 6 | 5 | 14 |
| 8357 | 20 | 9(1) | 1 | 10 | 5 | 3 | 5 | 3 | 5 | 3 | 5 | 3 | 5 | 3 | 12 |
| 8358 | 19 | 10 | 1 | 11 | 5 | 5 | - | - | - | - | - | - | - | - | 12 |
| 8359 | 20 | 16 | 0 | 16 | 7 | 9 | 7 | 9 | 7 | 9 | 7 | 8 | 7 | 8 | 17 |
| 8360 | 20 | 13 | 1 | 14 | 5 | 8 | 5 | 8 | 5 | 7 | 5 | 7 | 5 | 7 | 15 |
| 8361 | FOUND DEAD ON DAY 13 OF GESTATION | | | | | | | | | | | | | | |
| 8362 | 19 | 14 | 0 | 15[1] | 10 | 4 | 10 | 4 | 10 | 4 | 10 | 4 | 10 | 4 | 15 |
| 8363 | 22 | 2 | 0 | 2 | 2 | - | 2 | - | 2 | - | 2 | - | 2 | - | 2 |
| 8364 | 20 | 14 | 0 | 14 | 11 | 3 | 9 | 3 | 9 | 3 | 9 | 3 | 9 | 3 | 15 |
| 8365 | 20 | 8 | 0 | 8 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 10 |
| 8366 | 20 | 13 | 0 | 13 | 5 | 8 | 5 | 8 | 5 | 8 | 5 | 8 | 5 | 8 | 14 |
| 8367 | 20 | 12 | 0 | 12 | 7 | 5 | 7 | 4 | 7 | 4 | 7 | 4 | 7 | 4 | 13 |
| 8368 | 20 | 13 | 0 | 13 | 7 | 6 | 7 | 6 | 7 | 6 | 7 | 6 | 7 | 6 | 15 |
| 8369 | 20 | 12 | 0 | 12 | 5 | 7 | 5 | 6 | 5 | 6 | 5 | 6 | 5 | 6 | 14 |
| 8370 | 20 | 14 | 1 | 15 | 4 | 10 | 4 | 10 | 4 | 10 | 4 | 10 | 4 | 10 | 17 |

M = MALE F = FEMALE
( ) = NUMBER OF PUPS DYING PRIOR TO WEIGHING ON DAY 0 POSTPARTUM.
[ ] = NUMBER OF PUPS IN WHICH CANNIBALIZATION AND/OR AUTOLYSIS PRECLUDED THE DETERMINATION OF VIABILITY.

PROTOCOL 20005045: 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 500 MG/KG/DAY

| MOUSE/ LITTER NUMBER | DURATION OF GESTATION (DAYS) N | LITTER DELIVERED LIVE BORN N | STILL-BORN N | TOTAL BORN N | NUMBER OF LIVE PUPS AT COMPLETION OF DAY POSTPARTUM 0 M | 0 F | 4 M | 4 F | 7 M | 7 F | 14 M | 14 F | 20 M | 20 F | TOTAL IMPLANTATIONS N |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 8371 | 20 | 12 | 0 | 12 | 5 | 7 | 4 | 6 | 4 | 6 | 4 | 6 | 4 | 6 | 14 |
| 8372 | NOT PREGNANT | | | | | | | | | | | | | | |
| 8373 | 20 | 11 | 0 | 11 | 7 | 4 | 6 | 4 | 6 | 4 | 6 | 4 | 6 | 4 | 15 |
| 8374 | 20 | 10 | 0 | 10 | 4 | 6 | 4 | 6 | 4 | 6 | 4 | 6 | 4 | 6 | 11 |
| 8375 | 23 | 0 | 3 | 3 | - | - | - | - | - | - | - | - | - | - | 15 |
| 8376 | 19 | 12 | 0 | 12 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 14 |
| 8377 | 19 | 11 | 0 | 11 | 5 | 6 | 5 | 6 | 5 | 6 | 5 | 6 | 5 | 6 | 12 |
| 8378 | 20 | 1(1) | 9 | 10 | - | - | - | - | - | - | - | - | - | - | 16 |
| 8379 | 19 | 14(1) | 0 | 14 | 6 | 7 | 6 | 7 | 6 | 7 | 6 | 7 | 6 | 7 | 17 |
| 8380 | 22 | 7 | 0 | 7 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | 7 |
| 8381 | 20 | 11(2) | 1 | 12 | 3 | 6 | - | - | - | - | - | - | - | - | 14 |
| 8382 | 20 | 12 | 0 | 12 | 3 | 9 | 3 | 9 | 3 | 9 | 3 | 9 | 3 | 9 | 14 |
| 8383 | 22 | 6(6) | 2 | 8 | - | - | - | - | - | - | - | - | - | - | 15 |
| 8384 | NOT PREGNANT | | | | | | | | | | | | | | |
| 8385 | 20 | 6(6) | 1 | 14[7] | - | - | - | - | - | - | - | - | - | - | 15 |
| 8386 | FOUND DEAD ON DAY 8 OF GESTATION | | | | | | | | | | | | | | |
| 8387a | 20 | 14(4) | 0 | 14 | 4 | 6 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 18 |
| 8388a | 20 | 10(1) | 1 | 11 | 5 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 14 |
| 8389 | 19 | 2 | 0 | 6[4] | 1 | 1 | - | - | - | - | - | - | - | - | 14 |
| 8390 | 20 | 11 | 2 | 13 | 7 | 4 | 6 | 3 | 6 | 3 | 6 | 3 | 6 | 3 | 14 |

M = MALE F = FEMALE
( ) = NUMBER OF PUPS DYING PRIOR TO WEIGHING ON DAY 0 POSTPARTUM.
[ ] = NUMBER OF PUPS IN WHICH CANNIBALIZATION AND/OR AUTOLYSIS PRECLUDED THE DETERMINATION OF VIABILITY.
a. Mouse was found dead on day 13 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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

DOSAGE GROUP I CONTROL 0 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 |
| 8311 | 1.5 | 1.3 | 1.4 | 2.6 | 2.5 | 2.6 | 3.6 | 3.4 | 3.5 | 5.7 | 5.4 | 5.5 | 7.3 | 6.7 | 7.0 |
| 8312 | 1.6 | 1.4 | 1.5 | 2.7 | 2.4 | 2.5 | 3.7 | 3.4 | 3.5 | 6.4 | 6.0 | 6.2 | 9.4 | 9.0 | 9.2 |
| 8313 | NOT PREGNANT | | | | | | | | | | | | | | |
| 8314a | 1.6 | 1.7 | 1.6 | 3.4 | 3.2 | 3.3 | 4.9 | 5.0 | 4.9 | 8.3 | 8.5 | 8.4 | 11.9 | 11.8 | 11.9 |
| 8315 | 1.6 | 1.6 | 1.6 | 2.8 | 2.9 | 2.8 | 4.0 | 3.9 | 4.0 | 6.8 | 6.8 | 6.8 | 10.5 | 10.2 | 10.5 |
| 8316a | 1.5 | 1.5 | 1.5 | 2.9 | 2.7 | 2.8 | 4.1 | 3.8 | 3.9 | 6.9 | 6.4 | 6.6 | 9.8 | 9.1 | 9.4 |
| 8317 | 1.6 | 1.7 | 1.6 | 3.2 | 3.0 | 3.1 | 4.7 | 4.6 | 4.6 | 7.7 | 7.8 | 7.7 | 11.6 | 11.6 | 11.6 |
| 8318 | 1.9 | 2.0 | 2.0 | 3.8 | 3.7 | 3.7 | 5.6 | 5.8 | 5.8 | 11.1 | 11.1 | 11.1 | 16.8 | 16.8 | 16.8 |
| 8319 | 1.6 | 1.6 | 1.6 | 2.9 | 2.9 | 2.9 | 4.2 | 4.3 | 4.3 | 7.1 | 7.0 | 7.0 | 10.2 | 10.5 | 10.4 |
| 8320 | 1.8 | 1.8 | 1.8 | 4.0 | 3.9 | 4.0 | 6.4 | 6.3 | 6.3 | 11.8 | 11.7 | 11.7 | 17.8 | 16.8 | 17.2 |
| 8321 | 1.6 | 1.8 | 1.7 | 3.6 | 3.8 | 3.7 | 5.4 | 5.7 | 5.6 | 10.6 | 11.2 | 10.9 | 16.5 | 16.6 | 16.5 |
| 8322 | 1.5 | 1.5 | 1.5 | 2.5 | 2.5 | 2.5 | 4.0 | 3.9 | 3.9 | 6.6 | 6.4 | 6.5 | 10.0 | 9.7 | 9.8 |
| 8323 | 1.4 | 1.3 | 1.4 | 2.5 | 2.6 | 2.6 | 3.9 | 3.7 | 3.8 | 6.2 | 5.8 | 6.0 | 8.8 | 8.7 | 8.8 |
| 8324 | 1.6 | 1.6 | 1.6 | 3.3 | 3.4 | 3.3 | 5.2 | 5.2 | 5.2 | 8.1 | 8.1 | 8.1 | 12.7 | 12.5 | 12.6 |
| 8325 | 1.5 | 1.4 | 1.5 | 2.8 | 2.7 | 2.7 | 4.0 | 3.9 | 4.0 | 6.5 | 6.2 | 6.3 | 8.8 | 8.6 | 8.7 |
| 8326 | 1.6 | 1.5 | 1.6 | 2.9 | 2.9 | 2.9 | 4.4 | 4.1 | 4.3 | 6.7 | 6.5 | 6.6 | 9.8 | 9.8 | 9.8 |
| 8327 | 1.6 | 1.6 | 1.6 | 2.6 | 2.5 | 2.6 | 3.9 | 3.8 | 3.8 | 5.9 | 5.9 | 5.9 | 8.6 | 8.7 | 8.6 |
| 8328b | 1.5 | 1.5 | 1.5 | 2.8 | 2.8 | 2.8 | 4.0 | 3.9 | 4.0 | 6.3 | 6.4 | 6.3 | 8.3 | 8.5 | 8.4 |
| 8329 | --- | 1.9 | 1.9 | NO SURVIVING PUPS ON DAY 3 POSTPARTUM | | | | | | | | | | | |
| 8330 | 1.6 | 1.5 | 1.5 | 2.8 | 2.5 | 2.6 | 4.0 | 3.7 | 3.8 | 6.6 | 6.2 | 6.3 | 10.5 | 9.7 | 9.9 |

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.
a. Mouse was found dead on day 16 of lactation; pups remained on study to day 20 postpartum.
b. Mouse was found dead on day 14 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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

DOSAGE GROUP II LOW DOSAGE 100 MG/KG/DAY

| MOUSE/ LITTER | DAY 0 | | | DAY 4 | | | DAY 7 | | | DAY 14 | | | DAY 20 | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| NUMBER | M | F | T | M | F | T | M | F | T | M | F | T | M | F | T |
| 8331 | 1.5 | 1.3 | 1.4 | 2.8 | 2.6 | 2.7 | 4.2 | 3.7 | 4.0 | 6.4 | 5.6 | 6.1 | 9.7 | 8.4 | 9.2 |
| 8332 | 1.6 | 1.5 | 1.5 | 3.1 | 3.0 | 3.0 | 4.4 | 4.5 | 4.5 | 7.0 | 6.9 | 7.0 | 10.6 | 10.5 | 10.6 |
| 8333a | 1.4 | 1.3 | 1.3 | 2.8 | 2.8 | 2.8 | 3.9 | 4.0 | 4.0 | 6.2 | 6.4 | 6.3 | 8.0 | 8.4 | 8.2 |
| 8334 | 1.4 | 1.5 | 1.4 | 2.8 | 2.8 | 2.8 | 4.1 | 4.1 | 4.1 | 7.4 | 7.3 | 7.4 | 10.5 | 10.6 | 10.5 |
| 8335 | 1.5 | 1.3 | 1.4 | 3.1 | 2.9 | 3.0 | 4.6 | 4.2 | 4.4 | 7.6 | 7.1 | 7.3 | 11.8 | 10.5 | 11.2 |
| 8336 | 1.7 | 1.5 | 1.6 | 3.3 | 3.2 | 3.3 | 4.8 | 4.6 | 4.7 | 7.6 | 7.4 | 7.6 | 11.7 | 11.4 | 11.6 |
| 8337 | 1.5 | 1.5 | 1.5 | 2.9 | 3.0 | 2.9 | 4.6 | 4.6 | 4.6 | 7.5 | 7.5 | 7.5 | 10.7 | 11.2 | 11.0 |
| 8338 | 1.4 | 1.4 | 1.4 | 3.1 | 2.9 | 3.0 | 4.5 | 4.3 | 4.4 | 8.4 | 7.9 | 8.2 | 12.4 | 11.8 | 12.1 |
| 8339 | 1.4 | 1.3 | 1.3 | 2.7 | 2.4 | 2.6 | 3.9 | 3.6 | 3.7 | 6.8 | 6.4 | 6.6 | 9.8 | 9.4 | 9.6 |
| 8340 | 1.6 | 1.5 | 1.6 | 3.0 | 2.9 | 2.9 | 4.5 | 4.3 | 4.4 | 6.7 | 7.0 | 6.9 | 9.7 | 10.3 | 10.1 |
| 8341 | 1.4 | 1.3 | 1.4 | 2.5 | 2.4 | 2.5 | 3.6 | 3.4 | 3.5 | 6.0 | 5.7 | 5.9 | 8.7 | 7.9 | 8.4 |
| 8342 | 1.6 | 1.6 | 1.6 | 2.9 | 2.8 | 2.9 | 4.0 | 3.7 | 3.8 | 6.8 | 6.8 | 6.8 | 9.8 | 9.9 | 9.8 |
| 8343b | 1.5 | 1.6 | 1.5 | 2.5 | 2.6 | 2.5 | 4.0 | 3.9 | 4.0 | 5.3 | 5.1 | 5.2 | 7.7 | 7.1 | 7.4 |
| 8344c | 1.4 | 1.4 | 1.4 | 2.3 | 2.7 | 2.6 | 3.6 | 3.8 | 3.8 | 4.8 | 4.9 | 4.9 | 7.4 | 6.8 | 6.9 |
| 8345 | NOT PREGNANT | | | | | | | | | | | | | | |
| 8346b | 1.7 | 1.6 | 1.6 | 2.8 | 2.8 | 2.8 | 4.1 | 4.1 | 4.1 | 4.8 | 4.8 | 4.8 | 5.3 | 6.0 | 5.6 |
| 8347b | 1.5 | 1.5 | 1.5 | 2.4 | 2.3 | 2.4 | 3.3 | 3.2 | 3.2 | 4.3 | 4.2 | 4.2 | 6.4 | 5.4 | 5.9 |
| 8348b | 1.5 | 1.4 | 1.5 | 2.7 | 2.6 | 2.7 | 4.0 | 3.8 | 4.0 | 4.6 | 4.5 | 4.6 | 7.0 | 7.4 | 7.1 |
| 8349 | 1.6 | 1.6 | 1.6 | 3.1 | 2.9 | 3.0 | 4.8 | 4.4 | 4.6 | 7.4 | 7.2 | 7.2 | 10.6 | 10.4 | 10.4 |
| 8350 | 1.4 | 1.3 | 1.4 | 2.4 | 2.4 | 2.4 | 3.8 | 3.6 | 3.7 | 6.1 | 5.7 | 6.0 | 7.6 | 7.2 | 7.4 |

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.
a. Mouse was found dead on day 16 of lactation; pups remained on study to day 20 postpartum.
b. Mouse was found dead on day 13 of lactation; pups remained on study to day 20 postpartum.
c. Mouse was found dead on day 14 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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 3): PUP BODY WEIGHT LITTER AVERAGES FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION LITTERS

DOSAGE GROUP III MIDDLE DOSAGE 350 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 |
| 8351 | 1.3 | 1.3 | 1.3 | 2.2 | 2.1 | 2.2 | 3.3 | 3.2 | 3.3 | 5.4 | 5.0 | 5.3 | 7.1 | 6.3 | 6.8 |
| 8352 | 1.5 | 1.4 | 1.5 | 1.9 | 1.9 | 1.9 | 3.0 | 3.0 | 3.0 | 6.8 | 6.4 | 6.6 | 9.0 | 9.6 | 9.3 |
| 8353 | 1.1 | 1.1 | 1.1 | 1.7 | 1.7 | 1.7 | 2.3 | 2.5 | 2.4 | 5.1 | 5.0 | 5.0 | 6.4 | 6.2 | 6.3 |
| 8354 | 1.2 | 1.2 | 1.2 | NO SURVIVING PUPS ON DAY 1 POSTPARTUM | | | | | | | | | | | |
| 8355 | 1.3 | 1.2 | 1.2 | 1.7 | 1.9 | 1.8 | 2.8 | 3.1 | 3.0 | 6.1 | 6.6 | 6.3 | 7.4 | 8.0 | 7.7 |
| 8356 | 1.5 | 1.4 | 1.4 | 2.4 | 2.4 | 2.4 | 4.0 | 3.9 | 4.0 | 7.1 | 7.0 | 7.0 | 10.4 | 10.3 | 10.4 |
| 8357 | 1.4 | 1.3 | 1.4 | 2.5 | 2.4 | 2.4 | 4.3 | 4.0 | 4.2 | 8.4 | 8.1 | 8.3 | 7.0 | 8.9 | 7.7 |
| 8358 | 1.3 | 1.3 | 1.3 | NO SURVIVING PUPS ON DAY 1 POSTPARTUM | | | | | | | | | | | |
| 8359 | 1.2 | 1.2 | 1.2 | 2.0 | 2.0 | 2.0 | 3.0 | 2.9 | 3.0 | 5.2 | 5.6 | 5.4 | 5.8 | 6.6 | 6.2 |
| 8360 | 1.4 | 1.4 | 1.4 | 1.6 | 1.7 | 1.6 | 2.7 | 2.6 | 2.6 | 5.9 | 5.8 | 5.8 | 7.9 | 7.9 | 7.9 |
| 8361 | FOUND DEAD ON DAY 13 OF GESTATION | | | | | | | | | | | | | | |
| 8362 | 1.0 | 1.0 | 1.0 | 1.9 | 1.7 | 1.8 | 3.0 | 2.7 | 2.9 | 5.7 | 5.6 | 5.7 | 7.8 | 7.4 | 7.6 |
| 8363 | 2.2 | --- | 2.2 | 4.0 | --- | 4.0 | 5.8 | --- | 5.8 | 10.0 | --- | 10.0 | 16.4 | --- | 16.4 |
| 8364 | 1.4 | 1.3 | 1.4 | 1.3 | 1.3 | 1.3 | 2.0 | 2.3 | 2.1 | 5.4 | 5.9 | 5.6 | 7.2 | 8.1 | 7.4 |
| 8365 | 1.6 | 1.5 | 1.5 | 3.4 | 3.3 | 3.3 | 5.2 | 5.2 | 5.2 | 8.8 | 8.6 | 8.7 | 14.6 | 13.6 | 14.1 |
| 8366 | 1.5 | 1.4 | 1.4 | 2.9 | 2.6 | 2.7 | 4.2 | 4.0 | 4.1 | 6.2 | 5.9 | 6.0 | 9.2 | 8.7 | 8.9 |
| 8367 | 1.2 | 1.1 | 1.1 | 2.0 | 2.0 | 2.0 | 3.2 | 3.4 | 3.3 | 5.6 | 5.4 | 5.5 | 7.3 | 6.7 | 7.1 |
| 8368 | 1.5 | 1.5 | 1.5 | 2.3 | 2.3 | 2.3 | 3.6 | 3.7 | 3.7 | 6.2 | 6.4 | 6.3 | 8.4 | 8.8 | 8.6 |
| 8369 | 1.5 | 1.4 | 1.4 | 2.4 | 2.6 | 2.5 | 4.2 | 4.1 | 4.2 | 6.2 | 6.0 | 6.0 | 9.6 | 9.4 | 9.5 |
| 8370 | 1.4 | 1.4 | 1.4 | 2.4 | 2.2 | 2.2 | 3.8 | 3.6 | 3.6 | 6.1 | 5.7 | 5.8 | 8.0 | 7.9 | 7.9 |

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 20005045: 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

DOSAGE GROUP IV HIGH DOSAGE 500 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 |
| 8371 | 1.4 | 1.4 | 1.4 | 1.6 | 1.5 | 1.6 | 2.3 | 2.4 | 2.3 | 5.6 | 6.2 | 6.0 | 7.7 | 8.6 | 8.3 |
| 8372 | NOT PREGNANT | | | | | | | | | | | | | | |
| 8373 | 1.4 | 1.4 | 1.4 | 2.3 | 2.1 | 2.2 | 3.8 | 3.6 | 3.7 | 7.8 | 7.6 | 7.7 | 11.1 | 10.7 | 10.9 |
| 8374 | 1.4 | 1.4 | 1.4 | 2.8 | 2.8 | 2.8 | 4.3 | 4.3 | 4.3 | 7.8 | 8.0 | 7.9 | 11.2 | 11.3 | 11.3 |
| 8375 | NO SURVIVING PUPS ON DAY 0 POSTPARTUM | | | | | | | | | | | | | | |
| 8376 | 1.3 | 1.3 | 1.3 | 2.3 | 2.2 | 2.2 | 3.8 | 3.8 | 3.8 | 7.0 | 6.8 | 6.9 | 10.0 | 10.0 | 10.0 |
| 8377 | 1.1 | 1.1 | 1.1 | 2.2 | 2.1 | 2.1 | 5.8 | 3.7 | 4.6 | 6.9 | 6.8 | 6.9 | 10.1 | 9.4 | 9.7 |
| 8378 | NO SURVIVING PUPS ON DAY 0 POSTPARTUM | | | | | | | | | | | | | | |
| 8379 | 1.5 | 1.4 | 1.4 | 2.4 | 2.5 | 2.5 | 3.7 | 3.7 | 3.7 | 6.3 | 6.4 | 6.3 | 8.9 | 8.8 | 8.9 |
| 8380 | 1.9 | 1.9 | 1.9 | 3.6 | 3.4 | 3.5 | 5.6 | 5.5 | 5.5 | 8.9 | 8.9 | 8.9 | 13.9 | 13.4 | 13.7 |
| 8381 | 1.4 | 1.3 | 1.3 | NO SURVIVING PUPS ON DAY 1 POSTPARTUM | | | | | | | | | | | |
| 8382 | 1.3 | 1.3 | 1.3 | 2.2 | 2.2 | 2.2 | 3.5 | 3.6 | 3.6 | 5.1 | 5.5 | 5.4 | 6.5 | 6.9 | 6.8 |
| 8383 | NO SURVIVING PUPS ON DAY 0 POSTPARTUM | | | | | | | | | | | | | | |
| 8384 | NOT PREGNANT | | | | | | | | | | | | | | |
| 8385 | NO SURVIVING PUPS ON DAY 0 POSTPARTUM | | | | | | | | | | | | | | |
| 8386 | FOUND DEAD ON DAY 8 OF GESTATION | | | | | | | | | | | | | | |
| 8387a | 1.3 | 1.1 | 1.2 | 2.2 | 2.2 | 2.2 | 3.9 | 3.8 | 3.8 | 5.6 | 5.2 | 5.4 | 8.2 | 7.6 | 7.9 |
| 8388a | 1.5 | 1.6 | 1.5 | 2.1 | 2.3 | 2.2 | 3.7 | 3.9 | 3.8 | 5.9 | 6.2 | 6.0 | 7.7 | 8.4 | 8.1 |
| 8389 | 1.4 | 1.4 | 1.4 | NO SURVIVING PUPS ON DAY 1 POSTPARTUM | | | | | | | | | | | |
| 8390 | 1.5 | 1.4 | 1.4 | 2.6 | 2.5 | 2.5 | 4.1 | 4.0 | 4.1 | 6.9 | 6.8 | 6.9 | 11.2 | 10.6 | 11.0 |

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.
a. Mouse was found dead on day 13 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP I | | | | | | CONTROL | | | | | 0 MG/KG/DAY | | | | | DAY 0 POSTPARTUM | | |
| 8311 | 1.5 | 1.4 | 1.5 | 1.4 | 1.3 | 1.5 | 1.5 | 1.6 | 1.5 | 1.2 | 1.4 | 1.2 | 1.2 | 1.2 | 1.3 | 1.2 | | | |
| 8312 | 1.6 | 1.6 | 1.5 | 1.6 | 1.6 | 1.4 | 1.4 | 1.3 | 1.5 | 1.3 | 1.5 | 1.5 | 1.4 | 1.5 | 1.6 | | | | |
| 8313 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8314 | 1.7 | 1.6 | 1.5 | 1.6 | 1.8 | 1.5 | 1.6 | 1.8 | 1.6 | 1.7 | 1.8 | | | | | | | | |
| 8315 | 1.7 | 1.6 | 1.5 | 1.5 | 1.4 | 1.5 | 1.6 | 1.5 | 1.6 | 1.5 | 1.6 | 1.6 | 1.6 | | | | | | |
| 8316 | 1.7 | 1.6 | 1.6 | 1.2 | 1.5 | 1.3 | 1.3 | 1.5 | 1.6 | 1.5 | 1.5 | 1.6 | 1.5 | 1.5 | | | | | |
| 8317 | 1.6 | 1.8 | 1.7 | 1.6 | 1.5 | 1.7 | MS | 1.6 | 1.8 | 1.6 | 1.6 | 1.7 | | | | | | | |
| 8318 | 1.9 | 2.0 | 2.0 | 2.1 | | | | | | | | | | | | | | | |
| 8319 | 1.7 | 1.4 | 1.6 | 1.5 | 1.7 | 1.6 | 1.6 | 1.6 | 1.6 | 1.5 | 1.5 | 1.6 | 1.5 | | | | | | |
| 8320 | 1.8 | 1.8 | 1.7 | 1.8 | 1.8 | | | | | | | | | | | | | | |
| 8321 | 1.7 | 1.6 | MS | MS | 1.8 | 1.8 | FS | | | | | | | | | | | | |
| 8322 | 1.5 | 1.5 | 1.4 | 1.5 | 1.4 | 1.5 | 1.4 | 1.5 | 1.4 | 1.5 | 1.5 | 1.5 | 1.4 | 1.5 | | | | | |
| 8323 | 1.4 | 1.4 | 1.2 | 1.5 | 1.5 | 1.5 | 1.2 | 1.4 | 1.2 | 1.3 | 1.3 | 1.4 | 1.5 | 1.2 | 1.4 | 1.2 | | | |
| 8324 | 1.8 | 1.6 | 1.7 | 1.5 | 1.4 | 1.6 | 1.6 | 1.5 | 1.6 | 1.7 | 1.7 | 1.6 | | | | | | | |
| 8325 | 1.6 | 1.5 | 1.6 | 1.5 | 1.5 | 1.4 | 1.4 | 1.3 | 1.5 | 1.5 | 1.5 | 1.5 | 1.4 | 1.4 | | | | | |
| 8326 | 1.6 | 1.5 | 1.8 | 1.7 | 1.5 | 1.6 | 1.7 | 1.7 | 1.5 | 1.7 | 1.6 | 1.6 | 1.4 | 1.5 | 1.6 | | | | |
| 8327 | 1.4 | 1.6 | 1.7 | 1.8 | 1.6 | 1.7 | 1.8 | 1.5 | 1.6 | 1.7 | 1.5 | 1.6 | | | | | | | |
| 8328 | 1.4 | 1.5 | 1.4 | 1.5 | 1.6 | 1.4 | 1.3 | 1.6 | 1.5 | 1.5 | 1.4 | 1.9 | 1.5 | | | | | | |
| 8329 | 1.9 | | | | | | | | | | | | | | | | | | |
| 8330 | 1.6 | 1.7 | 1.4 | 1.7 | 1.7 | 1.3 | 1.5 | 1.7 | 1.6 | 1.5 | 1.6 | 1.6 | 1.5 | 1.2 | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP II | | | | | | LOW DOSAGE | | | | | 100 MG/KG/DAY | | | | | DAY 0 POSTPARTUM | | |
| 8331 | 1.5 | 1.5 | 1.6 | 1.5 | 1.6 | 1.3 | 1.3 | 1.6 | 1.4 | 1.2 | 1.2 | 1.3 | 1.5 | 1.3 | 1.5 | | | | |
| 8332 | 1.7 | 1.7 | 1.6 | 1.5 | 1.6 | 1.6 | 1.5 | 1.6 | 1.4 | 1.4 | 1.4 | 1.4 | 1.6 | | | | | | |
| 8333 | 1.3 | 1.4 | 1.4 | 1.3 | 1.3 | 1.4 | 1.4 | 1.2 | 1.4 | 1.3 | 1.3 | 1.4 | 1.3 | 1.3 | | | | | |
| 8334 | 1.3 | 1.5 | 1.4 | 1.3 | 1.3 | 1.7 | 1.4 | 1.4 | 1.6 | 1.4 | 1.5 | 1.4 | | | | | | | |
| 8335 | 1.5 | 1.6 | 1.6 | 1.4 | 1.5 | 1.6 | 1.5 | 1.3 | 1.4 | 1.4 | 1.4 | 1.0 | 1.5 | | | | | | |
| 8336 | 1.8 | 1.6 | 1.9 | 1.6 | 1.8 | 1.5 | 1.8 | 1.7 | 1.5 | 1.2 | 1.5 | 1.8 | | | | | | | |
| 8337 | 1.5 | 1.6 | 1.4 | 1.4 | 1.5 | 1.4 | 1.5 | 1.5 | 1.4 | 1.5 | | | | | | | | | |
| 8338 | 1.5 | 1.5 | 1.5 | 1.3 | 1.4 | 1.4 | 1.5 | 1.5 | 1.4 | 1.4 | 1.4 | 1.5 | 1.4 | | | | | | |
| 8339 | 1.4 | 1.3 | 1.1 | 1.4 | 1.4 | 1.5 | 1.4 | 1.3 | 1.5 | 1.4 | 1.2 | 1.5 | 1.2 | 1.2 | | | | | |
| 8340 | 1.6 | 1.7 | 1.5 | 1.5 | 1.6 | 1.5 | 1.5 | 1.6 | 1.5 | 1.5 | 1.5 | 1.6 | | | | | | | |
| 8341 | 1.4 | 1.4 | 1.4 | 1.5 | 1.5 | 1.4 | 1.4 | 1.4 | 1.3 | 1.5 | 1.3 | 1.3 | 1.2 | | | | | | |
| 8342 | 1.6 | 1.7 | 1.7 | 1.5 | 1.7 | 1.7 | 1.5 | 1.6 | 1.6 | 1.6 | 1.6 | 1.6 | | | | | | | |
| 8343 | 1.4 | 1.4 | 1.4 | 1.8 | 1.6 | 1.6 | 1.4 | 1.6 | 1.6 | 1.8 | 1.4 | | | | | | | | |
| 8344 | 1.3 | 1.2 | 1.6 | 1.6 | 1.5 | 1.5 | 1.4 | 1.5 | 1.4 | 1.4 | 1.4 | 1.3 | 1.6 | 1.5 | 1.4 | | | | |
| 8345 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8346 | 1.6 | 1.5 | 2.0 | 1.6 | 1.6 | 1.8 | 1.6 | 1.9 | 1.6 | 1.5 | 1.5 | 1.5 | 1.7 | | | | | | |
| 8347 | 1.6 | 1.5 | 1.5 | 1.5 | 1.6 | 1.5 | 1.6 | 1.6 | 1.5 | 1.4 | 1.5 | 1.5 | 1.6 | 1.5 | 1.6 | 1.4 | 1.4 | | |
| 8348 | 1.5 | 1.6 | 1.6 | 1.7 | 1.5 | 1.7 | 1.5 | 1.5 | 1.4 | 1.4 | 1.3 | 1.6 | 1.3 | 1.3 | 1.4 | | | | |
| 8349 | 1.5 | 1.6 | 1.7 | 1.6 | 1.6 | 1.8 | 1.6 | 1.6 | 1.6 | 1.5 | 1.6 | 1.6 | | | | | | | |
| 8350 | 1.3 | 1.5 | 1.4 | 1.3 | 1.3 | 1.3 | 1.4 | 1.4 | 1.3 | 1.4 | 1.1 | 1.3 | 1.4 | 1.5 | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP III | | | | | | MIDDLE DOSAGE | | | | | 350 MG/KG/DAY | | | | | DAY 0 POSTPARTUM | | |
| 8351 | 1.3 | 1.2 | 1.4 | 1.1 | 1.3 | 1.3 | 1.3 | 1.3 | 1.3 | 1.3 | 1.5 | 1.4 | 1.3 | 1.4 | 1.2 | 1.2 | 1.2 | 1.4 | |
| 8352 | 1.5 | 1.5 | 1.4 | 1.4 | 1.5 | 1.5 | 1.5 | 1.4 | 1.6 | 1.5 | 1.3 | | | | | | | | |
| 8353 | 1.0 | 1.2 | 0.8 | 1.1 | 1.1 | 1.1 | 1.2 | 1.2 | 0.9 | 1.1 | 1.1 | 1.2 | 1.1 | 1.2 | 1.2 | FS | | | |
| 8354 | 1.2 | 1.2 | 1.3 | 1.3 | 1.4 | 1.2 | 1.1 | UU | MU | 1.2 | 1.2 | 1.2 | 1.1 | FD 0 | MU | FU | FD 0 | UU | UU |
| 8355 | 1.4 | 1.3 | 1.3 | 1.2 | 1.3 | 1.4 | 1.2 | 1.1 | 1.2 | 1.3 | 1.2 | 1.2 | 1.1 | 1.2 | | | | | |
| 8356 | 1.5 | 1.5 | 1.4 | 1.6 | 1.5 | 1.4 | 1.4 | 1.3 | 1.5 | 1.4 | 1.4 | UU | | | | | | | |
| 8357 | 1.5 | 1.4 | 1.5 | 1.5 | 1.2 | 1.3 | 1.1 | 1.5 | FS | UD 0 | | | | | | | | | |
| 8358 | 1.4 | 1.1 | 1.3 | 1.3 | 1.2 | 1.3 | 1.3 | 1.1 | 1.3 | 1.3 | US | | | | | | | | |
| 8359 | 1.4 | 1.2 | 1.4 | 1.2 | 1.2 | 1.1 | 1.3 | 1.3 | 1.1 | 1.1 | 1.1 | 1.2 | 1.2 | 1.0 | 1.2 | 1.2 | | | |
| 8360 | 1.3 | 1.4 | 1.5 | 1.3 | 1.3 | 1.4 | 1.3 | 1.3 | 1.3 | 1.3 | 1.4 | 1.4 | 1.4 | FS | | | | | |
| 8361 | FOUND DEAD ON DAY 13 OF GESTATION | | | | | | | | | | | | | | | | | | |
| 8362 | 1.2 | 1.1 | 1.0 | 1.0 | 1.0 | 0.9 | 1.0 | 1.0 | 1.1 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | FU | | | | |
| 8363 | 2.2 | 2.1 | | | | | | | | | | | | | | | | | |
| 8364 | 1.5 | 1.3 | 1.4 | 1.6 | 1.4 | 1.4 | 1.3 | 1.3 | 1.3 | 1.3 | 1.4 | 1.3 | 1.3 | 1.3 | | | | | |
| 8365 | 1.5 | 1.6 | 1.5 | 1.6 | 1.5 | 1.5 | 1.5 | 1.5 | | | | | | | | | | | |
| 8366 | 1.5 | 1.5 | 1.4 | 1.5 | 1.4 | 1.4 | 1.5 | 1.5 | 1.5 | 1.4 | 1.4 | 1.4 | 1.2 | | | | | | |
| 8367 | 1.2 | 1.0 | 1.3 | 1.1 | 1.3 | 1.0 | 1.2 | 1.1 | 1.2 | 1.1 | 1.2 | 0.9 | | | | | | | |
| 8368 | 1.5 | 1.7 | 1.4 | 1.5 | 1.5 | 1.4 | 1.5 | 1.6 | 1.5 | 1.5 | 1.4 | 1.6 | 1.4 | | | | | | |
| 8369 | 1.6 | 1.5 | 1.6 | 1.5 | 1.5 | 1.6 | 1.5 | 1.6 | 1.4 | 1.4 | 1.4 | 0.8 | | | | | | | |
| 8370 | 1.5 | 1.3 | 1.5 | 1.5 | 1.4 | 1.3 | 1.3 | 1.3 | 1.3 | MS | 1.4 | 1.5 | 1.4 | 1.4 | 1.4 | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP IV | | | | | | HIGH DOSAGE | | | | | 500 MG/KG/DAY | | | | | DAY 0 POSTPARTUM | | |
| 8371 | 1.3 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.3 | 1.5 | 1.3 | 1.3 | 1.5 | | | | | | | |
| 8372 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8373 | 1.3 | 1.4 | 1.5 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.3 | | | | | | | | |
| 8374 | 1.5 | 1.5 | 1.5 | 1.3 | 1.5 | 1.4 | 1.3 | 1.4 | 1.3 | 1.5 | | | | | | | | | |
| 8375 | MS | MS | FS | | | | | | | | | | | | | | | | |
| 8376 | 1.2 | 1.3 | 1.4 | 1.3 | 1.4 | 1.4 | 1.4 | 1.3 | 1.3 | 1.4 | 1.3 | 1.2 | | | | | | | |
| 8377 | 1.3 | 1.0 | 1.1 | 1.1 | 1.1 | 1.2 | 1.0 | 1.0 | 1.1 | 1.2 | 1.2 | | | | | | | | |
| 8378 | MS | MS | MS | MS | MS | FD 0 | FS | FS | FS | US | | | | | | | | | |
| 8379 | 1.5 | 1.6 | 1.5 | 1.5 | 1.4 | 1.3 | 1.2 | 1.5 | 1.5 | 1.4 | 1.4 | 1.5 | 1.5 | FD 0 | | | | | |
| 8380 | 1.9 | 1.9 | 1.9 | 1.9 | 1.9 | 1.8 | 1.9 | | | | | | | | | | | | |
| 8381 | 1.3 | 1.5 | 1.3 | MD 0 | 1.3 | 1.4 | 1.2 | 1.2 | 1.6 | 0.9 | FD 0 | FS | | | | | | | |
| 8382 | 1.4 | 1.3 | 1.3 | 1.2 | 1.4 | 1.4 | 1.4 | 1.2 | 1.4 | 1.2 | 1.5 | 1.2 | | | | | | | |
| 8383 | MD 0 | MD 0 | MD 0 | MD 0 | MS | FD 0 | FD 0 | FS | | | | | | | | | | | |
| 8384 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8385 | MD 0 | MD 0 | FD 0 | MS | FD 0 | MU | MU | MU | FD 0 | FD 0 | FU | FU | FU | UU | | | | | |
| 8386 | FOUND DEAD ON DAY 8 OF GESTATION | | | | | | | | | | | | | | | | | | |
| 8387 | 1.5 | 1.2 | 1.2 | 1.2 | 1.2 | 1.1 | 1.1 | 0.9 | 1.0 | 1.2 | FD 0 | FD 0 | FD 0 | FD 0 | | | | | |
| 8388 | 1.5 | 1.6 | 1.3 | 1.6 | 1.6 | MD 0 | MS | 1.6 | 1.6 | 1.5 | 1.5 | | | | | | | | |
| 8389 | 1.4 | MU | MU | 1.4 | FU | FU | | | | | | | | | | | | | |
| 8390 | 1.7 | 1.4 | 1.4 | 1.6 | 1.4 | 1.5 | 1.5 | 1.3 | 1.4 | 1.5 | 1.3 | FS | FS | | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP I | | | | | | CONTROL | | | | | 0 MG/KG/DAY | | | | | DAY 4 POSTPARTUM | | |
| 8311 | 2.4 | 2.6 | 2.9 | 2.7 | 2.9 | 2.3 | 2.6 | 2.5 | 2.8 | 2.4 | 2.7 | 2.3 | 2.4 | 2.5 | 2.3 | 2.5 | | | |
| 8312 | 2.7 | 2.8 | 2.5 | 2.7 | 2.7 | 2.7 | 2.5 | 2.1 | 2.3 | 2.6 | 2.3 | 2.4 | 2.5 | 2.5 | FD 3 | | | | |
| 8313 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8314 | 3.5 | 3.5 | 3.6 | 3.2 | 3.4 | 3.0 | 3.6 | 3.1 | 3.5 | 2.9 | 3.1 | | | | | | | | |
| 8315 | 2.7 | 2.9 | 3.0 | 2.7 | 2.9 | 2.6 | 2.9 | 3.0 | 2.6 | 2.9 | 2.5 | 2.8 | 2.9 | | | | | | |
| 8316 | 3.2 | 2.9 | 2.7 | 2.8 | 2.9 | 3.0 | 2.5 | 2.7 | 3.0 | 2.8 | 2.3 | 2.5 | 2.7 | 2.9 | | | | | |
| 8317 | 3.0 | 3.1 | 3.2 | 3.3 | 3.3 | 3.0 | MS | 3.1 | 3.1 | 2.8 | 3.1 | 3.1 | | | | | | | |
| 8318 | 3.8 | 3.7 | 3.6 | 3.8 | | | | | | | | | | | | | | | |
| 8319 | 3.0 | 3.1 | 2.6 | 2.9 | 2.8 | 3.0 | 2.9 | 2.9 | 2.9 | 2.9 | 2.8 | 3.1 | 2.8 | | | | | | |
| 8320 | 4.0 | 4.1 | 3.8 | 3.8 | 4.1 | | | | | | | | | | | | | | |
| 8321 | 3.6 | 3.7 | MS | MS | 3.8 | 3.8 | FS | | | | | | | | | | | | |
| 8322 | 2.4 | 2.3 | 2.6 | 2.7 | 2.7 | 2.8 | 2.3 | 2.4 | 2.6 | 2.7 | 2.4 | 2.2 | 2.7 | 2.4 | | | | | |
| 8323 | 2.7 | 2.4 | 2.2 | 2.4 | 2.5 | 2.6 | 2.8 | 2.5 | 2.3 | 2.3 | 2.9 | 2.5 | 2.5 | 2.7 | 3.0 | 2.5 | | | |
| 8324 | 3.4 | 3.4 | 3.4 | 2.8 | 3.4 | 3.2 | 3.5 | 3.4 | 3.7 | 3.3 | 3.3 | 3.2 | | | | | | | |
| 8325 | 2.9 | 2.8 | 2.7 | 2.7 | 2.9 | 3.0 | 2.7 | 2.7 | 2.7 | 2.5 | 2.8 | 2.5 | 2.7 | 2.8 | | | | | |
| 8326 | 3.0 | 2.7 | 2.9 | 3.2 | 2.9 | 2.7 | 2.7 | 2.9 | 2.9 | 3.4 | 2.5 | 3.0 | 3.1 | 2.8 | 3.1 | | | | |
| 8327 | 2.9 | 2.7 | 2.6 | 1.7 | 2.8 | 2.7 | 3.1 | 2.5 | 2.5 | 2.6 | 2.6 | 2.3 | | | | | | | |
| 8328 | 3.0 | 2.5 | 2.8 | 3.2 | 2.8 | 2.5 | 2.9 | 2.6 | 2.8 | 2.9 | 2.9 | 2.6 | 2.7 | | | | | | |
| 8329 | FD 3 | | | | | | | | | | | | | | | | | | |
| 8330 | 2.7 | 2.9 | 2.7 | 2.8 | 1.7 | 2.6 | 2.9 | 2.7 | 2.8 | 2.6 | 2.3 | 2.4 | 2.5 | 2.7 | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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 20005045: 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 6): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP II | | | | | | LOW DOSAGE | | | | | 100 MG/KG/DAY | | | | | DAY 4 POSTPARTUM | | |
| 8331 | 3.0 | 3.0 | 2.5 | 2.7 | 2.0 | 3.1 | 2.9 | 2.9 | 2.2 | 2.4 | 2.4 | 2.5 | 3.3 | 2.9 | 2.5 | | | | |
| 8332 | 2.9 | 3.0 | 3.4 | 3.1 | 3.1 | 3.2 | 3.0 | 2.9 | 3.1 | 3.0 | 3.1 | 2.8 | FD 3 | | | | | | |
| 8333 | 2.7 | 3.0 | 2.8 | 2.6 | 2.7 | 2.9 | 2.9 | 2.8 | 2.7 | 2.7 | 2.7 | 3.0 | 2.8 | 2.5 | | | | | |
| 8334 | 2.6 | 2.5 | 2.5 | 2.7 | 3.4 | 3.0 | 2.6 | 2.8 | 3.0 | 2.8 | 2.5 | 2.8 | | | | | | | |
| 8335 | 3.2 | 2.9 | 3.4 | 3.0 | 3.2 | 2.8 | 3.2 | 3.2 | 2.3 | 2.8 | 3.2 | 2.9 | 2.8 | | | | | | |
| 8336 | 3.7 | 3.2 | 3.3 | 3.3 | 3.8 | 2.8 | 3.3 | 3.2 | 3.6 | 3.2 | 2.9 | FM 1 | | | | | | | |
| 8337 | 2.8 | 3.0 | 2.9 | 2.8 | 2.9 | 3.1 | 3.0 | 2.9 | 2.9 | 2.9 | | | | | | | | | |
| 8338 | 2.9 | 3.1 | 3.1 | 3.1 | 3.0 | 3.2 | 3.0 | 3.0 | 2.8 | 2.8 | 2.8 | 2.8 | 2.9 | | | | | | |
| 8339 | 2.5 | 3.1 | 2.8 | 2.4 | 2.7 | 2.5 | 2.7 | 2.5 | 2.3 | 2.4 | 2.3 | 2.5 | 2.6 | FM 1 | | | | | |
| 8340 | 3.1 | 3.1 | 3.0 | 3.0 | 3.0 | 2.7 | 2.8 | 2.5 | 2.9 | 3.1 | 3.1 | 3.0 | | | | | | | |
| 8341 | 2.8 | 2.6 | 2.6 | 2.6 | 2.5 | 2.4 | 2.3 | 2.3 | 2.4 | 2.6 | 2.3 | 2.7 | 2.1 | | | | | | |
| 8342 | 2.8 | 3.1 | 2.6 | 3.2 | 2.7 | 2.9 | 3.0 | 3.0 | 2.7 | 3.0 | 2.6 | 2.8 | | | | | | | |
| 8343 | 1.4 | 2.9 | 2.7 | 2.6 | 2.7 | 2.5 | 2.7 | 2.4 | 2.5 | 2.6 | 2.8 | | | | | | | | |
| 8344 | 2.8 | 2.4 | 2.8 | 1.8 | 2.4 | 2.6 | 2.5 | 2.5 | 2.8 | 2.6 | 2.7 | 2.7 | 3.0 | 2.7 | 2.7 | | | | |
| 8345 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8346 | 2.7 | 3.0 | 2.8 | 3.0 | 2.6 | 2.8 | 2.7 | 2.7 | 3.0 | 2.3 | 2.9 | 2.9 | 2.8 | | | | | | |
| 8347 | 2.5 | 2.5 | 2.3 | 2.3 | 2.4 | 2.5 | 2.4 | 2.5 | 2.2 | 2.1 | 2.3 | 2.2 | 2.3 | 2.4 | 2.4 | 2.5 | 2.4 | | |
| 8348 | 2.6 | 2.6 | 2.9 | 2.6 | 2.6 | 2.4 | 2.7 | 2.9 | 3.0 | 3.0 | 2.6 | 2.4 | 2.9 | 2.5 | 2.5 | | | | |
| 8349 | 3.1 | 3.1 | 3.0 | 3.1 | 3.1 | 3.1 | 3.0 | 2.6 | 2.9 | 3.0 | 3.1 | 3.0 | | | | | | | |
| 8350 | 2.3 | 2.3 | 2.5 | 2.4 | 2.5 | 2.5 | 2.2 | 2.4 | 2.6 | 2.4 | 2.6 | 2.3 | 2.6 | 1.8 | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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 20005045: 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 7): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP III | | | | | | MIDDLE DOSAGE | | | | | 350 MG/KG/DAY | | | | | DAY 4 POSTPARTUM | | |
| 8351 | 2.1 | 2.2 | 2.2 | 1.6 | 2.3 | 2.0 | 2.2 | 2.2 | 2.6 | 2.4 | 2.7 | 2.0 | 2.2 | 1.7 | 2.5 | 1.8 | 2.4 | 2.1 | |
| 8352 | 2.3 | 1.7 | 2.0 | 1.8 | 2.0 | 1.9 | 1.8 | 2.1 | 2.0 | 1.4 | 2.1 | | | | | | | | |
| 8353 | 0.8 | 1.7 | 1.7 | 2.1 | 1.9 | 1.6 | 2.0 | 1.7 | 1.8 | 1.6 | 1.8 | 1.5 | 1.8 | 1.9 | 1.5 | FS | | | |
| 8354 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | UU | MU | FM 1 | FM 1 | FM 1 | FM 1 | FD 0 | MU | FU | FD 0 | UU | UU |
| 8355 | 1.1 | 1.7 | 1.4 | 1.8 | 1.6 | 1.9 | 1.9 | 2.0 | 2.0 | 1.8 | 2.2 | 1.6 | 1.9 | 1.9 | | | | | |
| 8356 | 2.5 | 2.3 | 2.4 | 2.6 | 2.0 | 2.5 | 2.7 | 2.3 | 2.4 | 2.2 | 2.4 | UU | | | | | | | |
| 8357 | 2.6 | 2.6 | 2.6 | 2.0 | 2.6 | 2.1 | 2.3 | 2.7 | FS | UD 0 | | | | | | | | | |
| 8358 | MD 1 | MD 1 | MD 1 | MD 1 | MD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | US | | | | | | | | |
| 8359 | 2.0 | 2.2 | 1.9 | 2.1 | 2.0 | 2.1 | 2.1 | 2.1 | 2.0 | 1.6 | 2.1 | 2.2 | 2.0 | 2.2 | 2.0 | 2.2 | | | |
| 8360 | 1.6 | 1.8 | 1.5 | 1.6 | 1.7 | 1.0 | 1.8 | 1.5 | 1.8 | 1.9 | 1.7 | 1.8 | 1.8 | FS | | | | | |
| 8361 | FOUND DEAD ON DAY 13 OF GESTATION | | | | | | | | | | | | | | | | | | |
| 8362 | 1.9 | 1.9 | 1.9 | 1.9 | 1.9 | 1.9 | 1.7 | 1.9 | 2.0 | 1.8 | 1.6 | 1.8 | 1.6 | 1.8 | FU | | | | |
| 8363 | 4.0 | 4.0 | | | | | | | | | | | | | | | | | |
| 8364 | 1.6 | 1.2 | 1.2 | 1.1 | 1.5 | 1.5 | 1.1 | 1.4 | MD 4 | MD 2 | 1.0 | 1.1 | 1.6 | 1.3 | | | | | |
| 8365 | 3.3 | 3.3 | 3.5 | 3.3 | 3.3 | 3.4 | 3.2 | 3.3 | | | | | | | | | | | |
| 8366 | 2.9 | 3.0 | 3.0 | 2.9 | 2.6 | 2.8 | 2.7 | 2.6 | 2.7 | 2.8 | 2.8 | 2.1 | 2.6 | | | | | | |
| 8367 | 2.0 | 2.2 | 2.0 | 2.2 | 2.0 | 2.1 | 1.7 | 1.8 | 2.0 | 1.9 | 2.2 | FD 1 | | | | | | | |
| 8368 | 2.3 | 2.6 | 2.5 | 2.1 | 2.0 | 2.3 | 2.6 | 2.2 | 2.5 | 2.5 | 2.4 | 2.3 | 2.0 | | | | | | |
| 8369 | 2.1 | 2.7 | 2.6 | 2.2 | 2.4 | 2.9 | 2.6 | 2.8 | 2.3 | 2.6 | 2.1 | FM 1 | | | | | | | |
| 8370 | 2.4 | 2.6 | 2.3 | 2.1 | 2.0 | 2.4 | 2.3 | 2.2 | 2.4 | MS | 2.1 | 1.9 | 2.4 | 2.1 | 2.4 | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP IV | | | | | | HIGH DOSAGE | | | | | 500 MG/KG/DAY | | | | | DAY 4 POSTPARTUM | | |
| 8371 | 1.8 | 1.5 | 1.7 | 1.5 | 1.2 | MD 2 | 1.4 | 1.6 | 1.9 | 1.3 | 1.8 | FD 1 | | | | | | | |
| 8372 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8373 | 2.3 | 2.3 | 1.9 | 2.3 | 2.5 | 2.3 | MD 2 | 2.2 | 2.0 | 2.0 | 2.3 | | | | | | | | |
| 8374 | 2.8 | 2.9 | 2.6 | 3.0 | 2.7 | 3.0 | 3.0 | 2.9 | 2.8 | 2.6 | | | | | | | | | |
| 8375 | MS | MS | FS | | | | | | | | | | | | | | | | |
| 8376 | 2.2 | 2.4 | 2.3 | 2.2 | 2.3 | 2.5 | 2.3 | 2.0 | 2.3 | 2.2 | 2.2 | 2.2 | | | | | | | |
| 8377 | 2.1 | 2.2 | 2.4 | 2.2 | 2.2 | 2.5 | 2.0 | 2.1 | 2.3 | 1.8 | 1.8 | | | | | | | | |
| 8378 | MS | MS | MS | MS | MS | FD 0 | FS | FS | FS | US | | | | | | | | | |
| 8379 | 2.4 | 2.4 | 2.3 | 2.5 | 2.7 | 2.4 | 2.8 | 2.2 | 2.6 | 2.6 | 2.5 | 2.4 | 2.5 | FD 0 | | | | | |
| 8380 | 3.6 | 3.7 | 3.4 | 3.5 | 3.5 | 3.5 | 3.3 | | | | | | | | | | | | |
| 8381 | MD 1 | MD 1 | MD 1 | MD 0 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 0 | FS | | | | | | | |
| 8382 | 2.6 | 2.2 | 1.7 | 2.1 | 2.1 | 2.0 | 2.0 | 2.4 | 2.6 | 2.6 | 2.2 | 2.1 | | | | | | | |
| 8383 | MD 0 | MD 0 | MD 0 | MD 0 | MS | FD 0 | FD 0 | FS | | | | | | | | | | | |
| 8384 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8385 | MD 0 | MD 0 | FD 0 | MS | FD 0 | MU | MU | MU | FD 0 | FD 0 | FU | FU | FU | UU | | | | | |
| 8386 | FOUND DEAD ON DAY 8 OF GESTATION | | | | | | | | | | | | | | | | | | |
| 8387 | 2.4 | 2.4 | 2.2 | 2.0 | 2.4 | 2.1 | 2.1 | 2.2 | FD 3 | FM 2 | FD 0 | FD 0 | FD 0 | FD 0 | | | | | |
| 8388 | 2.1 | 1.6 | 2.6 | MD 4 | MD 3 | MD 0 | MS | 2.3 | 2.4 | 2.3 | 2.3 | | | | | | | | |
| 8389 | MM 1 | MU | MU | FM 1 | FU | FU | | | | | | | | | | | | | |
| 8390 | 2.9 | 2.4 | 2.5 | 2.7 | 2.4 | MM 1 | 2.5 | 2.6 | 2.4 | 2.4 | FM 1 | FS | FS | | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP I | | | | | | CONTROL | | | | | 0 MG/KG/DAY | | | | | DAY 7 POSTPARTUM | | |
| 8311 | 4.0 | 3.8 | 3.8 | 3.0 | 3.1 | 3.7 | 3.3 | 4.1 | 3.4 | 3.2 | 3.1 | 3.3 | 3.6 | 3.4 | 3.5 | 3.4 | | | |
| 8312 | 3.9 | 3.8 | 3.4 | 3.6 | 3.8 | 3.7 | 3.5 | 3.2 | 3.6 | 3.0 | 3.6 | 3.5 | 2.9 | 3.5 | FD 3 | | | | |
| 8313 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8314 | 5.1 | 4.9 | 4.6 | 5.1 | 5.2 | 4.3 | 5.3 | 5.0 | 5.1 | 4.7 | 4.7 | | | | | | | | |
| 8315 | 4.2 | 4.0 | 4.2 | 3.9 | 3.9 | 3.5 | 4.1 | 4.1 | 3.7 | 3.9 | 4.4 | 4.2 | 3.9 | | | | | | |
| 8316 | 4.5 | 4.4 | 4.2 | 3.9 | 4.2 | 3.5 | 4.0 | 3.5 | 3.4 | 3.8 | 3.6 | 3.6 | 4.2 | 4.4 | | | | | |
| 8317 | 4.8 | 4.5 | 4.7 | 4.8 | 4.6 | 4.3 | MS | 4.3 | 4.7 | 4.8 | 4.3 | 4.9 | | | | | | | |
| 8318 | 5.6 | 5.9 | 5.6 | 5.9 | | | | | | | | | | | | | | | |
| 8319 | 4.1 | 4.3 | 4.6 | 3.9 | 4.3 | 4.4 | 4.2 | 4.3 | 4.5 | 4.0 | 4.5 | 4.4 | 4.1 | | | | | | |
| 8320 | 6.4 | 6.3 | 6.1 | 6.5 | 6.2 | | | | | | | | | | | | | | |
| 8321 | 5.5 | 5.4 | MS | MS | 5.9 | 5.5 | FS | | | | | | | | | | | | |
| 8322 | 4.3 | 3.9 | 3.5 | 4.0 | 4.2 | 3.6 | 4.1 | 4.0 | 3.7 | 3.9 | 3.9 | 4.1 | 4.2 | 3.4 | | | | | |
| 8323 | 4.0 | 3.9 | 4.4 | 3.6 | 3.6 | 4.1 | 4.1 | 4.2 | 3.6 | 3.9 | 4.2 | 3.5 | 3.7 | 3.6 | 4.1 | 3.1 | | | |
| 8324 | 5.3 | 5.6 | 5.3 | 5.5 | 5.3 | 5.2 | 4.5 | 5.0 | 5.3 | 5.0 | 5.3 | 5.4 | | | | | | | |
| 8325 | 4.3 | 4.0 | 4.0 | 4.0 | 4.0 | 4.0 | 4.2 | 3.9 | 3.8 | 3.8 | 4.0 | 3.5 | 3.8 | 4.1 | | | | | |
| 8326 | 4.8 | 4.5 | 3.9 | 4.4 | 4.4 | 4.9 | 3.8 | 4.5 | 4.3 | 4.0 | 3.7 | 4.3 | 3.8 | 4.3 | 4.3 | | | | |
| 8327 | 4.0 | 2.7 | 4.1 | 3.9 | 4.2 | 4.1 | 4.3 | 3.9 | 4.0 | 3.8 | 3.8 | 3.5 | | | | | | | |
| 8328 | 4.2 | 4.4 | 3.8 | 4.0 | 3.6 | MM 7 | 4.3 | 4.3 | 3.8 | 4.1 | 3.3 | 4.0 | 3.6 | | | | | | |
| 8329 | FD 3 | | | | | | | | | | | | | | | | | | |
| 8330 | 4.3 | 4.3 | 3.6 | 3.9 | 2.4 | 4.0 | 4.0 | 3.8 | 3.9 | 3.9 | 4.1 | 4.1 | 3.3 | 3.9 | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP II | | | | | | LOW DOSAGE | | | | | 100 MG/KG/DAY | | | | | DAY 7 POSTPARTUM | | |
| 8331 | 4.4 | 4.3 | 3.9 | 4.3 | 4.2 | 3.2 | 4.5 | 4.4 | 3.6 | 3.6 | 2.9 | 4.0 | 4.0 | 3.7 | 4.3 | | | | |
| 8332 | 4.5 | 4.5 | 4.5 | 4.3 | 4.7 | 4.3 | 4.4 | 4.2 | 4.6 | 4.5 | 4.6 | 4.6 | FD 3 | | | | | | |
| 8333 | 3.9 | 3.9 | 4.0 | 3.9 | 3.5 | 4.3 | 4.3 | 4.3 | 4.1 | 3.5 | 4.2 | 3.7 | 3.6 | 4.2 | | | | | |
| 8334 | 4.0 | 4.6 | 4.0 | 3.8 | 3.9 | 4.1 | 4.6 | 3.6 | 4.0 | 4.4 | 4.5 | 3.6 | | | | | | | |
| 8335 | 5.0 | 4.5 | 4.3 | 5.1 | 4.7 | 4.2 | 4.7 | 4.3 | 3.1 | 4.2 | 4.9 | 4.6 | 3.9 | | | | | | |
| 8336 | 4.5 | 4.7 | 5.1 | 4.6 | 5.2 | 4.4 | 5.3 | 4.4 | 4.5 | 5.0 | 4.5 | FM 1 | | | | | | | |
| 8337 | 4.6 | 4.4 | 4.6 | 4.5 | 4.7 | 4.7 | 4.5 | 4.5 | 4.7 | 4.6 | | | | | | | | | |
| 8338 | 4.6 | 4.5 | 4.4 | 4.4 | 4.6 | 4.7 | 4.3 | 4.3 | 4.1 | 4.4 | 4.4 | 4.5 | 4.4 | | | | | | |
| 8339 | 3.8 | 4.4 | 3.6 | 3.9 | 4.2 | 3.8 | 3.4 | 3.7 | 3.7 | 3.6 | 3.6 | 3.7 | 3.3 | FM 1 | | | | | |
| 8340 | 4.5 | 4.4 | 4.5 | 4.5 | 4.5 | 4.0 | 4.3 | 4.5 | 4.6 | 4.4 | 4.8 | 3.8 | | | | | | | |
| 8341 | 3.7 | 3.1 | 3.4 | 4.2 | 3.9 | 3.5 | 3.5 | 3.2 | 4.0 | 3.2 | 3.6 | 3.2 | 3.2 | | | | | | |
| 8342 | 3.7 | 4.4 | 4.2 | 3.7 | 3.8 | 4.0 | 3.8 | 3.5 | 3.7 | 3.9 | 3.4 | 3.7 | | | | | | | |
| 8343 | 4.0 | 3.9 | 4.1 | 4.0 | 4.1 | 4.2 | 4.0 | 3.7 | 3.7 | 4.0 | 3.8 | | | | | | | | |
| 8344 | 3.9 | 3.2 | 3.5 | MD 5 | 3.6 | 4.0 | 3.3 | 3.9 | 3.7 | 4.1 | 3.8 | 4.0 | 3.6 | 4.2 | 4.1 | | | | |
| 8345 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8346 | 4.2 | 4.3 | 4.3 | 3.8 | 3.7 | 4.3 | 3.6 | 4.3 | 4.6 | 4.1 | 4.1 | 4.1 | 4.0 | | | | | | |
| 8347 | 3.6 | 3.2 | 2.8 | 3.6 | 2.6 | 3.5 | 3.6 | 3.6 | 3.1 | 3.4 | 3.3 | 3.4 | 3.5 | 2.8 | 2.8 | 3.2 | 3.1 | | |
| 8348 | 5.3 | 3.6 | 4.0 | 4.1 | 3.9 | 4.7 | 4.2 | 3.8 | 3.8 | 3.3 | 3.9 | 4.0 | 3.8 | 3.6 | 3.4 | | | | |
| 8349 | 4.8 | 4.4 | 4.8 | 4.8 | 4.9 | 5.0 | 4.3 | 4.3 | 4.3 | 4.3 | 4.4 | 4.5 | | | | | | | |
| 8350 | 3.7 | 3.9 | 3.7 | 3.9 | 3.7 | 3.5 | 3.9 | 3.7 | 3.7 | 3.9 | 3.8 | 3.7 | 2.7 | 4.1 | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP III | | | | | | MIDDLE DOSAGE | | | | | 350 MG/KG/DAY | | | | | DAY 7 POSTPARTUM | | |
| 8351 | 3.2 | 3.1 | 2.4 | 3.4 | 3.3 | 3.4 | 3.5 | 4.1 | 3.8 | 3.2 | 3.4 | 2.8 | 3.5 | 3.5 | 4.2 | 3.0 | 2.4 | 3.2 | |
| 8352 | 3.6 | 2.8 | 3.2 | 2.9 | 2.7 | 3.2 | 2.8 | 3.0 | 3.2 | 3.4 | 2.5 | | | | | | | | |
| 8353 | 2.4 | 2.9 | 1.5 | 2.3 | 2.1 | 2.6 | 2.3 | 2.3 | 2.7 | 2.6 | 2.3 | 2.7 | 2.5 | 2.4 | FD 5 | FS | | | |
| 8354 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | UU | MU | FM 1 | FM 1 | FM 1 | FM 1 | FD 0 | MU | FU | FD 0 | UU | UU |
| 8355 | 1.2 | 3.1 | 3.2 | 3.3 | 3.4 | 3.2 | MM 5 | 2.6 | 3.3 | 3.3 | 2.8 | 3.3 | 2.9 | 3.0 | | | | | |
| 8356 | 4.2 | 4.0 | 4.1 | 4.3 | 3.5 | 3.8 | 4.0 | 3.7 | 3.7 | 3.9 | 4.3 | UU | | | | | | | |
| 8357 | 4.4 | 4.4 | 3.6 | 4.5 | 4.5 | 4.5 | 3.8 | 3.8 | FS | UD 0 | | | | | | | | | |
| 8358 | MD 1 | MD 1 | MD 1 | MD 1 | MD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | US | | | | | | | | |
| 8359 | 3.1 | 3.0 | 3.2 | 2.8 | 3.1 | 2.9 | 3.1 | 3.4 | 2.9 | 3.1 | 3.2 | 3.0 | 3.3 | 1.7 | 3.0 | 2.9 | | | |
| 8360 | 2.6 | 2.6 | 2.8 | 2.8 | 2.5 | 2.7 | 2.7 | 2.7 | 2.4 | 2.7 | 2.8 | 2.6 | FD 5 | FS | | | | | |
| 8361 | FOUND DEAD ON DAY 13 OF GESTATION | | | | | | | | | | | | | | | | | | |
| 8362 | 2.9 | 2.9 | 2.9 | 3.1 | 3.0 | 3.6 | 3.0 | 3.0 | 3.0 | 2.9 | 2.5 | 3.0 | 2.7 | 2.5 | FU | | | | |
| 8363 | 5.8 | 5.9 | | | | | | | | | | | | | | | | | |
| 8364 | 2.4 | 1.4 | 1.9 | 1.6 | 2.3 | 2.0 | 2.7 | 1.5 | MD 4 | MD 2 | 2.7 | 1.9 | 2.8 | 2.1 | | | | | |
| 8365 | 5.3 | 5.2 | 5.2 | 5.3 | 5.3 | 5.0 | 5.2 | 5.2 | | | | | | | | | | | |
| 8366 | 4.1 | 4.7 | 4.4 | 3.8 | 4.2 | 4.3 | 4.3 | 4.3 | 4.2 | 4.3 | 4.0 | 3.9 | 2.9 | | | | | | |
| 8367 | 3.7 | 3.4 | 3.4 | 3.1 | 2.9 | 3.3 | 3.0 | 3.7 | 3.2 | 3.1 | 3.4 | FD 1 | | | | | | | |
| 8368 | 3.0 | 4.0 | 3.3 | 4.2 | 3.3 | 4.0 | 3.7 | 4.1 | 3.6 | 3.8 | 3.8 | 3.9 | 3.1 | | | | | | |
| 8369 | 3.9 | 3.9 | 4.7 | 4.2 | 4.3 | 3.5 | 4.6 | 3.9 | 3.8 | 4.3 | 4.7 | FM 1 | | | | | | | |
| 8370 | 4.2 | 3.8 | 3.2 | 3.9 | 3.0 | 3.3 | 3.3 | 4.0 | 3.9 | MS | 3.1 | 3.9 | 3.9 | 3.6 | 3.6 | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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 20005045: 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 12): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP IV | | | | | | HIGH DOSAGE | | | | | 500 MG/KG/DAY | | | | | DAY 7 POSTPARTUM | | |
| 8371 | 2.4 | 1.9 | 2.3 | 2.5 | 2.6 | MD 2 | 2.8 | 2.6 | 1.9 | 2.1 | 2.3 | FD 1 | | | | | | | |
| 8372 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8373 | 3.7 | 3.1 | 4.0 | 3.8 | 4.1 | 3.9 | MD 2 | 3.3 | 3.6 | 3.5 | 4.0 | | | | | | | | |
| 8374 | 4.5 | 3.9 | 4.1 | 4.6 | 4.4 | 4.0 | 4.0 | 4.5 | 4.4 | 4.4 | | | | | | | | | |
| 8375 | MS | MS | FS | | | | | | | | | | | | | | | | |
| 8376 | 3.4 | 4.1 | 3.9 | 3.5 | 3.9 | 3.7 | 3.9 | 3.6 | 4.0 | 3.7 | 3.7 | 3.7 | | | | | | | |
| 8377 | 3.8 | 13.1 | 3.8 | 4.0 | 4.1 | 3.3 | 4.3 | 3.7 | 3.7 | 3.7 | 3.3 | | | | | | | | |
| 8378 | MS | MS | MS | MS | MS | FD 0 | FS | FS | FS | US | | | | | | | | | |
| 8379 | 4.0 | 3.6 | 3.4 | 3.7 | 4.1 | 3.5 | 3.4 | 3.6 | 3.8 | 4.0 | 3.9 | 3.8 | 3.2 | FD 0 | | | | | |
| 8380 | 5.8 | 5.3 | 5.4 | 5.7 | 5.5 | 5.4 | 5.6 | | | | | | | | | | | | |
| 8381 | MD 1 | MD 1 | MD 1 | MD 0 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 0 | FS | | | | | | | |
| 8382 | 3.8 | 4.0 | 2.8 | 3.6 | 3.4 | 2.8 | 4.0 | 3.3 | 3.3 | 4.0 | 3.8 | 3.9 | | | | | | | |
| 8383 | MD 0 | MD 0 | MD 0 | MD 0 | MS | FD 0 | FD 0 | FS | | | | | | | | | | | |
| 8384 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8385 | MD 0 | MD 0 | FD 0 | MS | FD 0 | MU | MU | MU | FD 0 | FD 0 | FU | FU | FU | UU | | | | | |
| 8386 | FOUND DEAD ON DAY 8 OF GESTATION | | | | | | | | | | | | | | | | | | |
| 8387 | 3.9 | 4.0 | 4.1 | 3.7 | 3.5 | 4.1 | 3.7 | 3.7 | FD 3 | FM 2 | FD 0 | FD 0 | FD 0 | FD 0 | | | | | |
| 8388 | 2.9 | 3.7 | 4.4 | MD 4 | MD 3 | MD 0 | MS | 4.2 | 3.5 | 4.0 | 3.9 | | | | | | | | |
| 8389 | MM 1 | MU | MU | FM 1 | FU | FU | | | | | | | | | | | | | |
| 8390 | 4.3 | 4.6 | 4.0 | 4.1 | 3.9 | MM 1 | 3.8 | 4.0 | 4.2 | 3.8 | FM 1 | FS | FS | | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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 20005045: 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 13): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP I | | | | | | CONTROL | | | | | 0 MG/KG/DAY | | | | | DAY 14 POSTPARTUM | | |
| 8311 | 5.4 | 6.4 | 5.7 | 4.7 | 6.6 | 4.9 | 6.2 | 6.0 | 4.7 | 5.9 | 5.5 | 5.5 | 5.6 | 5.3 | 5.0 | 5.3 | | | |
| 8312 | 6.4 | 6.9 | 6.0 | 6.5 | 6.2 | 6.7 | 5.6 | 5.8 | 6.3 | 6.6 | 5.7 | 5.8 | 5.7 | 6.1 | FD 3 | | | | |
| 8313 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8314 | 7.8 | 8.5 | 8.3 | 8.2 | 8.6 | 8.6 | 8.8 | 8.2 | 8.6 | 8.9 | 8.1 | | | | | | | | |
| 8315 | 6.7 | 7.0 | 7.4 | 6.3 | 7.3 | 6.6 | 6.9 | 6.7 | 6.9 | 6.9 | 6.7 | 6.9 | 6.8 | | | | | | |
| 8316 | 6.3 | 7.3 | 7.0 | 6.7 | 7.2 | 6.7 | 6.2 | 7.1 | 6.7 | 6.5 | 5.2 | 6.6 | 6.4 | 6.2 | | | | | |
| 8317 | 7.6 | 7.7 | 7.3 | 8.1 | 7.7 | 7.9 | MS | 7.4 | 7.6 | 7.7 | 7.8 | 8.1 | | | | | | | |
| 8318 | 11.1 | 11.2 | 11.2 | 10.9 | | | | | | | | | | | | | | | |
| 8319 | 7.1 | 7.5 | 7.1 | 7.4 | 6.2 | 7.0 | 7.3 | 7.3 | 7.7 | 6.6 | 7.0 | 6.6 | 6.9 | | | | | | |
| 8320 | 12.1 | 11.5 | 11.8 | 11.5 | 11.8 | | | | | | | | | | | | | | |
| 8321 | 10.5 | 10.7 | MS | MS | 11.2 | 11.1 | FS | | | | | | | | | | | | |
| 8322 | 6.5 | 6.4 | 6.4 | 7.0 | 6.5 | 6.8 | 6.8 | 6.9 | 5.5 | 6.3 | 6.6 | 6.1 | 6.8 | 6.1 | | | | | |
| 8323 | 7.0 | 5.5 | 6.3 | 5.7 | 5.5 | 6.1 | 7.3 | 6.4 | 5.7 | 6.2 | 5.8 | 6.2 | 4.6 | 7.2 | 5.5 | 4.8 | | | |
| 8324 | 8.1 | 8.0 | 8.3 | 8.3 | 8.5 | 7.1 | 8.7 | 7.9 | 8.4 | 8.1 | 8.3 | 7.8 | | | | | | | |
| 8325 | 6.2 | 6.6 | 6.7 | 6.3 | 6.6 | 6.4 | 6.1 | 6.3 | 5.7 | 6.3 | 6.9 | 5.9 | 5.8 | 6.5 | | | | | |
| 8326 | 5.6 | 7.1 | 7.2 | 7.0 | 7.5 | 7.4 | 5.5 | 6.6 | 6.6 | 6.4 | 6.9 | 6.8 | 6.3 | 6.3 | 6.2 | | | | |
| 8327 | 5.9 | 6.3 | 4.3 | 5.9 | 6.2 | 6.0 | 6.6 | 6.3 | 5.5 | 6.0 | 6.0 | 5.9 | | | | | | | |
| 8328a | 5.7 | 6.0 | 6.8 | 6.7 | 6.3 | MM 7 | 5.9 | 6.0 | 6.9 | 6.8 | 6.6 | 6.3 | 6.1 | | | | | | |
| 8329 | FD 3 | | | | | | | | | | | | | | | | | | |
| 8330 | 6.5 | 7.0 | 6.4 | 6.6 | 6.6 | 6.5 | 6.4 | 6.7 | 6.2 | 6.0 | 4.0 | 6.3 | 6.3 | 6.5 | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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.
a. Mouse was found dead on day 14 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP II | | | | | | LOW DOSAGE | | | | | 100 MG/KG/DAY | | | | | DAY 14 POSTPARTUM | | |
| 8331 | 7.2 | 6.8 | 5.5 | 6.5 | 6.5 | 6.9 | 5.6 | 6.5 | 6.2 | 6.1 | 6.0 | 5.6 | 5.8 | 5.4 | 4.3 | | | | |
| 8332 | 7.5 | 7.1 | 7.2 | 7.0 | 6.8 | 6.3 | 6.8 | 6.9 | 6.9 | 7.2 | 6.9 | 6.8 | FD 3 | | | | | | |
| 8333 | 5.7 | 6.5 | 6.4 | 6.3 | 6.0 | 6.4 | 6.6 | 6.1 | 6.2 | 6.2 | 6.4 | 6.1 | 6.9 | 6.9 | | | | | |
| 8334 | 8.2 | 8.3 | 6.8 | 8.4 | 7.4 | 6.7 | 7.3 | 6.5 | 8.0 | 6.6 | 7.4 | FM11 | | | | | | | |
| 8335 | 7.4 | 7.3 | 7.4 | 7.5 | 7.5 | 8.1 | 7.9 | 7.2 | 6.5 | 5.5 | 7.7 | 7.6 | 7.9 | | | | | | |
| 8336 | 7.2 | 7.3 | 8.1 | 8.0 | 7.6 | 8.0 | 7.4 | 7.1 | 7.6 | 6.8 | 8.0 | FM 1 | | | | | | | |
| 8337 | 7.5 | 7.6 | 7.3 | 7.3 | 7.9 | 7.6 | 7.4 | 7.7 | 7.6 | 7.3 | | | | | | | | | |
| 8338 | 8.6 | 8.3 | 8.1 | 8.3 | 9.0 | 8.3 | 8.4 | 7.3 | 8.3 | 8.3 | 7.6 | 7.7 | 7.9 | | | | | | |
| 8339 | 7.7 | 6.6 | 7.4 | 7.0 | 6.7 | 6.7 | 5.6 | 6.2 | 6.7 | 6.7 | 5.6 | 6.2 | 6.8 | FM 1 | | | | | |
| 8340 | 7.3 | 6.5 | 7.1 | 6.4 | 6.4 | 7.3 | 6.7 | 7.1 | 6.6 | 7.8 | 6.1 | 7.6 | | | | | | | |
| 8341 | 5.4 | 6.2 | 6.7 | 4.9 | 5.9 | 6.3 | 6.8 | 6.2 | 6.0 | 5.6 | 5.4 | 5.1 | 5.7 | | | | | | |
| 8342 | 7.3 | 7.0 | 6.9 | 6.0 | 6.7 | 6.7 | 6.3 | 6.9 | 6.9 | 6.8 | 7.4 | 7.1 | | | | | | | |
| 8343a | 5.5 | 5.8 | 4.9 | 5.3 | 5.1 | 5.1 | 4.9 | 5.0 | 5.7 | 4.9 | 5.0 | | | | | | | | |
| 8344b | 5.0 | 4.7 | 5.1 | MD 5 | 5.3 | 4.0 | 4.9 | 4.6 | 3.9 | 4.5 | 5.6 | 5.2 | 5.2 | 5.4 | 4.8 | | | | |
| 8345 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8346a | 5.3 | 4.5 | 4.6 | 4.9 | MD14 | 5.3 | 4.8 | 4.6 | 4.8 | 5.7 | 4.5 | 4.0 | 4.6 | | | | | | |
| 8347a | 3.9 | 3.8 | 5.4 | 4.3 | 4.1 | 4.3 | 4.2 | 4.5 | MD14 | 4.0 | 4.2 | 4.4 | 4.5 | 4.5 | 4.6 | 3.4 | 3.6 | | |
| 8348a | 5.7 | 6.0 | 4.7 | 3.9 | 4.2 | 4.0 | 5.0 | 4.7 | 3.7 | 4.3 | 5.0 | 4.3 | 3.9 | 5.2 | 3.7 | | | | |
| 8349 | 7.6 | 6.8 | 7.5 | 7.2 | 7.6 | 7.4 | 7.2 | 7.4 | 7.3 | 6.9 | 7.1 | 7.1 | | | | | | | |
| 8350 | 5.9 | 6.1 | 6.6 | 5.5 | 6.3 | 6.6 | 5.9 | 6.2 | 5.7 | 6.3 | 6.6 | 6.1 | 5.2 | 4.4 | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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.
a. Mouse was found dead on day 13 of lactation; pups remained on study to day 20 postpartum.
b. Mouse was found dead on day 14 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP III | | | | | | MIDDLE DOSAGE | | | | | 350 MG/KG/DAY | | | | | DAY 14 POSTPARTUM | | |
| 8351 | 6.9 | 3.8 | 5.1 | 5.9 | 5.5 | 5.4 | 5.3 | 5.5 | 4.8 | 5.8 | 5.9 | 6.2 | 6.1 | 5.8 | 4.0 | 3.6 | 4.5 | 4.8 | |
| 8352 | 6.9 | 6.8 | 5.0 | 7.2 | 6.5 | 8.1 | 7.0 | 7.2 | 5.7 | 6.8 | 5.7 | | | | | | | | |
| 8353 | 5.5 | 6.0 | 4.9 | 4.3 | 5.3 | 4.7 | MM11 | 5.4 | 6.0 | 4.3 | 5.2 | 4.1 | 4.9 | 5.1 | FD 5 | FS | | | |
| 8354 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | UU | MU | FM 1 | FM 1 | FM 1 | FM 1 | FD 0 | MU | FU | FD 0 | UU | UU |
| 8355 | 6.5 | 6.5 | 6.4 | 5.8 | 5.0 | MM 8 | MM 5 | 6.3 | 6.9 | 6.6 | 7.0 | 5.9 | 7.0 | 6.2 | | | | | |
| 8356 | 7.2 | 7.2 | 6.6 | 7.4 | 7.1 | 6.9 | 7.3 | 6.9 | 7.5 | 6.7 | 6.8 | UU | | | | | | | |
| 8357 | 8.6 | 8.5 | 8.6 | 7.9 | 8.5 | 8.7 | 7.9 | 7.7 | FS | UD 0 | | | | | | | | | |
| 8358 | MD 1 | MD 1 | MD 1 | MD 1 | MD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | US | | | | | | | | |
| 8359 | 5.1 | 5.2 | 4.9 | 5.2 | 5.0 | 5.2 | 5.7 | 4.9 | 5.7 | 5.3 | 6.3 | 5.2 | 5.3 | 6.4 | 5.7 | FM 9 | | | |
| 8360 | 5.6 | 6.0 | 5.3 | 6.3 | 6.1 | 6.0 | 6.2 | 5.8 | 5.9 | 5.3 | 6.0 | 5.8 | FD 5 | FS | | | | | |
| 8361 | FOUND DEAD ON DAY 13 OF GESTATION | | | | | | | | | | | | | | | | | | |
| 8362 | 6.4 | 6.4 | 5.0 | 6.0 | 5.8 | 4.7 | 5.7 | 5.9 | 5.9 | 5.6 | 5.7 | 6.2 | 5.2 | 5.4 | FU | | | | |
| 8363 | 10.1 | 10.0 | | | | | | | | | | | | | | | | | |
| 8364 | 6.3 | 5.5 | 4.5 | 6.4 | 6.5 | 5.5 | 4.4 | 6.1 | MD 4 | MD 2 | 3.7 | 7.0 | 5.5 | 5.3 | | | | | |
| 8365 | 8.7 | 8.8 | 9.1 | 8.7 | 8.5 | 8.3 | 8.8 | 8.8 | | | | | | | | | | | |
| 8366 | 6.0 | 6.5 | 5.9 | 6.1 | 6.4 | 5.9 | 6.3 | 6.2 | 6.1 | 6.4 | 6.2 | 6.0 | 4.2 | | | | | | |
| 8367 | 5.6 | 5.6 | 5.6 | 6.1 | 5.7 | 5.6 | 5.2 | 5.3 | 5.8 | 4.8 | 5.5 | FD 1 | | | | | | | |
| 8368 | 6.7 | 6.5 | 6.1 | 6.5 | 6.2 | 6.5 | 5.2 | 5.9 | 6.3 | 6.2 | 6.7 | 5.9 | 7.1 | | | | | | |
| 8369 | 5.9 | 6.4 | 5.5 | 6.2 | 6.8 | 5.1 | 6.5 | 5.3 | 5.9 | 6.6 | 6.4 | FM 1 | | | | | | | |
| 8370 | 5.1 | 6.6 | 6.4 | 6.3 | 5.8 | 5.1 | 6.0 | 6.3 | 6.2 | MS | 4.9 | 5.0 | 6.1 | 6.3 | 5.2 | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP IV | | | | | | HIGH DOSAGE | | | | | 500 MG/KG/DAY | | | | | DAY 14 POSTPARTUM | | |
| 8371 | 6.0 | 6.2 | 4.3 | 6.0 | 6.3 | MD 2 | 6.6 | 5.1 | 6.4 | 6.0 | 6.7 | FD 1 | | | | | | | |
| 8372 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8373 | 7.7 | 8.3 | 7.3 | 8.0 | 7.8 | 7.7 | MD 2 | 6.9 | 7.4 | 8.5 | 7.5 | | | | | | | | |
| 8374 | 7.8 | 7.7 | 7.6 | 7.9 | 8.1 | 7.6 | 8.1 | 8.1 | 8.0 | 8.3 | | | | | | | | | |
| 8375 | MS | MS | FS | | | | | | | | | | | | | | | | |
| 8376 | 7.3 | 6.4 | 6.9 | 7.1 | 6.9 | 7.3 | 7.2 | 6.5 | 6.6 | 7.1 | 6.7 | 7.0 | | | | | | | |
| 8377 | 7.2 | 7.1 | 7.1 | 6.8 | 6.5 | 6.8 | 6.4 | 7.0 | 6.9 | 7.6 | 6.3 | | | | | | | | |
| 8378 | MS | MS | MS | MS | MS | FD 0 | FS | FS | FS | US | | | | | | | | | |
| 8379 | 6.6 | 7.0 | 5.9 | 6.1 | 6.0 | 6.0 | 6.5 | 6.0 | 6.2 | 6.6 | 5.3 | 7.3 | 6.7 | FD 0 | | | | | |
| 8380 | 8.9 | 8.8 | 8.7 | 9.1 | 8.8 | 9.1 | 8.9 | | | | | | | | | | | | |
| 8381 | MD 1 | MD 1 | MD 1 | MD 0 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 0 | FS | | | | | | | |
| 8382 | 4.3 | 5.9 | 5.0 | 5.8 | 5.6 | 4.5 | 5.1 | 5.3 | 5.9 | 5.5 | 5.3 | 6.2 | | | | | | | |
| 8383 | MD 0 | MD 0 | MD 0 | MD 0 | MS | FD 0 | FD 0 | FS | | | | | | | | | | | |
| 8384 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8385 | MD 0 | MD 0 | FD 0 | MS | FD 0 | MU | MU | MU | FD 0 | FD 0 | FU | FU | FU | UU | | | | | |
| 8386 | FOUND DEAD ON DAY 8 OF GESTATION | | | | | | | | | | | | | | | | | | |
| 8387a | 5.7 | 5.4 | 5.6 | 5.9 | 5.4 | 5.2 | 4.9 | 5.1 | FD 3 | FM 2 | FD 0 | FD 0 | FD 0 | FD 0 | | | | | |
| 8388a | 6.2 | 6.7 | 4.7 | MD 4 | MD 3 | MD 0 | MS | 6.3 | 6.3 | 5.5 | 6.5 | | | | | | | | |
| 8389 | MM 1 | MU | MU | FM 1 | FU | FU | | | | | | | | | | | | | |
| 8390 | 7.5 | 6.7 | 7.1 | 6.9 | 6.7 | MM 1 | 6.7 | 6.5 | 7.1 | 6.8 | FM 1 | FS | FS | | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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.
a. Mouse was found dead on day 13 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP I | | | | | | CONTROL | | | | | | 0 MG/KG/DAY | | | | | | DAY 20 POSTPARTUM |
| 8311 | 5.1 | 7.8 | 8.8 | 8.5 | 9.1 | 6.0 | 6.9 | 5.9 | 6.0 | 5.7 | 7.3 | 7.3 | 6.5 | 6.8 | 6.9 | 7.1 | | | |
| 8312 | 8.7 | 9.6 | 8.9 | 9.2 | 10.2 | 9.9 | 8.7 | 8.7 | 8.2 | 9.1 | 9.2 | 8.5 | 10.2 | 9.1 | FD 3 | | | | |
| 8313 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8314a | 11.8 | 12.4 | 11.8 | 12.5 | 11.9 | 10.9 | 12.5 | 11.7 | 12.2 | 12.0 | 10.8 | | | | | | | | |
| 8315 | 10.2 | 10.9 | 9.6 | 10.4 | 10.7 | 11.4 | 10.0 | 11.1 | 10.7 | 10.2 | 10.9 | 10.2 | 10.2 | | | | | | |
| 8316a | 9.4 | 10.0 | 9.4 | 10.5 | 9.1 | 10.3 | 10.0 | 7.5 | 8.7 | 10.7 | 8.7 | 9.6 | 9.1 | 8.8 | | | | | |
| 8317 | 11.5 | 11.0 | 11.0 | 12.8 | 11.6 | 11.2 | MS | 11.3 | 11.7 | 11.4 | 12.4 | 11.8 | | | | | | | |
| 8318 | 16.8 | 16.5 | 16.5 | 17.5 | | | | | | | | | | | | | | | |
| 8319 | 8.8 | 10.8 | 10.7 | 10.8 | 10.0 | 10.3 | 10.8 | 10.5 | 10.2 | 10.5 | 11.2 | 10.7 | 9.6 | | | | | | |
| 8320 | 17.8 | 17.7 | 16.8 | 17.2 | 16.5 | | | | | | | | | | | | | | |
| 8321 | 16.9 | 16.1 | MS | MS | 16.8 | 16.3 | FS | | | | | | | | | | | | |
| 8322 | 10.0 | 9.3 | 10.1 | 11.3 | 9.6 | 10.5 | 9.4 | 10.8 | 9.6 | 10.0 | 7.7 | 9.2 | 10.1 | 9.6 | | | | | |
| 8323 | 8.2 | 7.5 | 8.6 | 10.6 | 8.4 | 9.3 | 7.8 | 10.3 | 9.0 | 6.5 | 6.5 | 9.1 | 9.8 | 10.8 | 9.7 | 8.4 | | | |
| 8324 | 12.8 | 10.1 | 13.5 | 12.9 | 12.6 | 12.9 | 13.9 | 13.2 | 12.4 | 12.3 | 11.7 | 12.7 | | | | | | | |
| 8325 | 9.6 | 8.9 | 8.5 | 9.1 | 8.0 | 9.0 | 9.0 | 8.2 | 9.0 | 7.9 | 7.8 | 8.4 | 9.5 | 9.3 | | | | | |
| 8326 | 7.8 | 7.6 | 11.6 | 10.5 | 10.7 | 9.2 | 11.3 | 9.3 | 9.7 | 10.7 | 9.2 | 8.7 | 11.6 | 9.7 | 9.8 | | | | |
| 8327 | 5.8 | 9.0 | 8.8 | 8.6 | 9.5 | 9.2 | 9.6 | 7.8 | 8.6 | 9.0 | 9.5 | 8.5 | | | | | | | |
| 8328b | 9.4 | 6.5 | 9.5 | 7.3 | 8.8 | MM 7 | 7.0 | 6.2 | 7.5 | 8.9 | 9.5 | 10.4 | 10.2 | | | | | | |
| 8329 | FD 3 | | | | | | | | | | | | | | | | | | |
| 8330 | 9.9 | 11.5 | 10.8 | 9.9 | 10.2 | 11.0 | 10.2 | 10.9 | 9.9 | 10.1 | 9.5 | 9.4 | 9.6 | 6.0 | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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.
a. Mouse was found dead on day 16 of lactation; pups remained on study to day 20 postpartum.
b. Mouse was found dead on day 14 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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 18): PUP BODY WEIGHTS FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP II | | | | | LOW DOSAGE | | | | | | 100 MG/KG/DAY | | | | | | DAY 20 POSTPARTUM | |
| 8331 | 8.0 | 8.8 | 10.9 | 7.9 | 9.8 | 10.3 | 10.6 | 11.3 | 5.6 | 9.9 | 9.2 | 8.2 | 8.1 | 9.6 | FD19 | | | | |
| 8332 | 10.2 | 9.8 | 11.2 | 11.6 | 10.5 | 10.9 | 10.4 | 10.6 | 10.4 | 10.6 | 10.6 | 10.1 | FD 3 | | | | | | |
| 8333a | 7.2 | 7.6 | 8.1 | 8.6 | 8.1 | 8.6 | 8.1 | 8.6 | 7.7 | 9.4 | 9.0 | 7.6 | 9.1 | 7.9 | | | | | |
| 8334 | 9.7 | 12.0 | 9.7 | 9.2 | 10.2 | 11.9 | 10.9 | 10.7 | 9.8 | 11.5 | 10.4 | FM11 | | | | | | | |
| 8335 | 11.9 | 10.9 | 10.9 | 11.5 | 13.3 | 11.9 | 12.6 | 8.6 | 9.5 | 11.3 | 11.1 | 11.4 | 11.3 | | | | | | |
| 8336 | 11.8 | 13.0 | 11.3 | 12.6 | 9.9 | 10.8 | 12.3 | 10.8 | 12.9 | 10.8 | 11.0 | FM 1 | | | | | | | |
| 8337 | 10.2 | 11.1 | 10.6 | 10.6 | 11.2 | 11.1 | 11.1 | 11.4 | 11.3 | 11.1 | | | | | | | | | |
| 8338 | 12.4 | 13.1 | 12.3 | 10.9 | 12.9 | 13.1 | 12.8 | 12.5 | 10.6 | 11.4 | 12.2 | 11.7 | 11.5 | | | | | | |
| 8339 | 9.3 | 8.0 | 9.7 | 9.2 | 10.6 | 11.3 | 10.3 | 8.0 | 10.5 | 9.2 | 10.3 | 9.6 | 8.9 | FM 1 | | | | | |
| 8340 | 8.8 | 8.9 | 10.9 | 10.4 | 9.6 | 9.6 | 11.9 | 9.8 | 8.3 | 11.4 | 10.7 | 10.6 | | | | | | | |
| 8341 | 6.5 | 9.2 | 8.1 | 7.8 | 10.2 | 9.6 | 9.5 | 7.1 | 8.4 | 8.6 | 7.4 | 8.1 | FD18 | | | | | | |
| 8342 | 10.4 | 9.7 | 8.4 | 10.6 | 9.9 | 10.8 | 9.4 | 9.9 | 9.4 | 9.3 | 10.4 | 10.0 | | | | | | | |
| 8343b | 6.8 | 8.4 | 7.7 | 7.0 | 8.7 | 6.2 | 6.1 | 6.0 | 7.9 | 7.1 | 9.2 | | | | | | | | |
| 8344c | 6.8 | 8.1 | 4.4 | MD 5 | 8.3 | 7.2 | 7.5 | 6.7 | 6.4 | 6.1 | 6.8 | 8.0 | FD16 | FD15 | FD15 | | | | |
| 8345 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8346b | 4.5 | 6.2 | 5.2 | MD16 | MD14 | 4.9 | 5.9 | 7.1 | FD16 | FD16 | FD16 | FD15 | FD15 | | | | | | |
| 8347b | 5.1 | 7.7 | MD17 | MD17 | MD16 | MD16 | MD15 | MD15 | MD14 | 5.0 | 5.7 | FD17 | FD16 | FD16 | FD16 | FD15 | FD15 | | |
| 8348b | 4.3 | 5.9 | 5.4 | 7.4 | 9.7 | 9.5 | 7.2 | MD18 | MD16 | MD15 | 7.5 | FD16 | FD16 | FD16 | FD15 | | | | |
| 8349 | 9.1 | 10.2 | 11.0 | 10.8 | 10.8 | 11.5 | 10.7 | 10.2 | 10.0 | 10.6 | 10.3 | 10.3 | | | | | | | |
| 8350 | 8.1 | 7.3 | 8.2 | 7.5 | 7.4 | 7.7 | 7.6 | 6.8 | 8.9 | 4.7 | 7.2 | 8.2 | 7.0 | 7.3 | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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.
a. Mouse was found dead on day 16 of lactation; pups remained on study to day 20 postpartum.
b. Mouse was found dead on day 13 of lactation; pups remained on study to day 20 postpartum.
c. Mouse was found dead on day 14 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP III | | | | | | MIDDLE DOSAGE | | | | | 350 MG/KG/DAY | | | | | DAY 20 POSTPARTUM | | |
| 8351 | 6.3 | 7.0 | 4.6 | 6.2 | 6.3 | 10.0 | 7.6 | 7.9 | 7.5 | 6.9 | 8.1 | 5.1 | 8.4 | 5.0 | 4.1 | 7.9 | 7.9 | 5.7 | |
| 8352 | 5.8 | 7.3 | 10.8 | 10.2 | 9.9 | 8.9 | 10.4 | 9.9 | 8.2 | 9.0 | 11.5 | | | | | | | | |
| 8353 | 5.5 | 6.5 | 6.9 | 5.8 | 6.4 | 7.1 | MM11 | 7.2 | 6.6 | 5.3 | 6.3 | 6.1 | 5.7 | 6.2 | FD 5 | FS | | | |
| 8354 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | UU | MU | FM 1 | FM 1 | FM 1 | FM 1 | FD 0 | MU | FU | FD 0 | UU | UU |
| 8355 | 9.0 | 7.4 | 6.7 | 8.0 | 5.3 | MM 8 | MM 5 | 8.1 | 6.7 | 8.2 | 8.7 | 8.4 | 8.2 | 8.0 | | | | | |
| 8356 | 11.0 | 11.3 | 10.0 | 10.6 | 10.4 | 9.1 | 11.2 | 10.8 | 10.2 | 9.8 | 9.7 | UU | | | | | | | |
| 8357 | 5.1 | 9.5 | 7.6 | 5.1 | 7.7 | 6.5 | 11.1 | 9.2 | FS | UD 0 | | | | | | | | | |
| 8358 | MD 1 | MD 1 | MD 1 | MD 1 | MD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | US | | | | | | | | |
| 8359 | 6.3 | 6.3 | 5.7 | 5.2 | 5.9 | 5.4 | 5.7 | 8.1 | 6.2 | 7.2 | 7.5 | 6.2 | 5.9 | 5.8 | 6.0 | FM 9 | | | |
| 8360 | 7.4 | 7.8 | 8.3 | 8.5 | 7.5 | 8.3 | 7.1 | 8.0 | 8.2 | 8.1 | 8.2 | 7.2 | FD 5 | FS | | | | | |
| 8361 | FOUND DEAD ON DAY 13 OF GESTATION | | | | | | | | | | | | | | | | | | |
| 8362 | 6.5 | 7.8 | 8.3 | 8.2 | 8.5 | 8.2 | 6.6 | 7.3 | 7.9 | 8.5 | 7.9 | 6.6 | 7.6 | 7.3 | FU | | | | |
| 8363 | 15.9 | 16.8 | | | | | | | | | | | | | | | | | |
| 8364 | 6.9 | 5.7 | 4.7 | 5.7 | 8.3 | 7.2 | 9.1 | 7.8 | MD 4 | MD 2 | 9.0 | 7.4 | 9.5 | 7.4 | | | | | |
| 8365 | 14.6 | 14.4 | 14.8 | 14.7 | 12.8 | 13.8 | 13.6 | 14.1 | | | | | | | | | | | |
| 8366 | 9.1 | 8.9 | 9.6 | 8.9 | 9.5 | 5.3 | 9.2 | 10.2 | 9.2 | 8.6 | 9.2 | 9.3 | 8.8 | | | | | | |
| 8367 | 6.6 | 7.3 | 6.8 | 8.1 | 6.9 | 8.1 | 7.3 | 5.7 | 6.1 | 7.4 | 7.6 | FD 1 | | | | | | | |
| 8368 | 9.3 | 8.6 | 8.6 | 8.8 | 8.4 | 6.5 | 8.6 | 8.1 | 9.9 | 9.3 | 8.8 | 8.7 | 7.9 | | | | | | |
| 8369 | 8.7 | 9.6 | 11.1 | 9.9 | 8.7 | 10.3 | 10.1 | 8.2 | 9.0 | 8.4 | 10.3 | FM 1 | | | | | | | |
| 8370 | 6.1 | 8.1 | 9.1 | 8.8 | 8.4 | 8.5 | 7.8 | 8.8 | 8.7 | MS | 6.9 | 6.3 | 5.9 | 8.1 | 9.5 | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP IV | | | | | | HIGH DOSAGE | | | | | 500 MG/KG/DAY | | | | | DAY 20 POSTPARTUM | | |
| 8371 | 5.6 | 8.3 | 8.6 | 8.4 | 9.5 | MD 2 | 8.6 | 6.7 | 8.9 | 8.7 | 9.4 | FD 1 | | | | | | | |
| 8372 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8373 | 10.2 | 11.5 | 11.5 | 11.4 | 11.3 | 10.8 | MD 2 | 10.2 | 10.3 | 11.8 | 10.4 | | | | | | | | |
| 8374 | 10.3 | 11.4 | 11.5 | 11.4 | 10.8 | 11.6 | 10.5 | 11.9 | 11.8 | 11.4 | | | | | | | | | |
| 8375 | MS | MS | FS | | | | | | | | | | | | | | | | |
| 8376 | 8.7 | 9.9 | 10.7 | 10.0 | 10.4 | 10.0 | 9.9 | 10.8 | 9.1 | 9.8 | 10.1 | 10.0 | | | | | | | |
| 8377 | 10.0 | 10.4 | 9.4 | 10.1 | 10.4 | 10.5 | 8.7 | 9.5 | 9.5 | 8.4 | 9.7 | | | | | | | | |
| 8378 | MS | MS | MS | MS | MS | FD 0 | FS | FS | FS | US | | | | | | | | | |
| 8379 | 7.9 | 8.5 | 10.5 | 8.3 | 8.5 | 9.9 | 7.6 | 9.7 | 9.3 | 9.3 | 8.7 | 9.7 | 7.4 | FD 0 | | | | | |
| 8380 | 14.9 | 13.2 | 13.4 | 14.1 | 14.0 | 13.5 | 12.8 | | | | | | | | | | | | |
| 8381 | MD 1 | MD 1 | MD 1 | MD 0 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 0 | FS | | | | | | | |
| 8382 | 4.9 | 8.4 | 6.1 | 8.8 | 5.0 | 8.5 | 6.6 | 5.9 | 8.1 | 6.8 | 6.2 | 6.4 | | | | | | | |
| 8383 | MD 0 | MD 0 | MD 0 | MD 0 | MS | FD 0 | FD 0 | FS | | | | | | | | | | | |
| 8384 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8385 | MD 0 | MD 0 | FD 0 | MS | FD 0 | MU | MU | MU | FD 0 | FD 0 | FU | FU | FU | UU | | | | | |
| 8386 | FOUND DEAD ON DAY 8 OF GESTATION | | | | | | | | | | | | | | | | | | |
| 8387a | 7.7 | 7.3 | 9.2 | 8.5 | 5.8 | 9.1 | 7.0 | 8.5 | FD 3 | FM 2 | FD 0 | FD 0 | FD 0 | FD 0 | | | | | |
| 8388a | 8.1 | 8.9 | 6.0 | MD 4 | MD 3 | MD 0 | MS | 7.6 | 7.9 | 8.7 | 9.3 | | | | | | | | |
| 8389 | MM 1 | MU | MU | FM 1 | FU | FU | | | | | | | | | | | | | |
| 8390 | 10.5 | 11.2 | 11.2 | 11.4 | 10.7 | MM 1 | 12.4 | 9.9 | 11.4 | 10.6 | FM 1 | FS | FS | | | | | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G).
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.
a. Mouse was found dead on day 13 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP I | | | | | | | | | CONTROL | | | | | | | | 0 MG/KG/DAY | |
| 8311 | 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 | F A | F A | | | |
| 8312 | 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 | FD 3 | | | | |
| 8313 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8314a | M A | M A | M A | M A | M A | M A | F A | F A | F A | F A | F A | | | | | | | | |
| 8315 | M A | M A | M A | M A | M A | M A | M A | M A | M A | M A | M A | M A | M A | F A | | | | | |
| 8316a | 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 | | | | | |
| 8317 | M A | M A | M A | M A | M A | F A | M S | F A | F A | F A | F A | F A | | | | | | | |
| 8318 | M A | F A | F A | F A | | | | | | | | | | | | | | | |
| 8319 | 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 | | | | | | |
| 8320 | M A | M A | F A | F A | F A | | | | | | | | | | | | | | |
| 8321 | M A | M A | M S | M S | F A | F A | F S | | | | | | | | | | | | |
| 8322 | M A | M A | M A | M A | F A | F A | M A | F A | F A | F A | F A | F A | F A | F A | | | | | |
| 8323 | 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 | F A | F A | F A | | |
| 8324 | M A | M A | M A | M A | M A | M A | M A | F A | F A | F A | F A | F A | | | | | | | |
| 8325 | 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 | | | | | |
| 8326 | 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 | F A | | | | |
| 8327 | M A | M A | M A | M A | M A | M A | M A | F A | F A | F A | F A | F A | | | | | | | |
| 8328b | M A | M A | M A | M A | M A | MM 7 | F A | F A | F A | F A | F A | F A | F A | F A | | | | | |
| 8329 | FD 3 | | | | | | | | | | | | | | | | | | |
| 8330 | 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 | | | | | |

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.
a. Mouse was found dead on day 16 of lactation; pups remained on study to day 20 postpartum.
b. Mouse was found dead on day 14 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP II | | | | | | | | | LOW DOSAGE | | | | | | | | 100 MG/KG/DAY | |
| 8331 | 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 | | | | |
| 8332 | 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 | FD 3 | | | | | |
| 8333a | 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 | | | | | |
| 8334 | M A | M A | M A | M A | M A | M A | M A | M A | M A | F A | F A | F A | FM11 | | | | | | |
| 8335 | 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 | | | | | | |
| 8336 | M A | M A | M A | M A | M A | M A | M A | F A | F A | F A | F A | FM 1 | | | | | | | |
| 8337 | M A | M A | M A | M A | M A | F A | F A | F A | F A | F A | | | | | | | | | |
| 8338 | 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 | | | | | | |
| 8339 | 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 | FM 1 | | | | | |
| 8340 | M A | M A | M A | M A | M A | F A | F A | F A | F A | F A | F A | F A | | | | | | | |
| 8341 | M A | M A | M A | M A | M A | M A | M A | F A | F A | F A | F A | F A | FD18 | | | | | | |
| 8342 | M A | M A | M A | M A | F A | F A | F A | F A | F A | F A | F A | F A | | | | | | | |
| 8343b | M A | M A | M A | M A | M A | F A | F A | F A | F A | F A | F A | | | | | | | | |
| 8344c | M A | M A | F A | MD 5 | F A | F A | F A | F A | F A | F A | F A | F A | FD16 | FD15 | FD15 | | | | |
| 8345 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8346b | M A | M A | M A | MD16 | MD14 | F A | F A | F A | FD16 | FD16 | FD16 | FD15 | FD15 | | | | | | |
| 8347b | M A | M A | MD17 | MD17 | MD16 | MD16 | MD15 | MD15 | MD14 | F A | F A | FD17 | FD16 | FD16 | FD16 | FD15 | FD15 | | |
| 8348b | M A | M A | M A | M A | M A | M A | F A | MD18 | MD16 | MD15 | F A | FD16 | FD16 | FD16 | FD15 | | | | |
| 8349 | M A | M A | M A | M A | M A | M A | F A | F A | F A | F A | F A | F A | | | | | | | |
| 8350 | 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 | | | | | |

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.
a. Mouse was found dead on day 16 of lactation; pups remained on study to day 20 postpartum.
b. Mouse was found dead on day 13 of lactation; pups remained on study to day 20 postpartum.
c. Mouse was found dead on day 14 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP III | | | | | | | | MIDDLE DOSAGE | | | | | | | | | 350 MG/KG/DAY | |
| 8351 | M A | M A | 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 | F A | F A | |
| 8352 | M A | M A | M A | M A | M A | M A | M A | F A | F A | F A | F A | | | | | | | | |
| 8353 | M A | M A | M A | M A | M A | M A | MM11 | F A | F A | F A | F A | F A | F A | F A | FD 5 | F S | | | |
| 8354 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | MM 1 | U U | M U | FM 1 | FM 1 | FM 1 | FM 1 | FD 0 | M U | F U | FD 0 | U U | U U |
| 8355 | M A | M A | M A | M A | M A | MM 8 | MM 5 | M A | F A | F A | F A | F A | F A | F A | | | | | |
| 8356 | M A | M A | M A | M A | M A | M A | F A | F A | F A | F A | F A | U U | | | | | | | |
| 8357 | M A | M A | M A | M A | M A | F A | F A | F A | F S | UD 0 | | | | | | | | | |
| 8358 | MD 1 | MD 1 | MD 1 | MD 1 | MD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | U S | | | | | | | | |
| 8359 | 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 | FM 9 | | | |
| 8360 | 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 5 | F S | | | | | |
| 8361 | FOUND DEAD ON DAY 13 OF GESTATION | | | | | | | | | | | | | | | | | | |
| 8362 | 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 | F U | | | | |
| 8363 | M A | M A | | | | | | | | | | | | | | | | | |
| 8364 | M A | M A | M A | M A | M A | M A | M A | M A | MD 4 | MD 2 | M A | F A | F A | F A | | | | | |
| 8365 | M A | M A | M A | M A | F A | F A | F A | F A | | | | | | | | | | | |
| 8366 | 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 | | | | | | |
| 8367 | M A | M A | M A | M A | M A | M A | M A | F A | F A | F A | F A | FD 1 | | | | | | | |
| 8368 | 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 | | | | | | |
| 8369 | M A | M A | M A | M A | M A | F A | F A | F A | F A | F A | F A | FM 1 | | | | | | | |
| 8370 | M A | M A | M A | M A | F A | F A | F A | F A | F A | M S | 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 20005045: 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 4): PUP VITAL STATUS AND SEX FROM BIRTH TO DAY 20 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

| PUP # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MOUSE/ LITTER # | MATERNAL DOSAGE GROUP IV | | | | | | | HIGH DOSAGE | | | | | | | | | 500 MG/KG/DAY | | |
| 8371 | M A | M A | M A | M A | F A | MD 2 | F A | F A | F A | F A | F A | FD 1 | | | | | | | |
| 8372 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8373 | M A | M A | M A | M A | M A | M A | MD 2 | F A | F A | F A | F A | | | | | | | | |
| 8374 | M A | M A | M A | M A | F A | F A | F A | F A | F A | F A | | | | | | | | | |
| 8375 | M S | M S | F S | | | | | | | | | | | | | | | | |
| 8376 | M A | M A | M A | M A | M A | M A | F A | F A | F A | F A | F A | F A | | | | | | | |
| 8377 | M A | M A | M A | M A | M A | F A | F A | F A | F A | F A | F A | | | | | | | | |
| 8378 | M S | M S | M S | M S | M S | FD 0 | F S | F S | F S | U S | | | | | | | | | |
| 8379 | 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 0 | | | | | |
| 8380 | M A | M A | M A | M A | F A | F A | F A | | | | | | | | | | | | |
| 8381 | MD 1 | MD 1 | MD 1 | MD 0 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 1 | FD 0 | F S | | | | | | | |
| 8382 | M A | M A | M A | F A | F A | F A | F A | F A | F A | F A | F A | | | | | | | | |
| 8383 | MD 0 | MD 0 | MD 0 | MD 0 | M S | FD 0 | FD 0 | F S | | | | | | | | | | | |
| 8384 | NOT PREGNANT | | | | | | | | | | | | | | | | | | |
| 8385 | MD 0 | MD 0 | FD 0 | M S | FD 0 | M U | M U | M U | FD 0 | FD 0 | F U | F U | F U | U U | | | | | |
| 8386 | FOUND DEAD ON DAY 8 OF GESTATION | | | | | | | | | | | | | | | | | | |
| 8387a | M A | M A | M A | M A | F A | F A | F A | F A | FD 3 | FM 2 | FD 0 | FD 0 | FD 0 | FD 0 | | | | | |
| 8388a | M A | M A | M A | MD 4 | MD 3 | MD 0 | M S | F A | F A | F A | F A | | | | | | | | |
| 8389 | MM 1 | M U | M U | FM 1 | F U | F U | | | | | | | | | | | | | |
| 8390 | M A | M A | M A | M A | M A | MM 1 | M A | F A | F A | F A | FM 1 | F S | F S | | | | | | |

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.
a. Mouse was found dead on day 13 of lactation; pups remained on study to day 20 postpartum.

PROTOCOL 20005045: 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 1): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

| DOSAGE GROUP<br>DOSAGE (MG/KG/DAY) | MOUSE NUMBER | DAY OF NECROPSY | PREGNANCY STATUS | DOSES ADMINISTERED | OBSERVATIONS a |
|---|---|---|---|---|---|
| I<br>0 | 8311 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8312 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8313 | DG 23 | NP | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8314 | DL 16 | P | 13 | FOUND DEAD ON DAY 16 OF LACTATION.<br>ALL TISSUES APPEARED NORMAL FOR MODERATE DEGREE OF AUTOLYSIS. |
| | 8315 | DL 20 | P | 13 | STERNUM: BENT PROXIMAL TO XIPHOID PROCESS.<br>ALL OTHER TISSUES APPEARED NORMAL. |
| | 8316 | DL 16 | P | 13 | FOUND DEAD ON DAY 16 OF LACTATION.<br>ALL TISSUES APPEARED NORMAL FOR MODERATE DEGREE OF AUTOLYSIS. |
| | 8317 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8318 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8319 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8320 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8321 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8322 | DL 20 | P | 12b | ALL TISSUES APPEARED NORMAL. |
| | 8323 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8324 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8325 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8326 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8327 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8328 | DL 14 | P | 13 | FOUND DEAD ON DAY 14 OF LACTATION.<br>ALL TISSUES APPEARED NORMAL FOR MODERATE DEGREE OF AUTOLYSIS. |
| | 8329 | DL 3 | P | 13 | SACRIFICED ON DAY 3 OF LACTATION DUE TO NO SURVIVING PUPS.<br>ALL TISSUES APPEARED NORMAL. |
| | 8330 | 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 was not dosed on the day of delivery.

PROTOCOL 20005045: 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 100 | 8331 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8332 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8333 | DL 16 | P | 13 | FOUND DEAD ON DAY 16 OF LACTATION.<br>ALL TISSUES APPEARED NORMAL FOR SLIGHT DEGREE OF AUTOLYSIS. |
| | 8334 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8335 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8336 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8337 | DL 20 | P | 12b | ALL TISSUES APPEARED NORMAL. |
| | 8338 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8339 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8340 | DL 20 | P | 13 | STERNUM: BENT PROXIMAL TO XIPHOID PROCESS.<br>ALL OTHER TISSUES APPEARED NORMAL. |
| | 8341 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8342 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8343 | DL 13 | P | 13 | FOUND DEAD ON DAY 13 OF LACTATION.<br>ALL TISSUES APPEARED NORMAL FOR MODERATE DEGREE OF AUTOLYSIS. |
| | 8344 | DL 14 | P | 13 | FOUND DEAD ON DAY 14 OF LACTATION.<br>ALL TISSUES APPEARED NORMAL FOR MODERATE DEGREE OF AUTOLYSIS. |
| | 8345 | DG 23 | NP | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8346 | DL 13 | P | 13 | FOUND DEAD ON DAY 13 OF LACTATION.<br>ALL TISSUES APPEARED NORMAL FOR MODERATE DEGREE OF AUTOLYSIS. |
| | 8347 | DL 13 | P | 13 | FOUND DEAD ON DAY 13 OF LACTATION.<br>ALL TISSUES APPEARED NORMAL FOR MODERATE DEGREE OF AUTOLYSIS. |

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 was not dosed on the day of delivery.

PROTOCOL 20005045: 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 |
|---|---|---|---|---|---|
| II (CONT.) | | | | | |
| 100 | 8348 | DL 13 | P | 13 | FOUND DEAD ON DAY 13 OF LACTATION.<br>ALL TISSUES APPEARED NORMAL FOR MODERATE DEGREE OF AUTOLYSIS. |
| | 8349 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8350 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| III | | | | | |
| 350 | 8351 | DL 20 | P | 12b | ALL TISSUES APPEARED NORMAL. |
| | 8352 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8353 | DL 20 | P | 12b | ALL TISSUES APPEARED NORMAL. |
| | 8354 | DL 1 | P | 13 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS.<br>LIVER: ALL LOBES, NUMEROUS TAN AREAS (PINPOINT TO 4 MM X 3 MM).<br>ALL OTHER TISSUES APPEARED NORMAL. |
| | 8355 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8356 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8357 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8358 | DL 1 | P | 12b | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS.<br>ALL TISSUES APPEARED NORMAL. |
| | 8359 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8360 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8361 | DG 13 | P | 7 | FOUND DEAD ON DAY 13 OF GESTATION (DEATH OCCURRED OVERNIGHT).<br>ALL TISSUES APPEARED NORMAL.<br>GRAVID UTERINE WEIGHT: 2.78 G.<br>UTERINE CONTENTS: 14 IMPLANTATION SITES (14 EMBRYOS *IN UTERO*).c |
| | 8362 | DL 20 | P | 12b | ALL TISSUES APPEARED NORMAL. |
| | 8363 | 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 was not dosed on the day of delivery.
c. Viability of embryos at the time of maternal death could not be determined. Early developmental ages precluded further evaluation.

PROTOCOL 20005045: 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 |
|---|---|---|---|---|---|
| III (CONT.) | | | | | |
| 350 | 8364 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8365 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8366 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8367 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8368 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8369 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8370 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| IV | | | | | |
| 500 | 8371 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8372 | DG 23 | NP | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8373 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8374 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8375 | DL 0 | P | 13 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS.<br>INTESTINES: DISTENDED WITH GAS.<br>ALL OTHER TISSUES APPEARED NORMAL. |
| | 8376 | DL 20 | P | 12b | ALL TISSUES APPEARED NORMAL. |
| | 8377 | DL 20 | P | 12b | ALL TISSUES APPEARED NORMAL. |
| | 8378 | DL 0 | P | 13 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS.<br>LIVER: ALL LOBES, NUMEROUS TAN AREAS (PINPOINT TO 7 MM X 6 MM).<br>ALL OTHER TISSUES APPEARED NORMAL. |
| | 8379 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8380 | DL 20 | P | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8381 | DL 1 | P | 13 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS.<br>LIVER: MEDIAN LOBE, NUMEROUS TAN AREAS (PINPOINT TO 2 MM X 3 MM).<br>ALL OTHER TISSUES APPEARED NORMAL. |
| | 8382 | 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 was not dosed on the day of delivery.

PROTOCOL 20005045: 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 5): 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 (CONT.) 500 | 8383 | DL 0 | P | 13 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS.<br>LIVER: ALL LOBES, NUMEROUS TAN AREAS (PINPOINT TO 10 MM X 3 MM).<br>ALL OTHER TISSUES APPEARED NORMAL. |
| | 8384 | DG 23 | NP | 13 | ALL TISSUES APPEARED NORMAL. |
| | 8385 | DL 0 | P | 13 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS.<br>LIVER: LEFT LATERAL LOBE, TAN AREA (2 MM X 3 MM).<br>ALL OTHER TISSUES APPEARED NORMAL. |
| | 8386 | DG 8 | P | 2 | FOUND DEAD ON DAY 8 OF GESTATION (DEATH OCCURRED OVERNIGHT).<br>ALL TISSUES APPEARED NORMAL FOR SLIGHT DEGREE OF AUTOLYSIS.<br>UTERINE CONTENTS: 12 IMPLANTATION SITES (12 EMBRYOS *IN UTERO*).b |
| | 8387 | DL 13 | P | 13 | FOUND DEAD ON DAY 13 OF LACTATION.<br>ALL TISSUES APPEARED NORMAL FOR MODERATE DEGREE OF AUTOLYSIS. |
| | 8388 | DL 13 | P | 13 | FOUND DEAD ON DAY 13 OF LACTATION.<br>ALL TISSUES APPEARED NORMAL FOR MODERATE DEGREE OF AUTOLYSIS. |
| | 8389 | DL 1 | P | 13 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS.<br>LIVER: NUMEROUS TAN AREAS (PINPOINT TO 3 MM X 1 MM).<br>ALL OTHER TISSUES APPEARED NORMAL. |
| | 8390 | 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. Viability of embryos at the time of maternal death could not be determined. Early developmental ages precluded further evaluation.

PROTOCOL 20005045: 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. | LIVER REL. % TBW |
|---|---|---|---|---|
| DOSAGE GROUP I | | CONTROL | | 0 MG/KG/DAY |
| 8311 | P | 47.7 | 3.155 | 6.61 |
| 8312 | P | 43.5 | 3.441 | 7.91 |
| 8315 | P | 44.0 | 3.009 | 6.84 |
| 8317 | P | 44.0 | 3.247 | 7.38 |
| 8318 | P | 39.9 | 2.770 | 6.94 |
| DOSAGE GROUP II | | LOW DOSAGE | | 100 MG/KG/DAY |
| 8331 | P | 45.9 | 3.174 | 6.92 |
| 8332 | P | 37.8 | 2.789 | 7.38 |
| 8334 | P | 44.7 | 3.240 | 7.25 |
| 8335 | P | 43.2 | 3.725 | 8.62 |
| 8336 | P | 43.7 | 3.070 | 7.02 |
| DOSAGE GROUP III | | MIDDLE DOSAGE | | 350 MG/KG/DAY |
| 8351 | P | 52.6 | 3.605 | 6.85 |
| 8352 | P | 44.4 | 2.877 | 6.48 |
| 8353 | P | 44.2 | 3.108 | 7.03 |
| 8355 | P | 40.7 | 3.170 | 7.79 |
| 8356 | P | 46.5 | 3.600 | 7.74 |
| DOSAGE GROUP IV | | HIGH DOSAGE | | 500 MG/KG/DAY |
| 8371 | P | 44.2 | 2.811 | 6.36 |
| 8373 | P | 38.7 | 2.917 | 7.54 |
| 8374 | P | 43.9 | 2.872 | 6.54 |
| 8376 | P | 37.3 | 3.080 | 8.26 |
| 8377 | P | 36.6 | 2.650 | 7.24 |

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

PROTOCOL 20005045: 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 2): TERMINAL BODY WEIGHTS, LIVER WEIGHTS AND RATIOS (%) OF LIVER WEIGHT TO TERMINAL BODY WEIGHT - INDIVIDUAL DATA - F0 GENERATION FEMALE MICE

MICE THAT WERE NOT PREGNANT, FOUND DEAD OR SACRIFICED DUE TO NO SURVIVING PUPS a

| MOUSE NUMBER | PREGNANCY STATUS | LIVER ABS. WT. | |
|---|---|---|---|
| DOSAGE GROUP I | | CONTROL | 0 MG/KG/DAY |
| 8313 | NP | 1.599 | |
| 8314 | P | 2.907 | FOUND DEAD ON DAY 16 OF LACTATION |
| 8316 | P | 3.029 | FOUND DEAD ON DAY 16 OF LACTATION |
| 8328 | P | 2.669 | FOUND DEAD ON DAY 14 OF LACTATION |
| 8329 | P | 1.291 | SACRIFICED ON DAY 3 OF LACTATION DUE TO NO SURVIVING PUPS |
| DOSAGE GROUP II | | LOW DOSAGE | 100 MG/KG/DAY |
| 8333 | P | 2.598 | FOUND DEAD ON DAY 16 OF LACTATION |
| 8343 | P | 2.292 | FOUND DEAD ON DAY 13 OF LACTATION |
| 8344 | P | 2.068 | FOUND DEAD ON DAY 14 OF LACTATION |
| 8345 | NP | 1.646 | |
| 8346 | P | 2.587 | FOUND DEAD ON DAY 13 OF LACTATION |
| 8347 | P | 2.877 | FOUND DEAD ON DAY 13 OF LACTATION |
| 8348 | P | 2.761 | FOUND DEAD ON DAY 13 OF LACTATION |
| DOSAGE GROUP III | | MIDDLE DOSAGE | 350 MG/KG/DAY |
| 8354 | P | 3.740 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS |
| 8358 | P | 3.469 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS |
| 8361 | P | 3.201 | FOUND DEAD ON DAY 13 OF GESTATION |
| DOSAGE GROUP IV | | HIGH DOSAGE | 500 MG/KG/DAY |
| 8372 | NP | 1.792 | |
| 8375 | P | 2.085 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS |
| 8378 | P | 3.173 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS |
| 8381 | P | 3.572 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS |
| 8383 | P | 3.447 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS |
| 8384 | NP | 2.210 | |
| 8385 | P | 4.663 | SACRIFICED ON DAY 0 OF LACTATION DUE TO NO SURVIVING PUPS |
| 8386 | P | 1.806 | FOUND DEAD ON DAY 8 OF GESTATION |
| 8387 | P | 2.895 | FOUND DEAD ON DAY 13 OF LACTATION |
| 8388 | P | 2.384 | FOUND DEAD ON DAY 13 OF LACTATION |
| 8389 | P | 4.034 | SACRIFICED ON DAY 1 OF LACTATION DUE TO NO SURVIVING PUPS |

ALL WEIGHTS WERE RECORDED IN GRAMS (G). ABS. WT. = ORGAN WEIGHT.

a. Values for mice that were not pregnant, found dead or sacrificed due to no surviving pups were excluded from summarization and statistical analyses.

PROTOCOL 20005045: 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<br>MATERNAL DOSAGE (MG/KG/DAY) | LITTER NUMBER | DAY (S) POSTPARTUM | OBSERVATIONS a |
|---|---|---|---|
| I<br>0 | 8311 | 16 | 16/16 PUPS: UNGROOMED COAT. |
| | 8319 | 0 | 1/13 PUPS: TAIL, SCAB (PINPOINT). |
| II<br>100 | 8331 | 0- 5 | 1/15 PUPS: TIP OF TAIL, RED. |
| | 8344b | 16-17 | 11/11 PUPS: DEHYDRATION, MILD. |
| | 8346c | 15 | 10/10 PUPS: DEHYDRATION, MODERATE. |
| | | 16-17 | 6/ 6 PUPS: DEHYDRATION, MODERATE. |
| | | 18-19 | 6/ 6 PUPS: DEHYDRATION, MILD. |
| | 8347c | 15 | 12/12 PUPS: DEHYDRATION, MILD. |
| | | 16 | 7/ 7 PUPS: DEHYDRATION, MODERATE. |
| | | 17-19 | 4/ 4 PUPS: DEHYDRATION, MODERATE. |
| | | 20 | 4/ 4 PUPS: DEHYDRATION, MILD. |
| | 8348c | 15 | 13/13 PUPS: DEHYDRATION, MODERATE. |
| | | 16-17 | 9/ 9 PUPS: DEHYDRATION, MODERATE. |
| | | 18-20 | 8/ 8 PUPS: DEHYDRATION, MILD. |
| | 8350 | 9 | 1/14 PUPS: DEHYDRATION, MILD. |

a. Tabulation restricted to adverse observations; all other pups appeared normal.
b. Mouse was found dead on day 14 of lactation; pups remained on study to day 20 postpartum. Clinical observations of pups after day 14 postpartum were excluded from summarization and statistical analyses.
c. Mouse was found dead on day 13 of lactation; pups remained on study to day 20 postpartum. Clinical observations of pups after day 13 postpartum were excluded from summarization and statistical analyses.

PROTOCOL 20005045: 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<br>MATERNAL DOSAGE (MG/KG/DAY) | LITTER NUMBER | DAY (S) POSTPARTUM | OBSERVATIONS a |
|---|---|---|---|
| III<br>350 | 8351 | 0- 1 | 1/18 PUPS: RIGHT HINDLIMB, SCAB (2 MM X 1 MM). |
| | | 14 | 3/18 PUPS: DEHYDRATION, MILD. |
| | 8353 | 4 | 1/15 PUPS: TIP OF TAIL MISSING; TIP OF TAIL, RED. |
| | | 5-10 | 1/14 PUPS: TIP OF TAIL MISSING; TIP OF TAIL, RED. |
| | | 14 | 2/13 PUPS: DEHYDRATION, MILD. |
| | 8354 | 0 | 11/11 PUPS: NOT NURSING; NOT NESTING. |
| | 8355 | 4 | 1/14 PUPS: DEHYDRATION, MILD. |
| | 8360 | 4 | 1/13 PUPS: DEHYDRATION, MODERATE. |
| | 8369 | 0 | 1/12 PUPS: TIP OF TAIL MISSING. |
| IV<br>500 | 8377 | 4- 5 | 1/11 PUPS: LEFT SIDE OF BACK, SCAB (1 MM X 1 MM). |
| | 8388b | 3 | 1/ 8 PUPS: DEHYDRATION, MODERATE. |
| | | 17-18 | 7/ 7 PUPS: DEHYDRATION, MILD. |
| | | 19 | 7/ 7 PUPS: CLINICAL OBSERVATIONS WERE NOT RECORDED. |

a. Tabulation restricted to adverse observations; all other pups appeared normal.
b. Mouse was found dead on day 13 of lactation; pups remained on study to day 20 postpartum. Clinical observations of pups after day 13 postpartum were excluded from summarization and statistical analyses.

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

| POSTPARTUM DAY | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|
| LITTER # | MATERNAL DOSAGE GROUP I | | | | CONTROL | | | 0 MG/KG/DAY |
| 8311 | 0/16 | 0/16 | 0/16 | 0/16 | 3/16 | 14/16 | 16/16 | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 18.8% | 87.5% | 100.0% | |
| 8312 | 0/14 | 0/14 | 0/14 | 0/14 | 11/14 | 14/14 | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 78.6% | 100.0% | | |
| 8313 | NOT PREGNANT | | | | | | | |
| 8314 | 0/11 | 0/11 | 0/11 | 1/11 | 11/11 | | | |
| | 0.0% | 0.0% | 0.0% | 9.1% | 100.0% | | | |
| 8315 | 0/13 | 0/13 | 0/13 | 0/13 | 12/13 | 13/13 | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 92.3% | 100.0% | | |
| 8316 | 0/14 | 0/14 | 0/14 | 0/14 | 12/14 | 14/14 | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 85.7% | 100.0% | | |
| 8317 | 0/11 | 0/11 | 0/11 | 0/11 | 11/11 | | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 100.0% | | | |
| 8318 | 0/ 4 | 0/ 4 | 0/ 4 | 3/ 4 | 4/ 4 | | | |
| | 0.0% | 0.0% | 0.0% | 75.0% | 100.0% | | | |
| 8319 | 0/13 | 0/13 | 1/13 | 6/13 | 13/13 | | | |
| | 0.0% | 0.0% | 7.7% | 46.2% | 100.0% | | | |
| 8320 | 0/ 5 | 0/ 5 | 0/ 5 | 5/ 5 | | | | |
| | 0.0% | 0.0% | 0.0% | 100.0% | | | | |
| 8321 | 0/ 4 | 0/ 4 | 4/ 4 | | | | | |
| | 0.0% | 0.0% | 100.0% | | | | | |
| 8322 | 0/14 | 0/14 | 0/14 | 0/14 | 4/14 | 14/14 | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 28.6% | 100.0% | | |
| 8323 | 0/16 | 0/16 | 0/16 | 4/16 | 12/16 | 16/16 | | |
| | 0.0% | 0.0% | 0.0% | 25.0% | 75.0% | 100.0% | | |
| 8324 | 0/12 | 0/12 | 0/12 | 12/12 | | | | |
| | 0.0% | 0.0% | 0.0% | 100.0% | | | | |
| 8325 | 1/14 | 1/14 | 1/14 | 7/14 | 14/14 | | | |
| | 7.1% | 7.1% | 7.1% | 50.0% | 100.0% | | | |
| 8326 | 0/15 | 0/15 | 0/15 | 5/15 | 14/15 | 15/15 | | |
| | 0.0% | 0.0% | 0.0% | 33.3% | 93.3% | 100.0% | | |
| 8327 | 0/12 | 0/12 | 1/12 | 1/12 | 8/12 | 11/12 | 12/12 | |
| | 0.0% | 0.0% | 8.3% | 8.3% | 66.7% | 91.7% | 100.0% | |
| 8328 | 0/12 | 0/12 | 0/12 | 2/12 | 9/12 | 12/12 | | |
| | 0.0% | 0.0% | 0.0% | 16.7% | 75.0% | 100.0% | | |
| 8329 | NO SURVIVING PUPS ON DAY 3 POSTPARTUM | | | | | | | |
| 8330 | 0/14 | 0/14 | 0/14 | 1/14 | 10/14 | 13/14 | 14/14 | |
| | 0.0% | 0.0% | 0.0% | 7.1% | 71.4% | 92.8% | 100.0% | |

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

PROTOCOL 20005045: 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 LITTERS

| POSTPARTUM DAY | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|
| LITTER # | MATERNAL DOSAGE GROUP II | | | | LOW DOSAGE | | | 100 MG/KG/DAY |
| 8331 | 0/15 | 0/15 | 0/15 | 0/15 | 12/15 | 15/15 | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 80.0% | 100.0% | | |
| 8332 | 0/12 | 0/12 | 0/12 | 4/12 | 12/12 | | | |
| | 0.0% | 0.0% | 0.0% | 33.3% | 100.0% | | | |
| 8333 | 0/14 | 0/14 | 0/14 | 1/14 | 14/14 | | | |
| | 0.0% | 0.0% | 0.0% | 7.1% | 100.0% | | | |
| 8334 | 0/12 | 0/11 | 0/11 | 2/11 | 9/11 | 11/11 | | |
| | 0.0% | 0.0% | 0.0% | 18.2% | 81.8% | 100.0% | | |
| 8335 | 0/13 | 0/13 | 0/13 | 8/13 | 13/13 | | | |
| | 0.0% | 0.0% | 0.0% | 61.5% | 100.0% | | | |
| 8336 | 0/11 | 0/11 | 0/11 | 3/11 | 11/11 | | | |
| | 0.0% | 0.0% | 0.0% | 27.3% | 100.0% | | | |
| 8337 | 0/10 | 0/10 | 0/10 | 0/10 | 4/10 | 10/10 | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 40.0% | 100.0% | | |
| 8338 | 0/13 | 0/13 | 0/13 | 3/13 | 13/13 | | | |
| | 0.0% | 0.0% | 0.0% | 23.1% | 100.0% | | | |
| 8339 | 0/13 | 0/13 | 0/13 | 1/13 | 12/13 | 13/13 | | |
| | 0.0% | 0.0% | 0.0% | 7.7% | 92.3% | 100.0% | | |
| 8340 | 0/12 | 0/12 | 0/12 | 7/12 | 12/12 | | | |
| | 0.0% | 0.0% | 0.0% | 58.3% | 100.0% | | | |
| 8341 | 0/13 | 0/13 | 0/13 | 0/13 | 9/13 | 13/13 | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 69.2% | 100.0% | | |
| 8342 | 0/12 | 0/12 | 0/12 | 0/12 | 6/12 | 10/12 | 12/12 | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 50.0% | 83.3% | 100.0% | |
| 8343 | 0/11 | 0/11 | 0/11 | 0/11 | 6/11 | 11/11 | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 54.5% | 100.0% | | |
| 8344 | 0/14 | 0/14 | 0/14 | 0/14 | 1/14 | 10/13 | 11/11 | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 7.1% | 76.9% | 100.0% | |
| 8345 | NOT PREGNANT | | | | | | | |
| 8346 | 0/13 | 0/13 | 0/13 | 0/13 | 0/13 | 3/10 | 6/ 6 | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 30.0% | 100.0% | |
| 8347 | 0/17 | 0/17 | 0/17 | 0/17 | 0/16 | 1/12 | 6/ 7 | 4/ 4 |
| | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 8.3% | 85.7% | 100.0% |
| 8348 | 1/15 | 1/15 | 1/15 | 1/15 | 11/15 | 11/13 | 9/ 9 | |
| | 6.7% | 6.7% | 6.7% | 6.7% | 73.3% | 84.6% | 100.0% | |
| 8349 | 0/12 | 0/12 | 1/12 | 2/12 | 11/12 | 12/12 | | |
| | 0.0% | 0.0% | 8.3% | 16.7% | 91.7% | 100.0% | | |
| 8350 | 0/14 | 0/14 | 0/14 | 1/14 | 9/14 | 13/14 | 14/14 | |
| | 0.0% | 0.0% | 0.0% | 7.1% | 64.3% | 92.8% | 100.0% | |

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

PROTOCOL 20005045: 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 LITTERS

| POSTPARTUM DAY | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|
| LITTER # | MATERNAL DOSAGE GROUP III | | | | MIDDLE DOSAGE | | | 350 MG/KG/DAY |
| 8351 | 0/18 | 0/18 | 0/18 | 0/18 | 0/18 | 8/18 | 15/18 | 18/18 |
| | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 44.4% | 83.3% | 100.0% |
| 8352 | 0/11 | 0/11 | 0/11 | 0/11 | 6/11 | 11/11 | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 54.5% | 100.0% | | |
| 8353 | 0/14 | 0/13 | 0/13 | 0/13 | 0/13 | 0/13 | 3/13 | 13/13 |
| | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 23.1% | 100.0% |
| 8354 | NO SURVIVING PUPS ON DAY 1 POSTPARTUM | | | | | | | |
| 8355 | 0/12 | 0/12 | 0/12 | 1/12 | 4/12 | 12/12 | | |
| | 0.0% | 0.0% | 0.0% | 8.3% | 33.3% | 100.0% | | |
| 8356 | 1/11 | 1/11 | 1/11 | 1/11 | 9/11 | 11/11 | | |
| | 9.1% | 9.1% | 9.1% | 9.1% | 81.8% | 100.0% | | |
| 8357 | 0/ 8 | 0/ 8 | 0/ 8 | 3/ 8 | 8/ 8 | | | |
| | 0.0% | 0.0% | 0.0% | 37.5% | 100.0% | | | |
| 8358 | NO SURVIVING PUPS ON DAY 1 POSTPARTUM | | | | | | | |
| 8359 | 0/15 | 0/15 | 0/15 | 0/15 | 3/15 | 15/15 | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 20.0% | 100.0% | | |
| 8360 | 0/12 | 0/12 | 0/12 | 0/12 | 2/12 | 10/12 | 12/12 | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 16.7% | 83.3% | 100.0% | |
| 8361 | FOUND DEAD ON DAY 13 OF GESTATION | | | | | | | |
| 8362 | 0/14 | 0/14 | 0/14 | 0/14 | 2/14 | 11/14 | 14/14 | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 14.3% | 78.6% | 100.0% | |
| 8363 | 0/ 2 | 0/ 2 | 0/ 2 | 2/ 2 | | | | |
| | 0.0% | 0.0% | 0.0% | 100.0% | | | | |
| 8364 | 0/12 | 0/12 | 0/12 | 0/12 | 0/12 | 0/12 | 5/12 | 12/12 |
| | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 41.7% | 100.0% |
| 8365 | 0/ 8 | 0/ 8 | 0/ 8 | 3/ 8 | 8/ 8 | | | |
| | 0.0% | 0.0% | 0.0% | 37.5% | 100.0% | | | |
| 8366 | 0/13 | 0/13 | 0/13 | 3/13 | 12/13 | 13/13 | | |
| | 0.0% | 0.0% | 0.0% | 23.1% | 92.3% | 100.0% | | |
| 8367 | 0/11 | 0/11 | 0/11 | 0/11 | 0/11 | 1/11 | 11/11 | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 9.1% | 100.0% | |
| 8368 | 0/13 | 0/13 | 0/13 | 0/13 | 2/13 | 13/13 | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 15.4% | 100.0% | | |
| 8369 | 0/11 | 0/11 | 1/11 | 1/11 | 7/11 | 11/11 | | |
| | 0.0% | 0.0% | 9.1% | 9.1% | 63.6% | 100.0% | | |
| 8370 | 0/14 | 0/14 | 0/14 | 0/14 | 3/14 | 11/14 | 14/14 | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 21.4% | 78.6% | 100.0% | |

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

PROTOCOL 20005045: 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 LITTERS

| POSTPARTUM DAY | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|
| LITTER # | MATERNAL DOSAGE GROUP IV | | | | HIGH DOSAGE | | | 500 MG/KG/DAY |
| 8371 | 0/10 | 0/10 | 0/10 | 0/10 | 1/10 | 1/10 | 10/10 | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 10.0% | 10.0% | 100.0% | |
| 8372 | NOT PREGNANT | | | | | | | |
| 8373 | 0/10 | 0/10 | 0/10 | 1/10 | 5/10 | 10/10 | | |
| | 0.0% | 0.0% | 0.0% | 10.0% | 50.0% | 100.0% | | |
| 8374 | 0/10 | 0/10 | 0/10 | 2/10 | 10/10 | | | |
| | 0.0% | 0.0% | 0.0% | 20.0% | 100.0% | | | |
| 8375 | NO SURVIVING PUPS ON DAY 0 POSTPARTUM | | | | | | | |
| 8376 | 0/12 | 0/12 | 0/12 | 0/12 | 2/12 | 12/12 | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 16.7% | 100.0% | | |
| 8377 | 0/11 | 0/11 | 0/11 | 1/11 | 9/11 | 11/11 | | |
| | 0.0% | 0.0% | 0.0% | 9.1% | 81.8% | 100.0% | | |
| 8378 | NO SURVIVING PUPS ON DAY 0 POSTPARTUM | | | | | | | |
| 8379 | 0/13 | 0/13 | 0/13 | 0/13 | 9/13 | 13/13 | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 69.2% | 100.0% | | |
| 8380 | 0/ 7 | 0/ 7 | 1/ 7 | 7/ 7 | | | | |
| | 0.0% | 0.0% | 14.3% | 100.0% | | | | |
| 8381 | NO SURVIVING PUPS ON DAY 1 POSTPARTUM | | | | | | | |
| 8382 | 0/12 | 0/12 | 0/12 | 2/12 | 7/12 | 10/12 | 11/12 | 12/12 |
| | 0.0% | 0.0% | 0.0% | 16.7% | 58.3% | 83.3% | 91.7% | 100.0% |
| 8383 | NO SURVIVING PUPS ON DAY 0 POSTPARTUM | | | | | | | |
| 8384 | NOT PREGNANT | | | | | | | |
| 8385 | NO SURVIVING PUPS ON DAY 0 POSTPARTUM | | | | | | | |
| 8386 | FOUND DEAD ON DAY 8 OF GESTATION | | | | | | | |
| 8387 | 0/ 8 | 0/ 8 | 0/ 8 | 0/ 8 | 0/ 8 | 0/ 8 | 8/ 8 | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 100.0% | |
| 8388 | 0/ 7 | 0/ 7 | 0/ 7 | 0/ 7 | 0/ 7 | 1/ 7 | 7/ 7 | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 14.3% | 100.0% | |
| 8389 | NO SURVIVING PUPS ON DAY 1 POSTPARTUM | | | | | | | |
| 8390 | 0/ 9 | 0/ 9 | 0/ 9 | 0/ 9 | 6/ 9 | 9/ 9 | | |
| | 0.0% | 0.0% | 0.0% | 0.0% | 66.7% | 100.0% | | |

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

PROTOCOL 20005045: 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<br>MATERNAL DOSAGE (MG/KG/DAY) | LITTER NUMBER | DAY POSTPARTUM | OBSERVATIONS a |
|---|---|---|---|
| I<br>0 | 8311 | 20 | 14 PUPS: APPEARED NORMAL. |
| | 8312 | 3 | 1 PUP: FOUND DEAD. PARTIALLY CANNIBALIZED. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | | 20 | 12 PUPS: APPEARED NORMAL. |
| | 8314 | 20 | 9 PUPS: APPEARED NORMAL. |
| | 8315 | 20 | 11 PUPS: APPEARED NORMAL. |
| | 8316 | 20 | 12 PUPS: APPEARED NORMAL. |
| | 8317 | 0 | 1 PUP: STILLBORN. PARTIALLY CANNIBALIZED. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 20 | 9 PUPS: APPEARED NORMAL. |
| | 8318 | 20 | 2 PUPS: APPEARED NORMAL. |
| | 8319 | 20 | 11 PUPS: APPEARED NORMAL. |
| | 8320 | 20 | 3 PUPS: APPEARED NORMAL. |
| | 8321 | 0 | 3 PUPS: STILLBORN. ALL TISSUES APPEARED NORMAL. |
| | | 20 | 2 PUPS: APPEARED NORMAL. |
| | 8322 | 20 | 12 PUPS: APPEARED NORMAL. |
| | 8323 | 20 | 13 PUPS: APPEARED NORMAL. |
| | 8324 | 20 | 8 PUPS: APPEARED NORMAL. |
| | 8325 | 20 | 11 PUPS: APPEARED NORMAL. |
| | 8326 | 20 | 13 PUPS: APPEARED NORMAL. |
| | 8327 | 20 | 10 PUPS: APPEARED NORMAL. |
| | 8328 | 20 | 10 PUPS: APPEARED NORMAL. |
| | 8329 | 3 | 1 PUP: FOUND DEAD. HEART AND LUNGS APPEARED NORMAL. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | 8330 | 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 20005045: 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<br>MATERNAL DOSAGE (MG/KG/DAY) | LITTER NUMBER | DAY POSTPARTUM | OBSERVATIONS a |
|---|---|---|---|
| II<br>100 | 8331 | 19 | 1 PUP: FOUND DEAD. PARTIALLY CANNIBALIZED. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | | 20 | 12 PUPS: APPEARED NORMAL. |
| | 8332 | 3 | 1 PUP: FOUND DEAD. PARTIALLY CANNIBALIZED. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 20 | 10 PUPS: APPEARED NORMAL. |
| | 8333 | 20 | 12 PUPS: APPEARED NORMAL. |
| | 8334 | 20 | 9 PUPS: APPEARED NORMAL. |
| | 8335 | 20 | 11 PUPS: APPEARED NORMAL. |
| | 8336 | 20 | 9 PUPS: APPEARED NORMAL. |
| | 8337 | 20 | 8 PUPS: APPEARED NORMAL. |
| | 8338 | 20 | 11 PUPS: APPEARED NORMAL. |
| | 8339 | 20 | 11 PUPS: APPEARED NORMAL. |
| | 8340 | 20 | 10 PUPS: APPEARED NORMAL. |
| | 8341 | 18 | 1 PUP: FOUND DEAD. ALL TISSUES APPEARED NORMAL. |
| | | 20 | 10 PUPS: APPEARED NORMAL. |
| | 8342 | 20 | 9 PUPS: APPEARED NORMAL. |
| | 8343 | 20 | 9 PUPS: APPEARED NORMAL. |
| | 8344b | 5 | 1 PUP: FOUND DEAD. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | | 15 | 2 PUPS: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 16 | 1 PUP: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 20 | 8 PUPS: APPEARED NORMAL. |
| | 8346c | 14 | 1 PUP: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 15 | 2 PUPS: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 16 | 4 PUPS: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 20 | 4 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 was found dead on day 14 of lactation; pups remained on study to day 20 postpartum. Any mortality of pups after day 14 postpartum were excluded from summarization and statistical analyses.
c. Mouse was found dead on day 13 of lactation; pups remained on study to day 20 postpartum. Any mortality of pups after day 13 postpartum were excluded from summarization and statistical analyses.

PROTOCOL 20005045: 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<br>MATERNAL DOSAGE (MG/KG/DAY) | LITTER NUMBER | DAY POSTPARTUM | OBSERVATIONS a |
|---|---|---|---|
| II (CONT.) | | | |
| 100 | 8347b | 14 | 1 PUP: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 15 | 4 PUPS: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 16 | 5 PUPS: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 17 | 3 PUPS: FOUND DEAD. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | | 20 | 2 PUPS: APPEARED NORMAL. |
| | 8348b | 15 | 2 PUPS: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 16 | 4 PUPS: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 18 | 1 PUP: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 20 | 6 PUPS: APPEARED NORMAL. |
| | 8349 | 20 | 10 PUPS: APPEARED NORMAL. |
| | 8350 | 20 | 12 PUPS: APPEARED NORMAL. |
| III | | | |
| 350 | 8351 | 20 | 15 PUPS: APPEARED NORMAL. |
| | 8352 | 20 | 7 PUPS: APPEARED NORMAL. |
| | 8353 | 0 | 1 PUP: STILLBORN. ALL TISSUES APPEARED NORMAL. |
| | | 5 | 1 PUP: FOUND DEAD. ALL TISSUES APPEARED NORMAL. |
| | | 20 | 11 PUPS: APPEARED NORMAL. |
| | 8354 | 0 | 2 PUPS: FOUND DEAD. ALL TISSUES APPEARED NORMAL. |
| | | | 3 PUPS: FOUND DEAD. PARTIALLY CANNIBALIZED. VIABILITY COULD NOT BE DETERMINED. ALL OTHER TISSUES APPEARED NORMAL. |
| | | | 3 PUPS: FOUND DEAD. PARTIALLY CANNIBALIZED. SEX AND VIABILITY COULD NOT BE DETERMINED. ALL OTHER TISSUES APPEARED NORMAL. |
| | 8355 | 20 | 10 PUPS: APPEARED NORMAL. |
| | 8356 | 0 | 1 PUP: FOUND DEAD. PARTIALLY CANNIBALIZED. SEX AND VIABILITY COULD NOT BE DETERMINED. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 20 | 9 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 was found dead on day 13 of lactation; pups remained on study to day 20 postpartum. Any mortality of pups after day 13 postpartum were excluded from summarization and statistical analyses.

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

| MATERNAL DOSAGE GROUP<br>MATERNAL DOSAGE (MG/KG/DAY) | LITTER NUMBER | DAY POSTPARTUM | OBSERVATIONS a |
|---|---|---|---|
| III (CONT.) | | | |
| 350 | 8357 | 0 | 1 PUP: STILLBORN. ALL TISSUES APPEARED NORMAL. |
| | | | 1 PUP: FOUND DEAD. PARTIALLY CANNIBALIZED. SEX COULD NOT BE DETERMINED. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 20 | 4 PUPS: APPEARED NORMAL. |
| | 8358 | 0 | 1 PUP: STILLBORN. PARTIALLY CANNIBALIZED. SEX COULD NOT BE DETERMINED. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 1 | 9 PUPS: FOUND DEAD. PARTIALLY CANNIBALIZED. ALL OTHER TISSUES APPEARED NORMAL. |
| | | | 1 PUP: FOUND DEAD. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | 8359 | 20 | 13 PUPS: APPEARED NORMAL. |
| | 8360 | 0 | 1 PUP: STILLBORN. ALL TISSUES APPEARED NORMAL. |
| | | 5 | 1 PUP: FOUND DEAD. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | | 20 | 10 PUPS: APPEARED NORMAL. |
| | 8362 | 0 | 1 PUP: FOUND DEAD. PARTIALLY CANNIBALIZED. VIABILITY COULD NOT BE DETERMINED. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 20 | 12 PUPS: APPEARED NORMAL. |
| | 8363 | 20 | 1 PUP: APPEARED NORMAL. |
| | 8364 | 2 | 1 PUP: FOUND DEAD. ALL TISSUES APPEARED NORMAL. |
| | | 4 | 1 PUP: FOUND DEAD. ALL TISSUES APPEARED NORMAL. |
| | | 20 | 10 PUPS: APPEARED NORMAL. |
| | 8365 | 20 | 5 PUPS: APPEARED NORMAL. |
| | 8366 | 20 | 10 PUPS: APPEARED NORMAL. |
| | 8367 | 1 | 1 PUP: FOUND DEAD. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | | 20 | 9 PUPS: APPEARED NORMAL. |
| | 8368 | 20 | 11 PUPS: APPEARED NORMAL. |
| | 8369 | 20 | 9 PUPS: APPEARED NORMAL. |
| | 8370 | 0 | 1 PUP: STILLBORN. ALL TISSUES APPEARED NORMAL. |
| | | 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 20005045: 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 5): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION PUPS

| MATERNAL DOSAGE GROUP<br>MATERNAL DOSAGE (MG/KG/DAY) | LITTER NUMBER | DAY POSTPARTUM | OBSERVATIONS a |
|---|---|---|---|
| IV<br>500 | 8371 | 1 | 1 PUP: FOUND DEAD. HEART AND LUNGS APPEARED NORMAL. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | | 2 | 1 PUP: FOUND DEAD. ALL TISSUES APPEARED NORMAL. |
| | | 20 | 6 PUPS: APPEARED NORMAL. |
| | 8373 | 2 | 1 PUP: FOUND DEAD. NO MILK IN STOMACH. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | | 20 | 7 PUPS: APPEARED NORMAL. |
| | 8374 | 20 | 6 PUPS: APPEARED NORMAL. |
| | 8375 | 0 | 3 PUPS: STILLBORN. PARTIALLY CANNIBALIZED. ALL OTHER TISSUES APPEARED NORMAL FOR DEVELOPMENTAL AGE AND SLIGHT DEGREE OF AUTOLYSIS. |
| | 8376 | 20 | 8 PUPS: APPEARED NORMAL. |
| | 8377 | 20 | 7 PUPS: APPEARED NORMAL. |
| | 8378 | 0 | 5 PUPS: STILLBORN. ALL TISSUES APPEARED NORMAL. |
| | | | 1 PUP: STILLBORN. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | | | 2 PUPS: STILLBORN. PARTIALLY CANNIBALIZED. ALL OTHER TISSUES APPEARED NORMAL. |
| | | | 1 PUP: STILLBORN. PARTIALLY CANNIBALIZED. SEX COULD NOT BE DETERMINED. ALL OTHER TISSUES APPEARED NORMAL. |
| | | | 1 PUP: FOUND DEAD. PARTIALLY CANNIBALIZED. ALL OTHER TISSUES APPEARED NORMAL. |
| | 8379 | 0 | 1 PUP: FOUND DEAD. ALL TISSUES APPEARED NORMAL. |
| | | 20 | 10 PUPS: APPEARED NORMAL. |
| | 8380 | 20 | 3 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 20005045: 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 6): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION PUPS

| MATERNAL DOSAGE GROUP<br>MATERNAL DOSAGE (MG/KG/DAY) | LITTER NUMBER | DAY POSTPARTUM | OBSERVATIONS a |
|---|---|---|---|
| IV (CONT.)<br>500 | 8381 | 0 | 1 PUP: STILLBORN. ALL TISSUES APPEARED NORMAL. |
| | | | 2 PUPS: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. |
| | | 1 | 9 PUPS: FOUND DEAD. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | 8382 | 20 | 8 PUPS: APPEARED NORMAL. |
| | 8383 | 0 | 2 PUPS: STILLBORN. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | | | 3 PUPS: FOUND DEAD. ALL TISSUES APPEARED NORMAL. |
| | | | 3 PUPS: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. |
| | 8385 | 0 | 1 PUP: STILLBORN. ALL TISSUES APPEARED NORMAL. |
| | | | 6 PUPS: FOUND DEAD. PARTIALLY CANNIBALIZED. VIABILITY COULD NOT BE DETERMINED. ALL OTHER TISSUES APPEARED NORMAL. |
| | | | 6 PUPS: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. |
| | | | 1 PUP: FOUND DEAD. SEX AND VIABILITY COULD NOT BE DETERMINED. FURTHER NECROPSY OBSERVATIONS WERE NOT RECORDED. |
| | 8387 | 0 | 4 PUPS: FOUND DEAD. ALL TISSUES APPEARED NORMAL. |
| | | 3 | 1 PUP: FOUND DEAD. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | | 20 | 4 PUPS: APPEARED NORMAL. |
| | 8388 | 0 | 1 PUP: STILLBORN. ALL TISSUES APPEARED NORMAL. |
| | | | 1 PUP: FOUND DEAD. ALL TISSUES APPEARED NORMAL. |
| | | 3 | 1 PUP: FOUND DEAD. ALL TISSUES APPEARED NORMAL. |
| | | 4 | 1 PUP: FOUND DEAD. AUTOLYSIS PRECLUDED FURTHER EVALUATION. |
| | | 20 | 4 PUPS: APPEARED NORMAL. |
| | 8389 | 0 | 4 PUPS: FOUND DEAD. PARTIALLY CANNIBALIZED. VIABILITY COULD NOT BE DETERMINED. ALL OTHER TISSUES APPEARED NORMAL. |
| | 8390 | 0 | 2 PUPS: STILLBORN. ALL TISSUES APPEARED NORMAL. |
| | | 20 | 6 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 20005045: 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 | CONTROL | 0 MG/KG/DAY |
|---|---|---|
| MOUSE # | DESCRIPTION | |
| 9001 | NO ADVERSE FINDINGS | |
| 9002 | NO ADVERSE FINDINGS | |
| 9003 | NO ADVERSE FINDINGS | |
| 9004 | NO ADVERSE FINDINGS | |
| 9005 | NO ADVERSE FINDINGS | |
| 9006 | NO ADVERSE FINDINGS | |
| 9007 | NO ADVERSE FINDINGS | |
| 9008 | NO ADVERSE FINDINGS | |
| 9009 | NO ADVERSE FINDINGS | |
| 9010 | NO ADVERSE FINDINGS | |
| 9011 | NO ADVERSE FINDINGS | |
| 9012 | NO ADVERSE FINDINGS | |
| 9013 | NO ADVERSE FINDINGS | |
| 9014 | NO ADVERSE FINDINGS | |
| 9015 | NO ADVERSE FINDINGS | |
| 9016 | NO ADVERSE FINDINGS | |
| 9017 | NO ADVERSE FINDINGS | |
| 9018 | NO ADVERSE FINDINGS | |
| 9019 | NO ADVERSE FINDINGS | |
| 9020 | NO ADVERSE FINDINGS | |

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE
DP = DAY POSTPARTUM

PROTOCOL 20005045: 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 | 100 MG/KG/DAY |
|---|---|---|
| MOUSE # | DESCRIPTION | |
| 9021 | NO ADVERSE FINDINGS | |
| 9022 | NO ADVERSE FINDINGS | |
| 9023 | NO ADVERSE FINDINGS | |
| 9024 | NO ADVERSE FINDINGS | |
| 9025 | NO ADVERSE FINDINGS | |
| 9026 | NO ADVERSE FINDINGS | |
| 9027 | NO ADVERSE FINDINGS | |
| 9028 | NO ADVERSE FINDINGS | |
| 9029 | NO ADVERSE FINDINGS | |
| 9030 | NO ADVERSE FINDINGS | |
| 9031 | NO ADVERSE FINDINGS | |
| 9032 | NO ADVERSE FINDINGS | |
| 9033 | NO ADVERSE FINDINGS | |
| 9034 | NO ADVERSE FINDINGS | |
| 9036 | NO ADVERSE FINDINGS | |
| 9037 | NO ADVERSE FINDINGS | |
| 9038 | NO ADVERSE FINDINGS | |
| 9039 | NO ADVERSE FINDINGS | |
| 9040 | NO ADVERSE FINDINGS | |
| 9102a | NO ADVERSE FINDINGS | |

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE
DP = DAY POSTPARTUM
a. Mouse 9102 was originally assigned to study as a female; however, at sexual maturation evaluation, mouse was discovered to be a male.

PROTOCOL 20005045: 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 | 350 MG/KG/DAY |
|---|---|---|
| MOUSE # | DESCRIPTION | |
| 9041 | NO ADVERSE FINDINGS | |
| 9042 | NO ADVERSE FINDINGS | |
| 9043 | NO ADVERSE FINDINGS | |
| 9044 | NO ADVERSE FINDINGS | |
| 9045 | NO ADVERSE FINDINGS | |
| 9046 | NO ADVERSE FINDINGS | |
| 9047 | NO ADVERSE FINDINGS | |
| 9048 | NO ADVERSE FINDINGS | |
| 9049 DP( 23 ) | FOUND DEAD | |
| 9050 | NO ADVERSE FINDINGS | |
| 9051 | NO ADVERSE FINDINGS | |
| 9052 | NO ADVERSE FINDINGS | |
| 9053 | NO ADVERSE FINDINGS | |
| 9054 | NO ADVERSE FINDINGS | |
| 9055 | NO ADVERSE FINDINGS | |
| 9056 | NO ADVERSE FINDINGS | |
| 9057 | NO ADVERSE FINDINGS | |
| 9058 | NO ADVERSE FINDINGS | |
| 9059 | NO ADVERSE FINDINGS | |
| 9060 | NO ADVERSE FINDINGS | |

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE
DP = DAY POSTPARTUM

PROTOCOL 20005045: 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 | 500 MG/KG/DAY |
|---|---|---|
| MOUSE # | DESCRIPTION | |
| 9061 | NO ADVERSE FINDINGS | |
| 9062 | NO ADVERSE FINDINGS | |
| 9063 | NO ADVERSE FINDINGS | |
| 9064 | DP( 28- 41) | TIP OF TAIL: CONSTRICTED a |
| | DP( 35- 37) | TIP OF TAIL: PURPLE |
| | DP( 38- 41) | TAIL BENT a |
| | DP( 38- 41) | TIP OF TAIL MISSING a |
| 9065 | NO ADVERSE FINDINGS | |
| 9066 | NO ADVERSE FINDINGS | |
| 9067 | NO ADVERSE FINDINGS | |
| 9068 | NO ADVERSE FINDINGS | |
| 9069 | NO ADVERSE FINDINGS | |
| 9070 | NO ADVERSE FINDINGS | |
| 9071 | NO ADVERSE FINDINGS | |
| 9072 | NO ADVERSE FINDINGS | |
| 9073 | NO ADVERSE FINDINGS | |
| 9074 | NO ADVERSE FINDINGS | |
| 9075 | NO ADVERSE FINDINGS | |
| 9076 | NO ADVERSE FINDINGS | |
| 9077 | NO ADVERSE FINDINGS | |
| 9078 | NO ADVERSE FINDINGS | |
| 9079 | NO ADVERSE FINDINGS | |
| 9080 | NO ADVERSE FINDINGS | |

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE
DP = DAY POSTPARTUM
a. Observation confirmed at necropsy.

PROTOCOL 20005045: 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 | CONTROL | 0 MG/KG/DAY |
|---|---|---|
| MOUSE # | DESCRIPTION | |
| 9081 | NO ADVERSE FINDINGS | |
| 9082 | NO ADVERSE FINDINGS | |
| 9083 | NO ADVERSE FINDINGS | |
| 9084 | NO ADVERSE FINDINGS | |
| 9085 | NO ADVERSE FINDINGS | |
| 9086 | NO ADVERSE FINDINGS | |
| 9087 | NO ADVERSE FINDINGS | |
| 9088 | NO ADVERSE FINDINGS | |
| 9089 | NO ADVERSE FINDINGS | |
| 9090 | NO ADVERSE FINDINGS | |
| 9091 | NO ADVERSE FINDINGS | |
| 9092 | NO ADVERSE FINDINGS | |
| 9093 | NO ADVERSE FINDINGS | |
| 9094 | DP( 21- 41) | TAIL BENT a |
| 9095 | NO ADVERSE FINDINGS | |
| 9096 | NO ADVERSE FINDINGS | |
| 9097 | NO ADVERSE FINDINGS | |
| 9098 | NO ADVERSE FINDINGS | |
| 9099 | NO ADVERSE FINDINGS | |
| 9100 | NO ADVERSE FINDINGS | |

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE
DP = DAY POSTPARTUM
a. Observation confirmed at necropsy.

PROTOCOL 20005045: 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 | 100 MG/KG/DAY |
|---|---|---|
| MOUSE # | DESCRIPTION | |
| 9035a | NO ADVERSE FINDINGS | |
| 9101 | NO ADVERSE FINDINGS | |
| 9103 | NO ADVERSE FINDINGS | |
| 9104 | NO ADVERSE FINDINGS | |
| 9105 | NO ADVERSE FINDINGS | |
| 9106 | NO ADVERSE FINDINGS | |
| 9107 | NO ADVERSE FINDINGS | |
| 9108 | NO ADVERSE FINDINGS | |
| 9109 | NO ADVERSE FINDINGS | |
| 9110 | NO ADVERSE FINDINGS | |
| 9111 | NO ADVERSE FINDINGS | |
| 9112 | NO ADVERSE FINDINGS | |
| 9113 | NO ADVERSE FINDINGS | |
| 9114 | NO ADVERSE FINDINGS | |
| 9115 | NO ADVERSE FINDINGS | |
| 9116 | NO ADVERSE FINDINGS | |
| 9117 | NO ADVERSE FINDINGS | |
| 9118 | NO ADVERSE FINDINGS | |
| 9119 | NO ADVERSE FINDINGS | |
| 9120 | NO ADVERSE FINDINGS | |

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE
DP = DAY POSTPARTUM
a. Mouse 9035 was originally assigned to study as a male; however, at sexual maturation evaluation, mouse was discovered to be a female.

PROTOCOL 20005045: 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 | 350 MG/KG/DAY |
|---|---|---|
| MOUSE # | DESCRIPTION | |
| 9121 | NO ADVERSE FINDINGS | |
| 9122 | NO ADVERSE FINDINGS | |
| 9123 | NO ADVERSE FINDINGS | |
| 9124 | NO ADVERSE FINDINGS | |
| 9125 | NO ADVERSE FINDINGS | |
| 9126 | NO ADVERSE FINDINGS | |
| 9127 | NO ADVERSE FINDINGS | |
| 9128 | NO ADVERSE FINDINGS | |
| 9129 | NO ADVERSE FINDINGS | |
| 9130 | NO ADVERSE FINDINGS | |
| 9131 | NO ADVERSE FINDINGS | |
| 9132 | NO ADVERSE FINDINGS | |
| 9133 | NO ADVERSE FINDINGS | |
| 9134 | NO ADVERSE FINDINGS | |
| 9135 | NO ADVERSE FINDINGS | |
| 9136 | NO ADVERSE FINDINGS | |
| 9137 | NO ADVERSE FINDINGS | |
| 9138 | NO ADVERSE FINDINGS | |
| 9139 | NO ADVERSE FINDINGS | |
| 9140 | NO ADVERSE FINDINGS | |

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE
DP = DAY POSTPARTUM

PROTOCOL 20005045: 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 | 500 MG/KG/DAY |
|---|---|---|
| MOUSE # | DESCRIPTION | |
| 9141 | NO ADVERSE FINDINGS | |
| 9142 | NO ADVERSE FINDINGS | |
| 9143 | NO ADVERSE FINDINGS | |
| 9144 | NO ADVERSE FINDINGS | |
| 9145 | NO ADVERSE FINDINGS | |
| 9146 | NO ADVERSE FINDINGS | |
| 9147 | NO ADVERSE FINDINGS | |
| 9148 | NO ADVERSE FINDINGS | |
| 9149 | NO ADVERSE FINDINGS | |
| 9150 | NO ADVERSE FINDINGS | |
| 9151 | NO ADVERSE FINDINGS | |
| 9152 | NO ADVERSE FINDINGS | |
| 9153 | NO ADVERSE FINDINGS | |
| 9154 | NO ADVERSE FINDINGS | |
| 9155 | NO ADVERSE FINDINGS | |
| 9156 | NO ADVERSE FINDINGS | |
| 9157 | NO ADVERSE FINDINGS | |
| 9158 | NO ADVERSE FINDINGS | |
| 9159 | NO ADVERSE FINDINGS | |
| 9160 | NO ADVERSE FINDINGS | |

CLINICAL OBSERVATIONS APPEARED NORMAL UNLESS NOTED OTHERWISE
DP = DAY POSTPARTUM

PROTOCOL 20005045: 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

| | DAY 21 | 28 | 35 | 41 |
|---|---|---|---|---|
| MOUSE # | MATERNAL DOSAGE GROUP I | | CONTROL | 0 MG/KG/DAY |
| 9001 | 9.5 | 18.3 | 25.1 | 26.4 |
| 9002 | 8.4 | 17.0 | 26.4 | 30.5 |
| 9003 | 10.9 | 20.1 | 25.5 | 27.3 |
| 9004 | 12.9 | 23.4 | 29.5 | 33.1 |
| 9005 | 10.8 | 22.5 | 29.0 | 32.7 |
| 9006 | 10.9 | 20.0 | 27.0 | 31.1 |
| 9007 | 12.0 | 22.7 | 28.0 | 30.6 |
| 9008 | 17.4 | 29.8 | 34.1 | 38.0 |
| 9009 | 11.6 | 23.1 | 29.0 | 30.5 |
| 9010 | 18.6 | 29.8 | 36.1 | 38.7 |
| 9011 | 11.6 | 23.1 | 30.2 | 31.3 |
| 9012 | 11.4 | 22.3 | 28.7 | 29.7 |
| 9013 | 14.4 | 27.0 | 31.5 | 34.6 |
| 9014 | 13.4 | 25.2 | 29.4 | 32.5 |
| 9015 | 15.2 | 19.7 | 27.4 | 32.0 |
| 9016 | 15.7 | 25.1 | 27.4 | 32.0 |
| 9017 | 12.9 | 24.7 | 31.5 | 35.1 |
| 9018 | 9.5 | 20.0 | 28.2 | 32.5 |
| 9019 | 10.0 | 20.2 | 27.4 | 33.9 |
| 9020 | 12.5 | 22.7 | 27.8 | 29.4 |

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

PROTOCOL 20005045: 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

| | DAY 21 | 28 | 35 | 41 |
|---|---|---|---|---|
| MOUSE # | MATERNAL DOSAGE GROUP II | | LOW DOSAGE | 100 MG/KG/DAY |
| 9021 | 11.0 | 20.8 | 28.3 | 29.6 |
| 9022 | 11.3 | 21.2 | 28.7 | 30.8 |
| 9023 | 10.9 | 20.8 | 27.8 | 30.9 |
| 9024 | 9.2 | 17.2 | 23.9 | 26.3 |
| 9025 | 13.0 | 24.1 | 32.5 | 35.8 |
| 9026 | 14.1 | 25.3 | 29.3 | 32.5 |
| 9027 | 13.2 | 26.2 | 31.5 | 34.2 |
| 9028 | 13.8 | 25.3 | 31.4 | 34.9 |
| 9029 | 11.9 | 23.7 | 29.9 | 33.1 |
| 9030 | 11.7 | 23.1 | 30.8 | 34.0 |
| 9031 | 10.9 | 20.8 | 28.2 | 31.1 |
| 9032 | 11.6 | 22.7 | 29.8 | 33.7 |
| 9033 | 9.0 | 17.9 | 25.6 | 30.5 |
| 9034 | 7.1 | 15.0 | 23.7 | 26.8 |
| 9036 | 6.3 | 15.1 | 24.0 | 28.6 |
| 9037 | 7.7 | 17.0 | 24.5 | 30.7 |
| 9038 | 10.1 | 19.7 | 27.4 | 32.2 |
| 9039 | 10.8 | 20.4 | 28.4 | 31.3 |
| 9040 | 8.3 | 17.2 | 24.3 | 28.3 |
| 9102a | 10.3 | 19.6 | 27.6 | 30.1 |

DAY = DAY POSTPARTUM
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. Mouse 9102 was originally assigned to study as a female; however, at sexual maturation evaluation, mouse was discovered to be a male.

PROTOCOL 20005045: 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

| | DAY 21 | 28 | 35 | 41 |
|---|---|---|---|---|
| MOUSE # | MATERNAL DOSAGE GROUP III | | MIDDLE DOSAGE | 350 MG/KG/DAY |
| 9041 | 10.4 | 20.8 | 28.3 | 30.0 |
| 9042 | 7.1 | 14.5 | 23.8 | 26.5 |
| 9043 | 11.0 | 20.4 | 28.3 | 31.8 |
| 9044 | 10.3 | 20.8 | 27.9 | 30.2 |
| 9045 | 8.2 | 17.9 | 27.5 | 30.6 |
| 9046 | 9.7 | 19.8 | 27.0 | 29.6 |
| 9047 | 12.0 | 22.9 | 30.1 | 32.1 |
| 9048 | 9.0 | 17.4 | 26.2 | 29.8 |
| 9049 | 6.4 | FOUND DEAD ON DAY 23 POSTPARTUM | | |
| 9050 | 6.7 | 14.5 | 22.7 | 27.4 |
| 9051 | 8.8 | 18.0 | 26.4 | 29.9 |
| 9052 | 9.1 | 20.0 | 29.5 | 32.6 |
| 9053 | 15.5 | 27.9 | 33.2 | 36.7 |
| 9054 | 16.2 | 27.2 | 30.6 | 33.7 |
| 9055 | 10.1 | 19.4 | 25.1 | 27.5 |
| 9056 | 8.1 | 18.6 | 27.9 | 31.6 |
| 9057 | 10.1 | 20.5 | 28.4 | 32.4 |
| 9058 | 16.0 | 27.1 | 31.7 | 34.4 |
| 9059 | 11.8 | 23.7 | 30.6 | 31.8 |
| 9060 | 9.1 | 19.3 | 26.9 | 30.6 |

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

PROTOCOL 20005045: 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

| | DAY 21 | 28 | 35 | 41 |
|---|---|---|---|---|
| MOUSE # | MATERNAL DOSAGE GROUP IV | | HIGH DOSAGE | 500 MG/KG/DAY |
| 9061 | 10.5 | 21.1 | 27.4 | 28.6 |
| 9062 | 11.5 | 21.9 | 29.7 | 30.8 |
| 9063 | 8.1 | 17.3 | 25.3 | 27.8 |
| 9064 | 8.7 | 17.4 | 24.9 | 28.1 |
| 9065 | 12.5 | 23.1 | 28.8 | 32.3 |
| 9066 | 12.4 | 22.4 | 28.0 | 30.7 |
| 9067 | 12.6 | 24.4 | 29.0 | 31.6 |
| 9068 | 12.3 | 22.1 | 27.2 | 29.5 |
| 9069 | 11.3 | 21.5 | 27.7 | 30.2 |
| 9070 | 10.8 | 20.6 | 28.2 | 30.3 |
| 9071 | 10.9 | 21.9 | 28.6 | 30.7 |
| 9072 | 7.7 | 17.1 | 26.5 | 29.9 |
| 9073 | 6.4 | 15.0 | 23.4 | 28.7 |
| 9074 | 9.5 | 18.3 | 25.3 | 30.7 |
| 9075 | 9.3 | 18.6 | 26.9 | 31.3 |
| 9076 | 8.8 | 16.9 | 24.2 | 29.0 |
| 9077 | 9.9 | 20.1 | 28.3 | 32.1 |
| 9078 | 16.4 | 29.9 | 34.4 | 38.2 |
| 9079 | 15.5 | 28.0 | 33.0 | 37.6 |
| 9080 | 11.0 | 20.2 | 25.9 | 30.1 |

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

PROTOCOL 20005045: 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

| | DAY 21 | 28 | 35 | 41 |
|---|---|---|---|---|
| MOUSE # | MATERNAL DOSAGE GROUP I | | CONTROL | 0 MG/KG/DAY |
| 9081 | 10.1 | 17.5 | 23.4 | 23.0 |
| 9082 | 11.5 | 15.1 | 23.0 | 25.4 |
| 9083 | 9.2 | 18.3 | 22.0 | 23.3 |
| 9084 | 12.7 | 22.7 | 25.2 | 27.4 |
| 9085 | 10.9 | 17.6 | 23.9 | 25.5 |
| 9086 | 11.4 | 19.1 | 23.8 | 25.2 |
| 9087 | 12.1 | 20.6 | 25.7 | 26.5 |
| 9088 | 16.9 | 24.1 | 27.9 | 29.1 |
| 9089 | 10.3 | 17.7 | 22.5 | 23.4 |
| 9090 | 16.5 | 22.9 | 27.3 | 29.6 |
| 9091 | 11.6 | 19.9 | 26.5 | 26.6 |
| 9092 | 12.5 | 20.2 | 24.4 | 24.7 |
| 9093 | 12.6 | 21.3 | 25.0 | 26.2 |
| 9094 | 9.8 | 17.6 | 22.0 | 24.0 |
| 9095 | 10.4 | 18.3 | 23.7 | 26.7 |
| 9096 | 16.8 | 22.5 | 26.3 | 28.4 |
| 9097 | 10.1 | 17.7 | 23.2 | 23.0 |
| 9098 | 8.7 | 17.6 | 22.8 | 23.9 |
| 9099 | 9.7 | 18.0 | 22.3 | 24.7 |
| 9100 | 11.4 | 21.2 | 23.7 | 25.5 |

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

PROTOCOL 20005045: 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

| | DAY 21 | 28 | 35 | 41 |
|---|---|---|---|---|
| MOUSE # | MATERNAL DOSAGE GROUP II | | LOW DOSAGE | 100 MG/KG/DAY |
| 9035a | 8.2 | 15.9 | 21.3 | 23.1 |
| 9101 | 11.6 | 19.7 | 24.3 | 25.1 |
| 9103 | 11.6 | 18.2 | 21.8 | 24.0 |
| 9104 | 10.6 | 18.7 | 22.6 | 24.1 |
| 9105 | 11.5 | 19.9 | 26.1 | 27.7 |
| 9106 | 12.3 | 20.4 | 24.9 | 26.8 |
| 9107 | 13.2 | 22.0 | 28.2 | 27.8 |
| 9108 | 12.5 | 19.8 | 24.3 | 24.2 |
| 9109 | 10.9 | 18.5 | 23.5 | 24.6 |
| 9110 | 12.7 | 20.8 | 25.8 | 26.7 |
| 9111 | 9.1 | 15.0 | 20.4 | 22.3 |
| 9112 | 11.7 | 19.1 | 25.4 | 26.2 |
| 9113 | 10.1 | 19.2 | 25.6 | 25.9 |
| 9114 | 9.9 | 17.1 | 21.9 | 22.7 |
| 9115 | 8.2 | 16.3 | 23.1 | 25.6 |
| 9116 | 7.2 | 15.1 | 24.3 | 25.2 |
| 9117 | 4.9 | 12.2 | 17.6 | 20.8 |
| 9118 | 7.1 | 14.7 | 20.4 | 22.9 |
| 9119 | 10.1 | 17.3 | 22.8 | 25.5 |
| 9120 | 8.2 | 14.1 | 20.0 | 22.9 |

DAY = DAY POSTPARTUM
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. Mouse 9035 was originally assigned to study as a male; however, at sexual maturation evaluation, mouse was discovered to be a female.

PROTOCOL 20005045: 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

| | DAY 21 | 28 | 35 | 41 |
|---|---|---|---|---|
| MOUSE # | MATERNAL DOSAGE GROUP III | | MIDDLE DOSAGE | 350 MG/KG/DAY |
| 9121 | 9.3 | 16.0 | 23.8 | 23.5 |
| 9122 | 8.4 | 16.3 | 22.4 | 24.4 |
| 9123 | 6.9 | 13.1 | 19.7 | 21.1 |
| 9124 | 9.9 | 15.9 | 21.9 | 22.2 |
| 9125 | 11.3 | 16.6 | 21.9 | 22.8 |
| 9126 | 7.6 | 15.2 | 20.0 | 21.5 |
| 9127 | 9.0 | 14.8 | 20.5 | 22.5 |
| 9128 | 11.8 | 19.8 | 24.2 | 24.8 |
| 9129 | 11.6 | 18.8 | 24.5 | 26.5 |
| 9130 | 8.6 | 6.7 | 11.8 | 18.2 |
| 9131 | 9.2 | 16.9 | 21.6 | 24.0 |
| 9132 | 8.6 | 14.0 | 19.6 | 22.2 |
| 9133 | 10.0 | 19.4 | 23.8 | 25.0 |
| 9134 | 13.2 | 21.2 | 23.7 | 25.9 |
| 9135 | 10.0 | 17.1 | 21.7 | 23.4 |
| 9136 | 11.0 | 20.0 | 23.7 | 26.4 |
| 9137 | 8.0 | 15.0 | 21.8 | 24.5 |
| 9138 | 10.9 | 18.1 | 22.8 | 24.7 |
| 9139 | 10.8 | 18.3 | 23.7 | 24.2 |
| 9140 | 9.2 | 15.9 | 21.8 | 24.6 |

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

PROTOCOL 20005045: 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

| | DAY 21 | 28 | 35 | 41 |
|---|---|---|---|---|
| MOUSE # | MATERNAL DOSAGE GROUP IV HIGH DOSAGE 500 MG/KG/DAY | | | |
| 9141 | 10.4 | 17.8 | 21.4 | 22.7 |
| 9142 | 10.6 | 16.5 | 22.9 | 24.2 |
| 9143 | 9.5 | 17.3 | 22.6 | 25.2 |
| 9144 | 8.8 | 15.8 | 21.0 | 23.8 |
| 9145 | 12.1 | 20.6 | 23.7 | 25.0 |
| 9146 | 12.3 | 21.4 | 25.3 | 27.6 |
| 9147 | 12.1 | 19.7 | 24.0 | 25.6 |
| 9148 | 10.9 | 16.9 | 22.4 | 25.2 |
| 9149 | 9.6 | 16.1 | 20.5 | 23.1 |
| 9150 | 10.0 | 17.8 | 22.5 | 25.2 |
| 9151 | 10.0 | 17.8 | 22.9 | 25.1 |
| 9152 | 9.5 | 16.4 | 21.8 | 24.4 |
| 9153 | 8.5 | 15.3 | 21.5 | 24.4 |
| 9154 | 9.7 | 17.5 | 21.5 | 23.8 |
| 9155 | 9.3 | 16.4 | 20.9 | 23.5 |
| 9156 | 9.7 | 17.0 | 22.0 | 22.7 |
| 9157 | 15.2 | 24.3 | 25.9 | 28.1 |
| 9158 | 14.3 | 21.8 | 23.6 | 26.8 |
| 9159 | 12.1 | 18.6 | 21.9 | 24.5 |
| 9160 | 11.4 | 17.8 | 20.3 | 21.0 |

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

PROTOCOL 20005045: 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 | | | II | | | III | | | IV | | |
| 0 | | | 100 | | | 350 | | | 500 | | |
| 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 |
| 9001 | 29 | 20.9 | 9021 | 29 | 23.3 | 9041 | 29 | 22.0 | 9061 | 29 | 22.5 |
| 9002 | 33 | 24.2 | 9022 | 29 | 22.5 | 9042 | 31 | 19.5 | 9062 | 29 | 23.3 |
| 9003 | 27 | 19.2 | 9023 | 28 | 20.8 | 9043 | 29 | 21.9 | 9063 | 29 | 18.7 |
| 9004 | 30 | 25.7 | 9024 | 31 | 21.4 | 9044 | 29 | 22.3 | 9064 | 29 | 19.0 |
| 9005 | 30 | 24.2 | 9025 | 29 | 25.6 | 9045 | 31 | 23.0 | 9065 | 27 | 21.6 |
| 9006 | 27 | 18.8 | 9026 | 28 | 25.3 | 9046 | 29 | 21.5 | 9066 | 27 | 20.9 |
| 9007 | 29 | 24.0 | 9027 | 28 | 26.2 | 9047 | 27 | 21.0 | 9067 | 29 | 25.6 |
| 9008 | 28 | 29.8 | 9028 | 28 | 25.3 | 9048 | 30 | 20.2 | 9068 | 29 | 22.8 |
| 9009 | 28 | 23.1 | 9029 | 29 | 24.9 | 9049b | | | 9069 | 28 | 21.5 |
| 9010 | 28 | 29.8 | 9030 | 29 | 24.6 | 9050 | 37 | 24.3 | 9070 | 29 | 22.1 |
| 9011 | 30 | 25.5 | 9031 | 29 | 21.9 | 9051 | 30 | 21.2 | 9071 | 28 | 21.9 |
| 9012 | 31 | 25.6 | 9032 | 29 | 23.9 | 9052 | 30 | 23.2 | 9072 | 31 | 22.6 |
| 9013 | 27 | 25.7 | 9033 | 32 | 23.8 | 9053 | 27 | 25.4 | 9073 | 32 | 20.0 |
| 9014 | 28 | 25.2 | 9034 | 32 | 20.9 | 9054 | 27 | 25.7 | 9074 | 31 | 22.5 |
| 9015 | 32 | 24.6 | 9036 | 36 | 25.4 | 9055 | 29 | 20.8 | 9075 | 32 | 24.9 |
| 9016 | c | 23.4 | 9037 | 33 | 22.7 | 9056 | 29 | 20.3 | 9076 | 33 | 22.8 |
| 9017 | 30 | 27.2 | 9038 | 32 | 25.5 | 9057 | 27 | 19.3 | 9077 | 31 | 24.6 |
| 9018 | 29 | 21.5 | 9039 | 28 | 20.4 | 9058 | 27 | 25.9 | 9078 | 29 | 30.6 |
| 9019 | 33 | 25.8 | 9040 | 30 | 20.4 | 9059 | 30 | 26.9 | 9079 | 27 | 26.2 |
| 9020 | c | 19.7 | 9102d | 28 | 19.6 | 9060 | 29 | 21.3 | 9080 | 29 | 21.8 |

DAY = DAY POSTPARTUM

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

b. Mouse 9049 was found dead on day 23 postpartum.

c. The prepuce was separated on the first day of observation, day 26 postpartum, therefore the exact day of maturity could not be determined; body weight on this day was excluded from summarization and statistical analyses.

d. Mouse 9102 was originally assigned to study as a female; however, at sexual maturation evaluation, mouse was discovered to be a male.

PROTOCOL 20005045: 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 | | | II | | | III | | | IV | | | |
| 0 | | | 100 | | | 350 | | | 500 | | | |
| 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 | |
| 9081 | 27 | 16.6 | 9035b | c | 15.6 | 9121 | 31 | 19.1 | 9141 | 30 | 19.1 | |
| 9082 | 28 | 15.1 | 9101 | 28 | 19.7 | 9122 | 28 | 16.3 | 9142 | 32 | 20.4 | |
| 9083 | 28 | 18.3 | 9103 | 27 | 17.2 | 9123 | 32 | 17.4 | 9143 | 26 | 15.2 | |
| 9084 | 26 | 19.5 | 9104 | 27 | 18.0 | 9124 | 29 | 17.1 | 9144 | 30 | 18.0 | |
| 9085 | 29 | 18.9 | 9105 | 27 | 18.5 | 9125 | 27 | 15.8 | 9145 | 27 | 19.2 | |
| 9086 | 27 | 18.4 | 9106 | 27 | 19.7 | 9126 | 29 | 16.4 | 9146 | 29 | 21.9 | |
| 9087 | 27 | 19.9 | 9107 | 27 | 21.9 | 9127 | 27 | 14.3 | 9147 | 26 | 17.8 | |
| 9088 | d | 16.3 | 9108 | 27 | 19.1 | 9128 | 25 | 16.7 | 9148 | 29 | 17.8 | |
| 9089 | 29 | 18.7 | 9109 | 29 | 19.8 | 9129 | 29 | 19.4 | 9149 | 29 | 17.1 | |
| 9090 | 21 | 16.1 | 9110 | 28 | 20.8 | 9130 | e | | 9150 | 30 | 20.3 | |
| 9091 | 27 | 19.1 | 9111 | 29 | 15.9 | 9131 | 27 | 15.8 | 9151 | 29 | 18.8 | |
| 9092 | 27 | 19.8 | 9112 | 27 | 18.0 | 9132 | 27 | 13.7 | 9152 | 26 | 15.6 | |
| 9093 | 26 | 19.1 | 9113 | 27 | 17.6 | 9133 | 25 | 15.4 | 9153 | 28 | 15.3 | |
| 9094 | 28 | 17.6 | 9114 | 26 | 15.3 | 9134 | d | 12.2 | 9154 | 27 | 17.0 | |
| 9095 | 28 | 18.3 | 9115 | 27 | 15.2 | 9135 | 27 | 15.8 | 9155 | 25 | 13.9 | |
| 9096 | 24 | 19.6 | 9116 | 29 | 16.6 | 9136 | 26 | 17.3 | 9156 | 26 | 14.6 | |
| 9097 | 28 | 17.7 | 9117 | 26 | 9.5 | 9137 | 29 | 16.8 | 9157 | 25 | 20.0 | |
| 9098 | 28 | 17.6 | 9118 | 27 | 13.6 | 9138 | 28 | 18.1 | 9158 | 25 | 18.0 | |
| 9099 | 28 | 18.0 | 9119 | 28 | 17.3 | 9139 | 25 | 15.4 | 9159 | 25 | 16.0 | |
| 9100 | 24 | 15.3 | 9120 | 30 | 16.5 | 9140 | 25 | 12.8 | 9160 | 26 | 15.4 | |

DAY = DAY POSTPARTUM

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

b. Mouse 9035 was originally assigned to study as a male; however, at sexual maturation evaluation, mouse was discovered to be a female.

c. Mouse 9035 was observed to have reached sexual maturity on day 27 postpartum. However, the exact day of maturity could not be determined because this mouse was not observed for vaginal patency on the previous day; body weight on day 27 postpartum was excluded from summarization and statistical analyses.

d. The vagina was patent on the first day of observation, day 20 postpartum, therefore the exact day of maturity could not be determined; body weight on this day was excluded from summarization and statistical analyses.

e. Mouse 9130 had not reached sexual maturity by day 41 postpartum, the day of scheduled sacrifice.

PROTOCOL 20005045: 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<br>MATERNAL DOSAGE (MG/KG/DAY) | MOUSE NUMBER | DAY OF NECROPSY | OBSERVATIONS a |
|---|---|---|---|
| I | | | |
| 0 | 9001 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9002 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9003 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9004 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9005 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9006 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9007 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9008 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9009 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9010 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9011 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9012 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9013 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9014 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9015 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9016 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9017 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9018 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9019 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9020 | 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 20005045: 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<br>MATERNAL DOSAGE (MG/KG/DAY) | MOUSE NUMBER | DAY OF NECROPSY | OBSERVATIONS a |
|---|---|---|---|
| II<br>100 | 9021 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9022 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9023 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9024 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9025 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9026 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9027 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9028 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9029 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9030 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9031 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9032 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9033 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9034 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9036 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9037 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9038 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9039 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9040 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9102b | 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.

b. Mouse 9102 was originally assigned to study as a female; however, at sexual maturation evaluation, mouse was discovered to be a male.

PROTOCOL 20005045: 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<br>MATERNAL DOSAGE (MG/KG/DAY) | MOUSE NUMBER | DAY OF NECROPSY | OBSERVATIONS a |
|---|---|---|---|
| III<br>350 | 9041 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9042 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9043 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9044 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9045 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9046 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9047 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9048 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9049 | DP 23 | FOUND DEAD ON DAY 23 POSTPARTUM.<br>ALL TISSUES APPEARED NORMAL FOR MODERATE DEGREE OF AUTOLYSIS. |
| | 9050 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9051 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9052 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9053 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9054 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9055 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9056 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9057 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9058 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9059 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9060 | 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 20005045: 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<br>MATERNAL DOSAGE (MG/KG/DAY) | MOUSE NUMBER | DAY OF NECROPSY | OBSERVATIONS a |
|---|---|---|---|
| IV<br>500 | 9061 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9062 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9063 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9064 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9065 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9066 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9067 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9068 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9069 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9070 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9071 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9072 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9073 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9074 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9075 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9076 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9077 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9078 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9079 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9080 | 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 20005045: 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<br>MATERNAL DOSAGE (MG/KG/DAY) | MOUSE NUMBER | DAY OF NECROPSY | OBSERVATIONS a |
|---|---|---|---|
| I | | | |
| 0 | 9081 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9082 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9083 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9084 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9085 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9086 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9087 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9088 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9089 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9090 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9091 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9092 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9093 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9094 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9095 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9096 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9097 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9098 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9099 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9100 | 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.

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

| MATERNAL DOSAGE GROUP<br>MATERNAL DOSAGE (MG/KG/DAY) | MOUSE NUMBER | DAY OF NECROPSY | OBSERVATIONS a |
|---|---|---|---|
| II<br>100 | 9035b | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9101 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9103 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9104 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9105 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9106 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9107 | DP 41 | KIDNEYS: LEFT, SMALL (0.098 G).<br>ALL OTHER TISSUES APPEARED NORMAL. |
| | 9108 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9109 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9110 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9111 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9112 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9113 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9114 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9115 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9116 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9117 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9118 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9119 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9120 | 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.
b. Mouse 9035 was originally assigned to study as a male; however, at sexual maturation evaluation, mouse was discovered to be a female.

PROTOCOL 20005045: 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<br>MATERNAL DOSAGE (MG/KG/DAY) | MOUSE NUMBER | DAY OF NECROPSY | OBSERVATIONS a |
|---|---|---|---|
| III<br>350 | 9121 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9122 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9123 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9124 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9125 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9126 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9127 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9128 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9129 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9130 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9131 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9132 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9133 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9134 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9135 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9136 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9137 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9138 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9139 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9140 | 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 20005045: 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<br>MATERNAL DOSAGE (MG/KG/DAY) | MOUSE NUMBER | DAY OF NECROPSY | OBSERVATIONS a |
|---|---|---|---|
| IV<br>500 | 9141 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9142 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9143 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9144 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9145 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9146 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9147 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9148 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9149 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9150 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9151 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9152 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9153 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9154 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9155 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9156 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9157 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9158 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9159 | DP 41 | ALL TISSUES APPEARED NORMAL. |
| | 9160 | 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 20005045: 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. | LIVER REL. % TBW | | |
|---|---|---|---|---|---|
| MATERNAL DOSAGE GROUP I | | | | CONTROL | 0 MG/KG/DAY |
| 9002 | 30.5 | 2.243 | 7.35 | | |
| 9003 | 27.3 | 1.908 | 6.99 | | |
| 9004 | 33.1 | 2.215 | 6.69 | | |
| 9005 | 32.7 | 2.159 | 6.60 | | |
| 9006 | 31.1 | 2.027 | 6.52 | | |
| MATERNAL DOSAGE GROUP II | | | | LOW DOSAGE | 100 MG/KG/DAY |
| 9022 | 30.8 | 2.008 | 6.52 | | |
| 9023 | 30.9 | 2.070 | 6.70 | | |
| 9024 | 26.3 | 1.780 | 6.77 | | |
| 9025 | 35.8 | 2.389 | 6.67 | | |
| 9026 | 32.5 | 2.357 | 7.25 | | |
| MATERNAL DOSAGE GROUP III | | | | MIDDLE DOSAGE | 350 MG/KG/DAY |
| 9043 | 31.8 | 2.195 | 6.90 | | |
| 9044 | 30.2 | 2.172 | 7.19 | | |
| 9045 | 30.6 | 2.210 | 7.22 | | |
| 9046 | 29.6 | 2.093 | 7.07 | | |
| 9047 | 32.1 | 2.432 | 7.58 | | |
| 9049a | ---- | 0.244 | ---- | | |
| MATERNAL DOSAGE GROUP IV | | | | HIGH DOSAGE | 500 MG/KG/DAY |
| 9063 | 27.8 | 1.749 | 6.29 | | |
| 9064 | 28.1 | 1.844 | 6.56 | | |
| 9065 | 32.3 | 2.002 | 6.20 | | |
| 9066 | 30.7 | 1.902 | 6.20 | | |
| 9067 | 31.6 | 2.153 | 6.81 | | |

ALL WEIGHTS WERE RECORDED IN GRAMS (G). ABS. WT. = ORGAN WEIGHT. REL. % TBW = (ORGAN WEIGHT/TERMINAL BODY WEIGHT) X 100.
a. Mouse 9049 was found dead on day 23 postpartum; values were excluded from summarization and statistical analyses.

PROTOCOL 20005045: 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. | LIVER REL. % TBW | | |
|---|---|---|---|---|---|
| MATERNAL DOSAGE GROUP I | | | | CONTROL | 0 MG/KG/DAY |
| 9082 | 25.4 | 1.637 | 6.44 | | |
| 9083 | 23.3 | 1.411 | 6.06 | | |
| 9084 | 27.4 | 1.652 | 6.03 | | |
| 9085 | 25.5 | 1.488 | 5.84 | | |
| 9086 | 25.2 | 1.490 | 5.91 | | |
| MATERNAL DOSAGE GROUP II | | | | LOW DOSAGE | 100 MG/KG/DAY |
| 9103 | 24.0 | 1.382 | 5.76 | | |
| 9104 | 24.1 | 1.357 | 5.63 | | |
| 9105 | 27.7 | 1.723 | 6.22 | | |
| 9106 | 26.8 | 1.633 | 6.09 | | |
| 9107 | 27.8 | 1.650 | 5.94 | | |
| MATERNAL DOSAGE GROUP III | | | | MIDDLE DOSAGE | 350 MG/KG/DAY |
| 9124 | 22.2 | 1.222 | 5.50 | | |
| 9125 | 22.8 | 1.489 | 6.53 | | |
| 9126 | 21.5 | 1.399 | 6.51 | | |
| 9127 | 22.5 | 1.471 | 6.54 | | |
| 9128 | 24.8 | 1.706 | 6.88 | | |
| MATERNAL DOSAGE GROUP IV | | | | HIGH DOSAGE | 500 MG/KG/DAY |
| 9143 | 25.2 | 1.480 | 5.87 | | |
| 9144 | 23.8 | 1.575 | 6.62 | | |
| 9145 | 25.0 | 1.651 | 6.60 | | |
| 9146 | 27.6 | 1.644 | 5.96 | | |
| 9147 | 25.6 | 1.497 | 5.85 | | |

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

# APPENDIX 1 – PROTOCOL AND AMENDMENTS

**FINAL PROTOCOL**

**Charles River Laboratories Study No. 20005045**

# 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 September 2010**

## TABLE OF CONTENTS

## 1. STUDY NUMBER

20005045

## 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

(Executive Director, Site Operations and Toxicology)
Address as cited for Testing Facility
E-mail:

## 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
Settsu City
Osaka, 566-8585
JAPAN
Tel: +81.6.6349.5336
Fax: +81.6.6349.1095
E-mail:

## 8. PRINCIPAL INVESTIGATOR – TEST SUBSTANCE ANALYSIS

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:

## 9. PRINCIPAL INVESTIGATOR - BIOANALYSIS

Principal Investigator:
Research Scientist, Bioanalysis
Charles River Preclinical Services Montreal
22022 Transcanadienne, Senneville
Quebec H9X 3R3
CANADA
Tel: +1.514.630.8200 ext. 2224
Fax: +1.514.630.8230
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 Agency[1], the Ministry of Agriculture, Forestry and Fisheries[2] and the Organisation for Economic Co-operation and Development[3] 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.

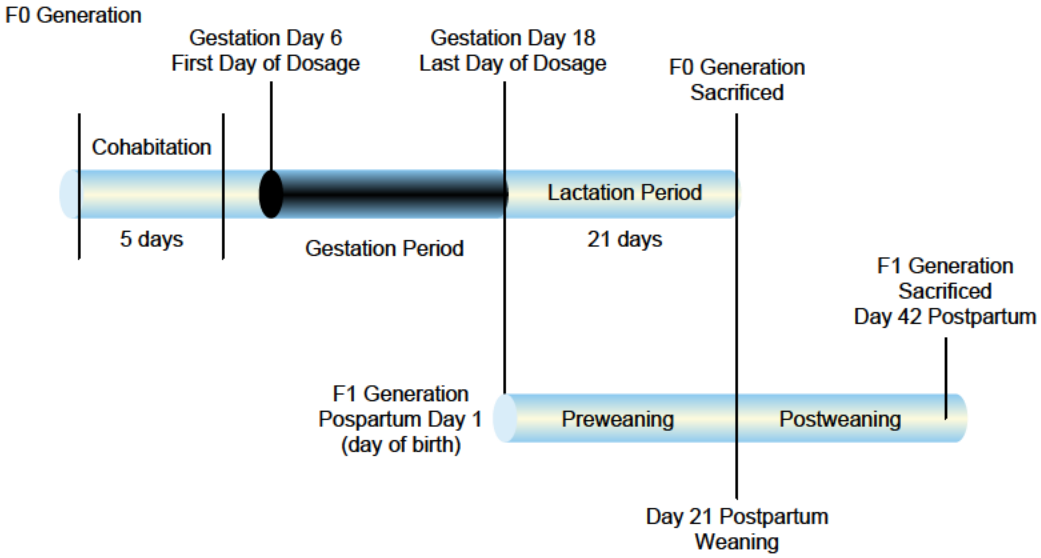
The final report will include a compliance statement signed by the Study Director that the report accurately reflects the raw data obtained during the performance of the study and that all applicable GLP regulations were followed in the conduct of the study. Should deviations from GLP regulations occur, 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

Page 7 of 46
Testing Facility Study No. 20005045

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 SCHEDULE[1]




[redacted] 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 and during dosage administration.

Detailed preparation procedures are 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 ± 10%; and 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 ≤ 5%. 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. A process audit, rather than a critical phase inspection, will be performed for analysis of the bulk test substance.

### 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 211271). The Test Site Reference number for the work in this current study is 211271. 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 stored at room temperature 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 stored at room temperature 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 assessed under Charles River Laboratories Preclinical Services Montreal Study Number 211271.

### 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. 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 (by dosage group) 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 (± 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 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

In the combined developmental and perinatal/postnatal reproduction toxicity study (UZS00010), mice were administered the test substance at doses of 7, 35 and 175 mg/kg on days 6 through 18 of gestation. No mortality related to the test substance occurred on study, and no adverse clinical signs occurred during this study. Due to a lack of observed toxicity, dosages of 100, 350 and 500 mg/kg/day were selected for this 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-20005045-A(Day.Month.Year) |
| II | 20 | 100 | 20 | 5 | B-20005045-B(Day.Month.Year) |
| III | 20 | 350 | 70 | 5 | B-20005045-C(Day.Month.Year) |
| IV | 20 | 500 | 100 | 5 | B-20005045-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

### 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.

### 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 (≤-70ºC) 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 sulfide[6].

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 (≤-70ºC) until shipment for analysis as described in section 23.4. Uteri will be stained with 10% ammonium sulfide to confirm the absence of implantation sites[6].

The liver samples will be analyzed at PCS-MTL (test site reference no. 142578) 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 sulfide[6]. Livers will be excised, weighed and frozen on dry ice. Livers will be maintained frozen (≤-70ºC) 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 (≤-70ºC) 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 sites[6]. The number and distribution of implantation sites for delivered mice will be recorded after staining with 10% ammonium sulfide[6].

Page 21 of 46
Testing Facility Study No. 20005045

### 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 (≤-70ºC) 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

| | |
|---|---|
| Preweaning 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

| | |
|---|---|
| Preweaning Period: | Daily. |
| Postweaning Period: | Daily. |

Clinical observations may be recorded more frequently than cited above.

### 24.3. Body Weights

| | |
|---|---|
| Preweaning 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 and liver collection for bioanalysis. [Blood samples will be collected as much as possible, but no less than 0.5 mL]. Livers will be excised, weighed and frozen on dry ice and maintained frozen (≤-70ºC) until shipment for analysis (as described in section 23.4). Blood samples will be collected via the 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$^{o}$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 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. 142577) 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 (Preweaning)

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)

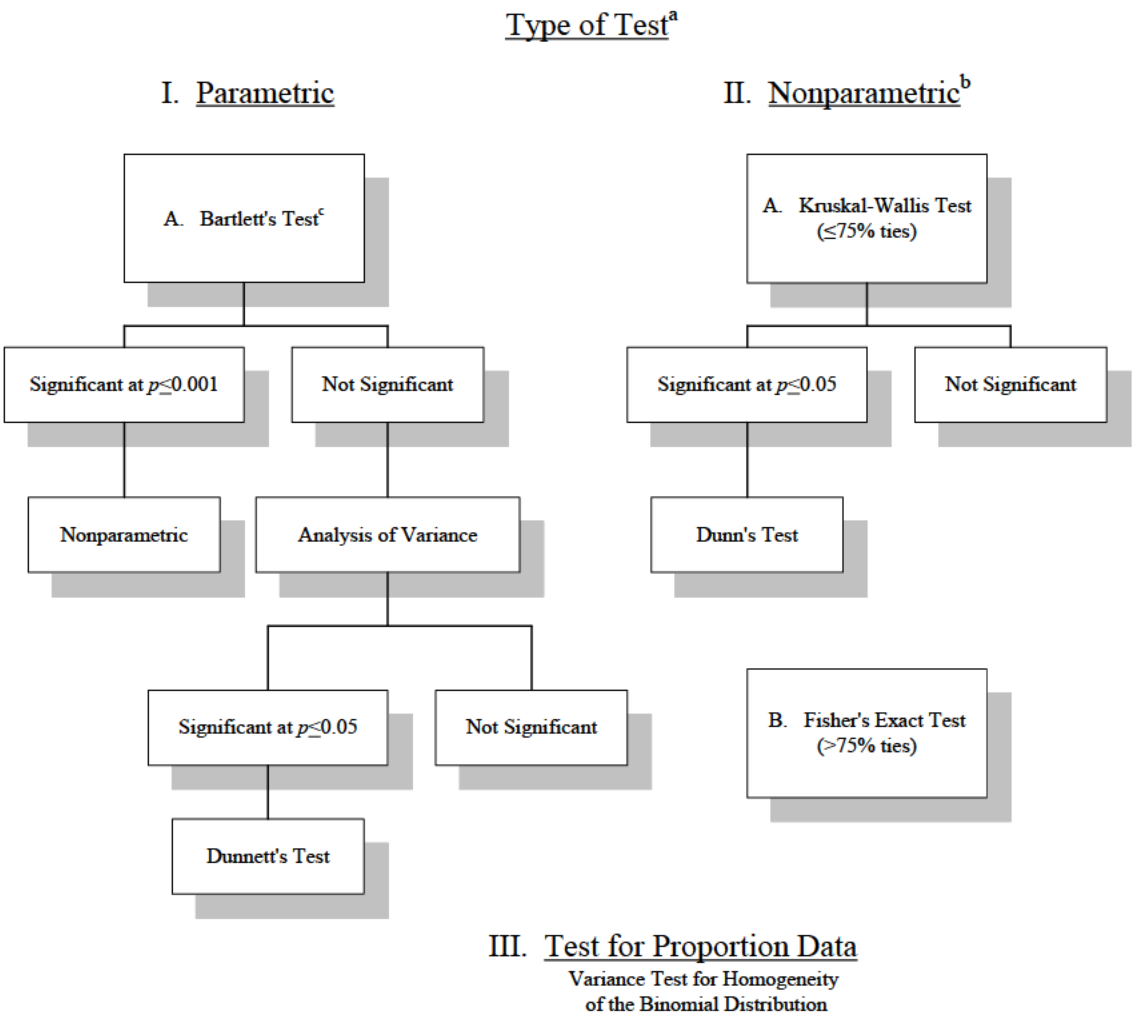
Mice that die or are sacrificed before scheduled termination will be examined for the cause of death or condition as soon as possible after the observation is made. The mice will be examined for gross lesions. When not precluded by autolysis, the heart, kidneys, lungs, stomach and spleen will be retained 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 (≤-70ºC) 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 Distribution[7].

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 Variances[8] and the Analysis of Variance[9], when appropriate [i.e., Bartlett's Test is not significant ($p>0.001$)]. If the Analysis of Variance is significant ($p\leq0.05$), Dunnett's Test[10] 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 ($p\leq0.001$)], the Kruskal-Wallis Test[11] is used (≤75% ties). In cases where the Kruskal-Wallis Test is statistically significant ($p\leq0.05$), Dunn's Method of Multiple Comparisons[12] will be used to identify the statistical significance of the individual groups. If there are greater than 75% ties, Fisher's Exact Test[13] will be used to analyze the data.

Count data will be evaluated using the procedures described above for the Kruskal-Wallis Test[11].

## 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 AB 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 Testing Facility 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: Aan M. Hoberman, Ph.D., DABT, Fellow ATS
Director of Reproductive and Neurobehavioral Toxicology: Elise M. Lewis, Ph.D.
Director of Operations: Matthew J. Vaneman, B.S.
Associate Director of Regulatory Compliance: Nancy A. Catricks, M.S.
Senior Manager of Study Management: Monica L. Davis, B.S., RQAP-GLP, ALAT
Senior Staff Veterinarian: Dena C. Lebo, V.M.D., Division Veterinarian
Chair, Institutional Animal Care and Use Committee: Joseph W. Lech, B.S., LAT
Consultant, Veterinary Pathology: W. Ray Brown, D.V.M., Ph.D., Diplomate, ACVP

## 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 Pharmakol* 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

Stephen K. Durham, DVM, Ph.D., DACVP
Corporate Vice President
Toxicology and Pathology
Global Preclinical Services

21-SEP-2016
Date

**35.1.1. Study Director**

21SEP-2010
Date

Executive Director, Site Operations
and Toxicology
Study Director

Page 33 of 46
Testing Facility Study No. 20005045

**35.2. For The Sponsor[a]**

---------- 22 Sep 2010
Date

Toxicologist
Study Monitor

a. Date of Sponsor Approval: 14 September 2010

**ATTACHMENT 1 -**

**PROPOSED STUDY SCHEDULE**

**PROPOSED SCHEDULE**[a,b]

| | |
|---|---|
| 21 SEP 2010 | Animal Receipt and Experimental Start Date - Acclimation Begins (F0 generation mice). |
| 29 SEP 2010 PM -04 OCT 2010 AM | Cohabitation Period. |
| 30 SEP 2010 | First Possible Day 0 of Presumed Gestation. |
| 04 OCT 2010 | Last Possible Day 0 of Presumed Gestation. |
| 06 OCT 2010 – 22 OCT 2010 | Dosage Period - Days 6 through 18 of presumed gestation. |
| 18 OCT 2010 | First Possible Delivery (Day 18 of presumed gestation). |
| 27 OCT 2010 | Last Possible Delivery (Day 23 of presumed gestation). |
| 23 OCT 2010 | First Possible Day 23 of Presumed Gestation Female Sacrifice. |
| 27 OCT 2010 | Last Possible Day 23 of Presumed Gestation Female Sacrifice. |
| 28 OCT 2010 | Earliest Possible F1 Generation Preweaning 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."

| | |
|---|---|
| 07 NOV 2010 | First Possible Day 21 Weaning (Dams and F1 generation pups not selected for continued observation sacrificed). |
| 16 NOV 2010 | Last Possible Day 21 Weaning. |
| 07 NOV 2010 | Earliest Possible F1 Generation Postweaning Observation - Sexual Maturation |
| 28 NOV 2010 – 07 DEC 2010 | F1 Generation Mice Scheduled Sacrificed and Blood Sample Collection. |
| 18 MAR 2011 | Audited Draft Report - Submission Date. |
| 11 MAY 2011 | Experimental Termination Date. |

**ATTACHMENT 2 -**

**MATERIAL SAFETY DATA SHEET**

DAIKIN

**Safety Data Sheet**
**according to 1907/2006/EC, Article 31**

*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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 3)

**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)

**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 : T1/2 = 1.0 hr, Female : T1/2 = 0.42 hr
Monkey : Male : T1/2 = 5.3 hr, Female : T1/2 = 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 (carcinogenity, 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.
· **Ecotoxical effects:**
· **Acquatic 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.

GB

(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. 20005045.

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:

X Double nitrile gloves, uniform/lab coat, goggles or safety glasses with side shields
X Dust mist/HEPA-filtered Mask
___ Half-Face Respirator
___ Full-Face Respirator/Positive Pressure Hood
X 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.

4. 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 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: 20005045(15.SEP.2010) # of pages: 3

charles river

**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. 20005045**

## 1. Section 23.3. Mice Found Dead or Unscheduled Sacrifice

Fecal samples previously collected from the following mice will be shipped to Zoologix for evaluation of *clostridium*. Samples will be shipped on dry ice to Zoologix, Inc., 9811 Owensmouth Ave, Suite 4, Chatsworth, CA 91311.

| Mouse No. | Day of Death | Number of Pellets |
|---|---|---|
| Group I [0 (Vehicle) mg/kg/day] | | |
| 8314 | Lactation Day 17 | 2 |
| 8316 | Lactation Day 17 | 2 |
| 8328 | Lactation Day 15 | 1 |
| Group II (100 mg/kg/day) | | |
| 8333 | Lactation Day 17 | 1 |
| 8343 | Lactation Day 14 | 3 |
| 8344 | Lactation Day 15 | 1 |
| 8346 | Lactation Day 14 | 3 |
| 8347 | Lactation Day 14 | 3 |
| 8348 | Lactation Day 14 | 3 |
| Group III (500 mg/kg/day) | | |
| 8387 | Lactation Day 14 | 3 |
| 8388 | Lactation Day 14 | 3 |

The analyses will be conducted using good scientific practices and according to the Standard Operating Procedures of the Test Site. Results of this evaluation will be reported in the final report.

**Justification(s):**

Fecal samples will be evaluated from these lactating mice that died prior to scheduled termination to rule out any other cause of death except stress from nursing.

Protocol Amendment No. 1



**Amendment Approval:**

Date: 17 Dec 2010

Executive Director, Site Operations and Toxicology
Study Director

**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. 20005045**

1. **Section 14.3. Analyses of Prepared Formulations**
   **Section 14.3.2. Stability**

The method validation number for formulation analysis was 211052 rather than 211271.

**Justification:**

This change is being made to correct the method validation number.

**Amendment Approval:**

Date: 14 JUN-2011

Executive Director, Site Operations and Toxicology
Study Director

# APPENDIX 2 - DEVIATIONS

## 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 that could have impacted the quality or integrity of the study are listed below.

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 (dams)
PPD – Postpartum day (litters)

### In-life Observations, Measurements and Evaluations

- Maternal observations for F0 generation mice 8331 and 8332 (Group II) were not recorded on DL 4 (23 October 2010), mouse 8362 (Group III) on DL 14 (2 November 2010) and mouse 8315 (Group I) on DL 20 (8 November 2010). These deviations did not adversely affect the outcome or interpretation of the study because sufficient data were collected from other mice.

- Litter observations were not recorded for dam 8388 (Group IV) on DL 19 (9 November 2010). All pups appeared normal the next day. This deviation did not adversely affect the outcome or interpretation of the study because there was no impact.

- F1 generation mouse 9035 (Group II) was discovered to be female after originally being weaned as a male. As a result, this mouse missed her vaginal patency testing between PPD 20 through PPD 26. This mouse passed vaginal patency on the day the error was discovered (17 November 2010). This deviation did not adversely affect the outcome or interpretation of the study because the data was handled appropriately and sufficient data were available from other mice.

- F1 generation mouse 9102 (Group II) was discovered to be male after originally being weaned as a female. As a result, this mouse missed his first day of preputial testing. This mouse did not pass testing on the first day the error was discovered (14 November 2010). This deviation did not adversely affect the outcome or interpretation of the study because the data was handled appropriately and sufficient data were available from other mice.

**Postmortem**

- F0 generation female mouse 8361 (Group III) did not receive a body weight prior to necropsy. This deviation did not adversely affect the outcome or interpretation of the study because sufficient data were available from other mice.

- A liver sample could not be located for F1 generation male mouse 9049 (Group III) on PPD 23 (12 November 2010). This deviation did not adversely affect the outcome or interpretation of the study because sufficient data were available from other mice.

**Formulations**

- The additional amount of vehicle prepared on 16 October 2010 did not mix overnight prior to dosing. This deviation did not adversely affect the outcome or interpretation of the study because this was the control article and there was no impact on the conduct of the study.

- On 5 and 16 October 2010, the samples taken for analysis were sampled outside of the 24 hour criteria stipulated in the protocol. The sample taken on 5 October was sampled 43 minutes late; while the latter sample was taken one hour early. This deviation did not adversely affect the outcome or interpretation of the study because the time deviated was minimal.

**Other**

- Pups belonging to dams that died (8343, 8346, 8348; Group II) remained on study at the discretion of the Study Director on DL 13 (3 November 2010). This deviation did not adversely affect the outcome or interpretation of the study because data was appropriately documented in the raw data.

- Fecal samples were collected on study per Veterinarian and Study Director request. The collection and shipping procedures were not documented in the raw data, there was no SOP in place for fecal collections and shipment, and there was no documentation of the collected/shipped amount of fecal samples and the shipping condition. These deviations did not adversely affect the outcome or interpretation of the study because there was no effect on the data. Samples were collected at the recommendation of the veterinarian and would fall within the scope of the veterinary procedures.

# APPENDIX 3 - CERTIFICATE OF ANALYSIS

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*

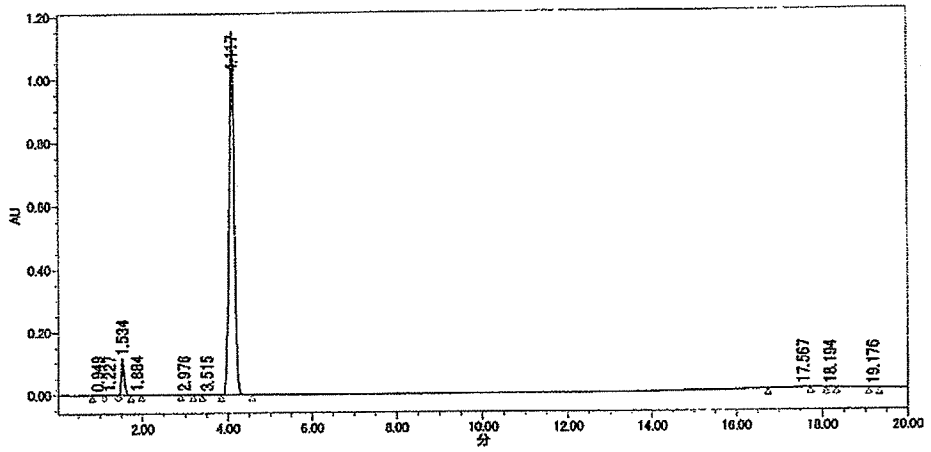
| | |
|---|---|
| *Column* | *: TOSOH TSKGel ODS120T 4.6mm×150mm* |
| *Temp.* | *: 40 ℃* |
| *Mobile phase* | *: A=acetonitrile 、B=Solution of 0.6% perchloric acid in water* |
| *Gradient* | *: A:B=50:50(mass%) (0-10min.) →90:10(mass%) (15-20min.)* |
| *Injection volume* | *: 20μL* |
| *Injection Concentration* | *: 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 | 分析担当者: | System |
| サンプルの種類: | 未知試料 | 分析日: | 2009/05/14 11:49:44 |
| バイアル: | 82 | 取り込みメソッドセット: | 090514S |
| 注入#: | 1 | 解析日: | 2009/05/14 13:55:17 |
| 注入量: | 20.00 μl | 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 (μVsec.) | Area (%) | Height (μV) | | |
|---|---|---|---|---|---|---|---|
| 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

charles river

**FINAL REPORT**

**Test Site Ref. No. 211271**
**Testing Facility Study No. 20005045**

# 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**
**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**

**17 June 2011**

**Page 1 of 27**

## TABLE OF CONTENTS

## LIST OF TABLES

## LIST OF FIGURES

## LIST OF APPENDICES

## 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 appropriate GLP principles of the Organization for Economic Co-operation and Development (OECD), (ENV/MC/CHEM(98)17.

_____ 17 Jun 2011

Date

Principal Investigator
Research Scientist, Analytical Chemistry
Laboratory Sciences
Charles River Laboratories

## 2. QUALITY ASSURANCE STATEMENT

In compliance with the Good Laboratory Practice Regulations, Reference No. 211271 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 | 14 October 2010 | 14 October 2010 | 07 December 2010 |
| Anchem Dose Data<br>Anchem Dose Report - Report Review<br>SOP Review - Report Review<br>Anchem Dose Report Tabulation | 17 November 2010 to 23 November 2010 | 23 November 2010 | 07 December 2010 |
| Final Report Review | 06 June 2011 to 07 June 2011 | 07 June 2011 | 15 June 2011 |
| Protocol Amendment Review | 14 June 2011 | 14 June 2011 | 15 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.

17 June 2011
Date

Inspector
Quality Assurance
Charles River Laboratories

## 3. SUMMARY

The purpose of this phase of the study was to determine the concentration, the purity and stability of the bulk drug substance of Perfluorinated Hexanoic Acid (PFH) ammonium salt in dose formulations from Charles River Laboratories Study No. 20005045 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.211271.SL.02 for concentration determination was previously validated under Study No. 211052. The method documented in Analytical Procedure AP.211271.PU.02, for bulk material purity and stability analysis was provided by the Sponsor.

The study samples analyzed were within the acceptance criteria of ±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 ≤ 5%. Homogeneity results show that the formulation technique used produces homogenous preparations.

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.

## 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. 20005045 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.211271.SL.02 for concentration determination was previously validated under Study No. 211052. The method documented in Analytical Procedure AP.211271.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 September 2010 (the signature date of the protocol) and the completion date is the signature date of the final report. The experimental start date was 07 October 2010 and the experimental end date was 01 November 2010.

## 5. REFERENCE STANDARD AND VEHICLE

### 5.1. Reference Standard (Bulk Substance)

| | |
|---|---|
| Identity: | PFH Ammonium Salt (C-1500N) |
| Lot number: | 7005 |
| CAS number: | 21645-47-4 |
| Purity: | 47.4% (total purity) as per CoA |
| Expiry date: | 31 July 2012 |
| Description: | Clear liquid |
| Storage conditions: | Room temperature, light |
| Handling precautions: | As per the material safety data sheets |
| Supplier: | Charles River Laboratories Preclinical Services Pennsylvania (PCS-PA) |

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 reference standard was supplied as a 50% aqueous solution.

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.

### 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 356 µg/mL.

### 6.3. Spiked Samples

Spiked samples were prepared in vehicle at nominal concentrations of 0.500 and 200 mg/mL. Each was diluted with diluent to give nominal concentrations of 40.0 and 200 µg/mL, respectively.

### 6.4. Study Samples

Formulation samples (top, middle and bottom) from Study No. 20005045, prepared on 04 October 2010, (Group 1 samples were prepared on 05 October 2010) were received at ambient room temperature on 06 October 2010 for concentration and homogeneity determination. Furthermore, formulation samples (middle) prepared on the 08 and 15 October 2010 (Group 1 samples prepared on the 09 and 16 October 2010, respectively), were received at ambient room temperature on the 18 and 19 October 2010, respectively, for concentration analysis. All samples were stored at ambient room temperature until analysis. The samples at nominal concentrations of 20, 70 and 100 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 ±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 ≤ 5%.

### 6.5. Bulk Test Substance Stability

A 10 mL sample of the test substance (50% w/w) was received from Study No. 20005045 for stability assessment. The sample was shipped at ambient room temperature on 26 October 2010 and received on 27 October 2010. The sample was stored at ambient room temperature and analyzed on 01 November 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 µm (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 µL

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 |
| 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: | ~3.6 min |

### 6.7. System Suitability

For concentration and homogeneity 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 ≤ 3% in peak area and a difference of ±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 table were calculated from rounded values, as per the raw data rounding procedure, 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 ≤ 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 ±10%. Acceptance criteria with respect to system suitability were met.

For bulk substance stability, the CV for 1% test sample solution was ≤ 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 ±10%.

### 7.2. Study Samples

All study samples analyzed for concentration were within the mean acceptance criteria of ±10% of their target values. For homogeneity, the relative standard deviation of the grand mean for all locations was ≤ 5% for all groups.

Study sample results are expressed using a purity of 95% and an effective component in water of 50% (w/v) for a total purity of 47.5%.

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

The dose formulations were within specification. Homogeneity results show that the formulation technique used produces homogenous preparations. In addition, purity and stability of the bulk reference material collected on the last day of the study was assessed and results were deemed acceptable.

**Table 1 Study Samples - Concentration and Homogeneity**

| Sampling date | Group | Nominal concentration (mg/mL) | Sampling location | Measured concentration (mg/mL) | Percent of nominal | Homogeneity (RSD) |
|---|---|---|---|---|---|---|
| 05 Oct 2010 | 1 | 0 | Top | < LLOQ | - | - |
| | | | | < LLOQ | - | |
| | | | Middle | < LLOQ | - | |
| | | | | < LLOQ | - | |
| | | | Bottom | < LLOQ | - | |
| | | | | < LLOQ | - | |
| | | | Mean | < LLOQ | - | |
| | 2 | 20 | Top | 20.9 | 104 | 1.2 |
| | | | | 20.2 | 101 | |
| | | | Middle | 20.3 | 102 | |
| | | | | 20.5 | 102 | |
| | | | Bottom | 20.3 | 102 | |
| | | | | 20.1 | 101 | |
| | | | Mean | 20.4 | 102 | |
| | 3 | 70 | Top | 70.6 | 101 | 1.1 |
| | | | | 68.9 | 98.5 | |
| | | | Middle | 68.5 | 97.8 | |
| | | | | 70.1 | 100 | |
| | | | Bottom | 69.2 | 99.1 | |
| | | | | 69.4 | 99.3 | |
| | | | Mean | 69.5 | 99.3 | |
| | 4 | 100 | Top | 98.4 | 98.4 | 0.7 |
| | | | | 100 | 100 | |
| | | | Middle | 99.5 | 99.4 | |
| | | | | 98.6 | 98.6 | |
| | | | Bottom | 99.1 | 99.1 | |
| | | | | 99.8 | 99.8 | |
| | | | Mean | 99.3 | 99.3 | |

LLOQ - lower limit of quantitation (0.500 mg/mL)

**Table 2 Study Samples - Concentration**

| Sampling date | Group identification/ level | Nominal concentration (mg/mL) | Measured concentration (mg/mL) | Mean measured concentration (mg/mL) | Percent of nominal | Mean percent of nominal |
|---|---|---|---|---|---|---|
| 09 Oct 2010 | 1/Mid | 0 | < LLOQ | < LLOQ | - | - |
| | | | < LLOQ | | - | |
| | 2/Mid | 20 | 20.5 | 20.4 | 102 | 102 |
| | | | 20.4 | | 102 | |
| | 3/Mid | 70 | 70.1 | 70.0 | 100 | 100 |
| | | | 69.9 | | 100 | |
| | 4/Mid | 100 | 101 | 101 | 101 | 101 |
| | | | 101 | | 101 | |
| 16 Oct 2010 | 1/Mid | 0 | < LLOQ | < LLOQ | - | - |
| | | | < LLOQ | | - | |
| | 2/Mid | 20 | 20.3 | 20.2 | 101 | 101 |
| | | | 20.1 | | 100 | |
| | 3/Mid | 70 | 70.4 | 70.3 | 101 | 100 |
| | | | 70.2 | | 100 | |
| | 4/Mid | 100 | 100 | 100 | 100 | 100 |
| | | | 100 | | 100 | |

LLOQ - lower limit of quantitation (0.500 mg/mL)

**Table 3 Bulk Substance Stability**

| 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 CoA

**Figure 1** **Representative Standard Chromatogram (Nominal Concentration: 190 µg/mL)**

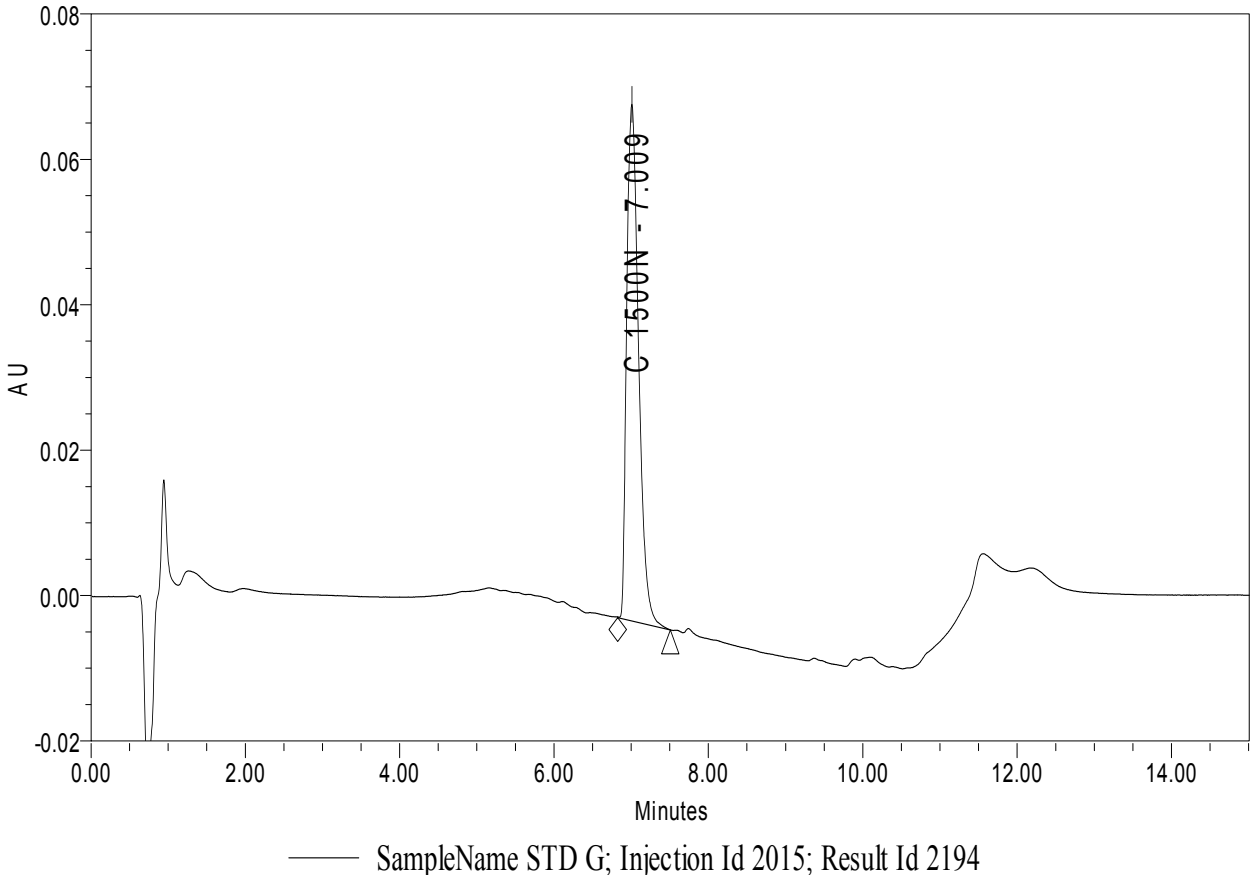


**Figure 2 Representative Blank Vehicle**

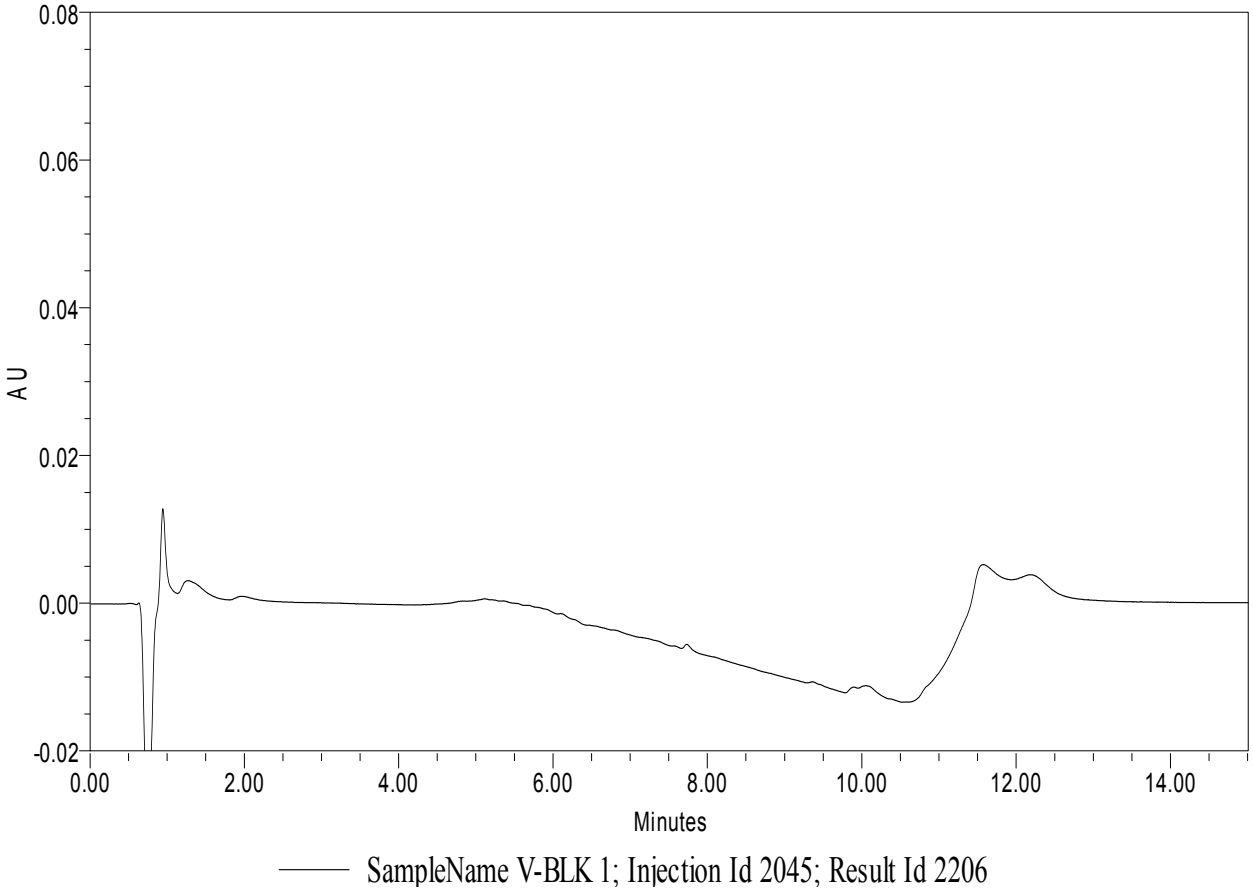


**Figure 3** **Representative Study Sample Chromatogram (Group 4, Mid Sampling Date: 16 October 2010, Nominal Concentration: 100 mg/mL; Nominal Injected Concentration: 200 µg/mL)**

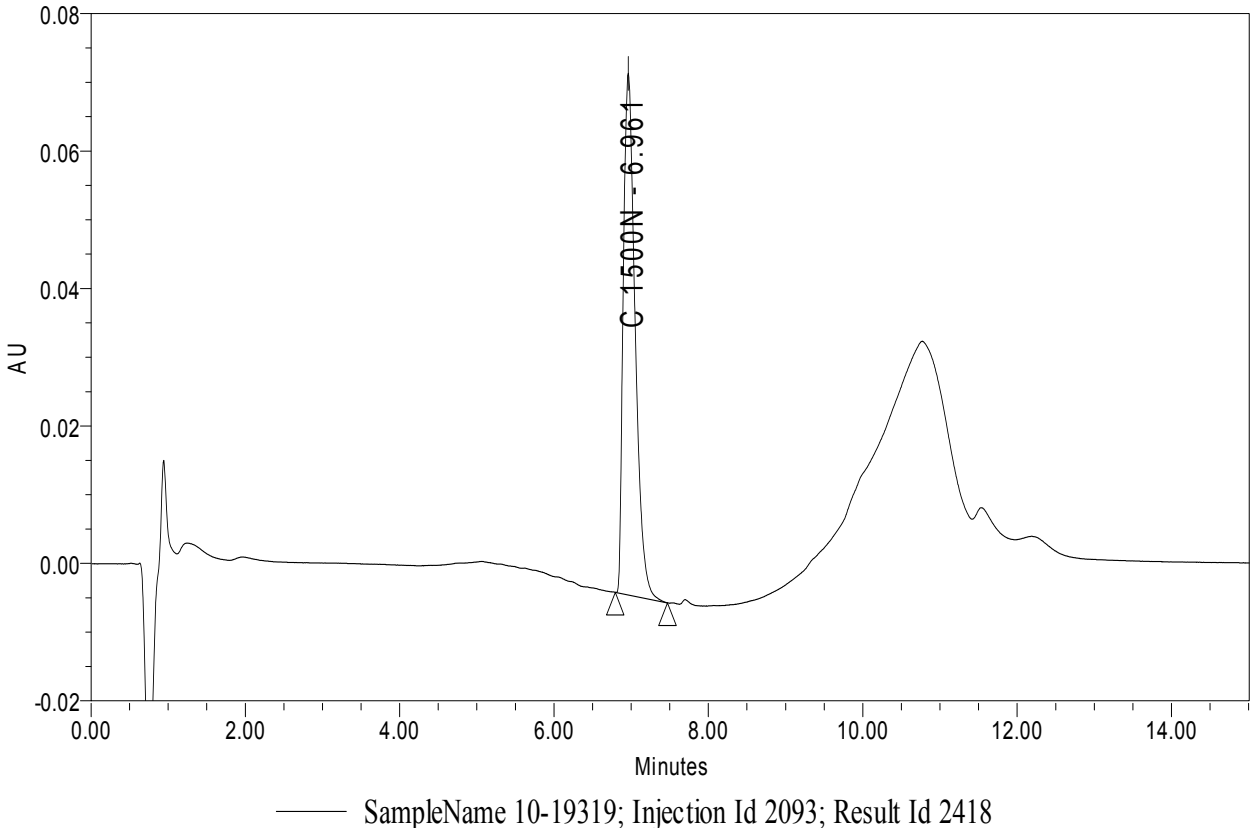
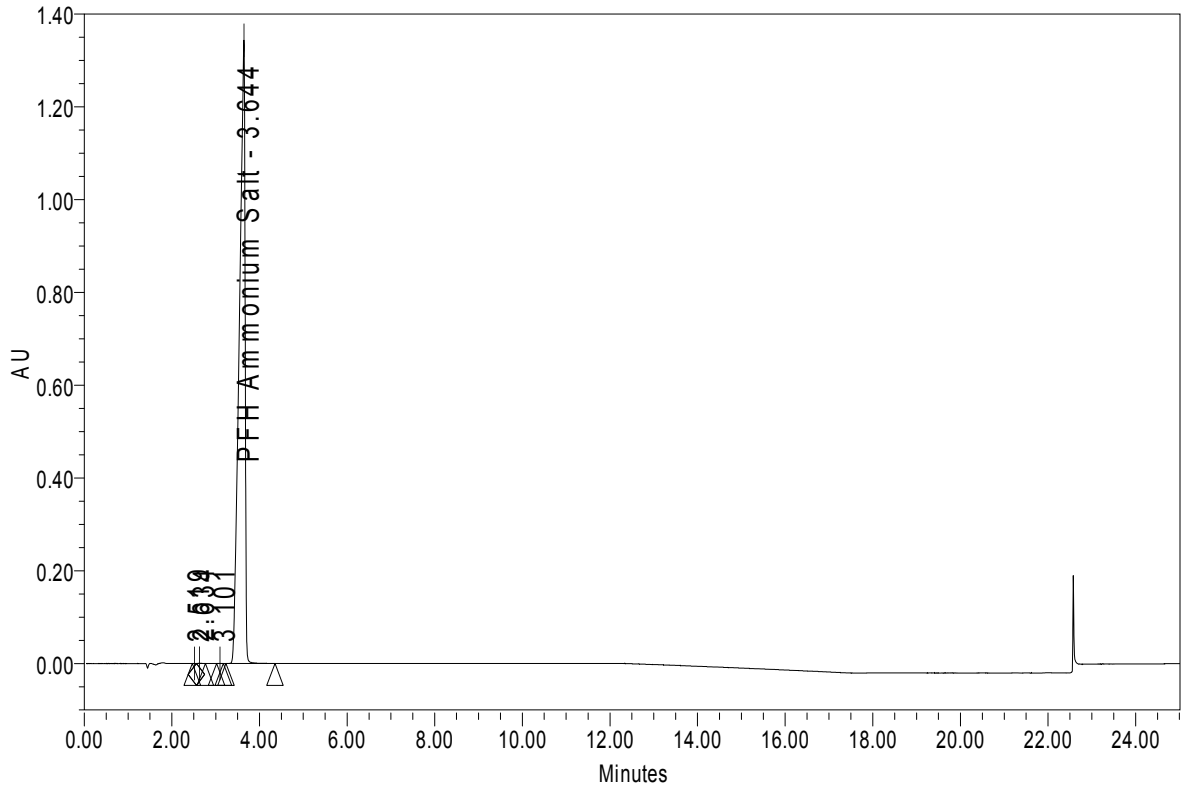


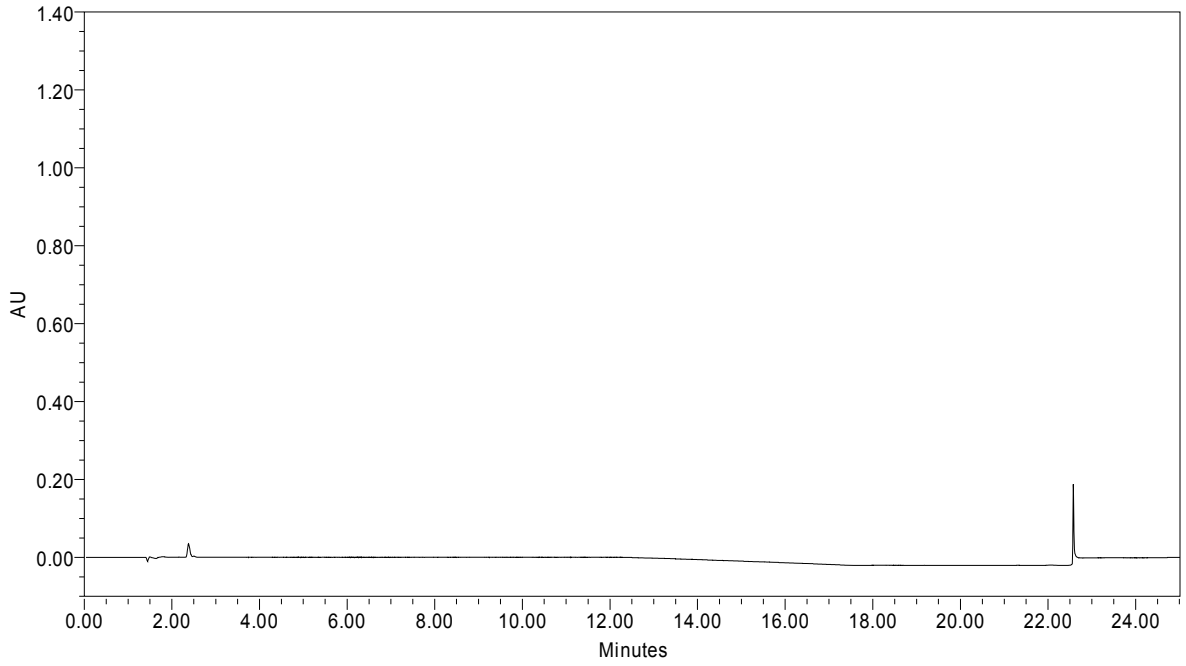
**Figure 4 Representative Bulk Substance Sample (Full Scale)**




**Peak Results**

| | Name | SMP_Name | Injection Id | Result Id | % Area | Area | RT |
|---|---|---|---|---|---|---|---|
| 1 | | 10-20648A | 2284 | 2336 | 0.01 | 752 | 2.519 |
| 2 | | 10-20648A | 2284 | 2336 | 0.03 | 3636 | 2.634 |
| 3 | | 10-20648A | 2284 | 2336 | 0.01 | 1046 | 3.101 |
| 4 | PFH Ammonium Salt | 10-20648A | 2284 | 2336 | 99.96 | 12171372 | 3.644 |

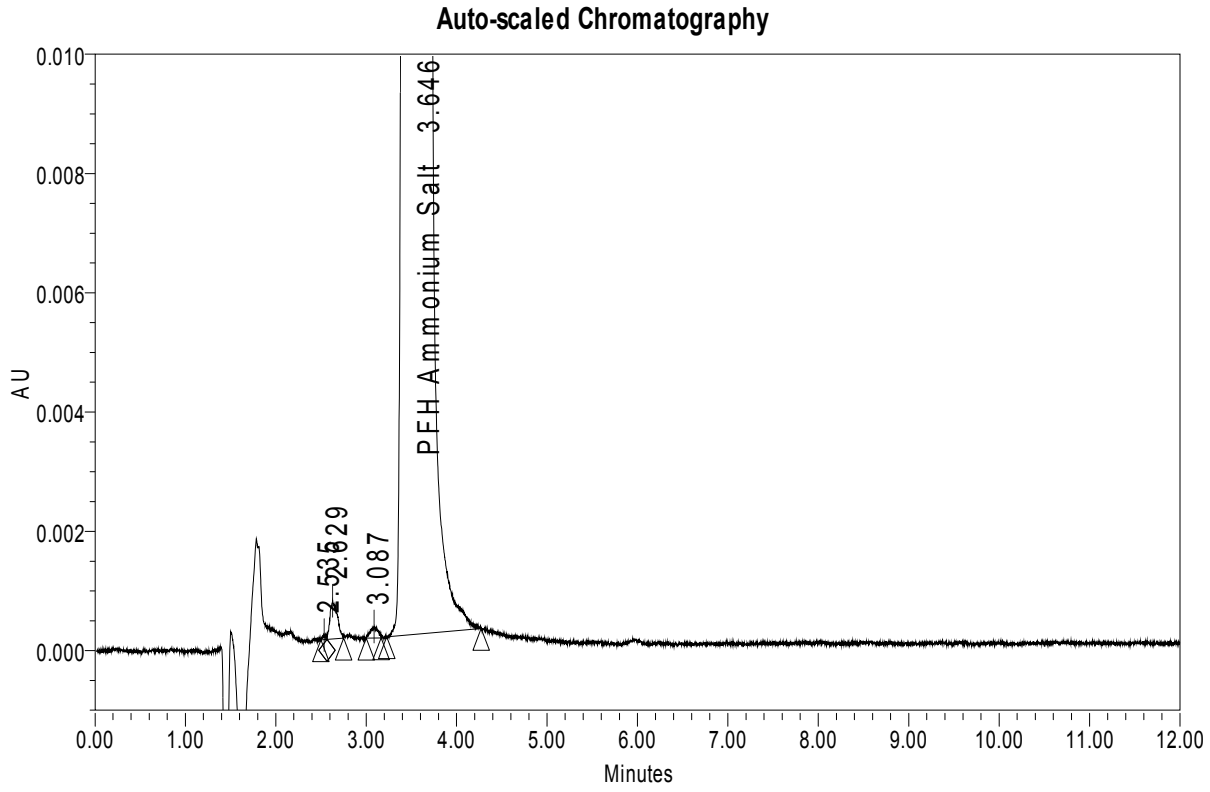
**Figure 5 Representative Blank Sample (Full Scale)**




**Peak Results**

| | Name | SMP_Name | Injection Id | Result Id | % Area | Area | RT |
|---|---|---|---|---|---|---|---|
| 1 | PFH Ammonium Salt | BLK | 2270 | 2339 | | | 3.570 |

**Figure 6 Representative Bulk Substance Sample (Auto-scaled)**




**Peak Results**

| | Name | SMP_Name | Injection Id | Result Id | % Area | Area | RT |
|---|---|---|---|---|---|---|---|
| 1 | | 10-20648B | 2288 | 2335 | 0.00 | 197 | 2.535 |
| 2 | | 10-20648B | 2288 | 2335 | 0.03 | 3552 | 2.629 |
| 3 | | 10-20648B | 2288 | 2335 | 0.01 | 1083 | 3.087 |
| 4 | PFH Ammonium Salt | 10-20648B | 2288 | 2335 | 99.96 | 12241385 | 3.646 |

**Appendix 1 Certificate of Analysis**

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%* |

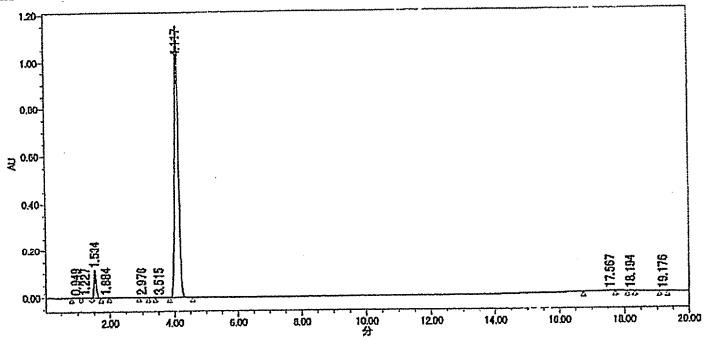
*Analysis system (HPLC)*
*Equipment* *: Waters Alliance2695*
*Detector* *: Waters 2487UV*
*Detection wavelength* *: 210nm*
*Analysis condition*
*Column* *: TOSOH TSKGel ODS120T 4.6mm×150mm*
*Temp.* *: 40 ℃*
*Mobile phase* *: A=acetonitrile 、B=Solution of 0.6% perchloric acid in water*
*Gradient* *: A:B=50:50(mass%) (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 | 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： | 090514S |
| 注入#： | 1 | 解析日： | 2009/05/14 13:55:17 |
| 注入量： | 20.00 μl | 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 (μVsec.) | Area (%) | Height (μV) | | |
|---|---|---|---|---|---|---|---|
| 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 | | |

1/1 ページ

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 5 - PHARMACOKINETIC REPORTS

**FINAL REPORT**

**Test Site Ref. No. 142577**
**Testing Facility Study No. 20005045**

# Determination of Perfluorohexanoic Acid (PFH) in Mouse Serum (CD1) by Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS) in Support of Toxicology Study No. 20005045

**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**
**United States**

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

**10 June 2011**

**Page 1 of 28**

## TABLE OF CONTENTS

## LIST OF TABLES

## LIST OF FIGURES

## LIST OF APPENDICES

## 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 Organization for Economic Co-operation and Development (OECD) Principles of GLP (ENV/MC/CHEM(98)17.

10 Jun 2011

Date

Bioanalytical Principal Investigator
Research Scientist, Bioanalysis
Laboratory Sciences
Charles River Laboratories

## 2. QUALITY ASSURANCE STATEMENT

In compliance with the Good Laboratory Practice Regulations, Reference No. 142577 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 | 07 October 2010 | 07 October 2010 | 25 February 2011 |
| Bioanalysis Data<br>Sample Management/Shipping Records - Data Review<br>SOP Review - Report Review<br>Bioanalysis Report Tabulation<br>Bioanalysis Matrix Report | 03 February 2011 to 14 February 2011 | 14 February 2011 | 25 February 2011 |
| Final Report Review | 27 May 2011 to 31 May 2011 | 31 May 2011 | 08 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.

10 Jun 2011
Date

Inspector
Quality Assurance
Charles River Laboratories

## 3. SUMMARY

The concentrations of Perfluorohexanoic Acid (PFH) in Mouse Serum samples in support of Testing Facility Study No. 20005045, 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.

## 4. INTRODUCTION

The concentrations of Perfluorohexanoic Acid (PFH) 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.142577.SE.01, was previously validated (Study No. 141837).

For the work detailed in this report, the experimental start date was 23 December 2010 and the experimental end date was 03 January 2011. The study 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) |
| Lot number: | 7005 |
| Purity: | 93.4% (correction factor: 0.474, corrected for effective component in solution) |
| Expiry date: | 31 July 2012 |
| 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: | MPFHxA0910 |
| Purity: | > 98% (50 µg/mL certified solution) |
| Expiry date: | 23 September 2013 |
| Storage condition: | In a refrigerator set to maintain 4°C, dark |

The reference standard characterization was the responsibility of the Sponsor who provided Certificates 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.

### 5.3. Blank Matrix

| | |
|---|---|
| Identity: | Mouse serum |
| Species: | *Mus musculus* |
| Strain: | CD1 |

## 6. EXPERIMENTAL PROCEDURES

### 6.1. Calibration Standards

Calibration standards of reference standard were prepared in blank mouse serum covering the theoretical concentration range of 1.00 to 1000 µg/mL. Calibration standards consisted of blank 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 mouse serum at theoretical concentrations of 3.00, 60.0 and 700 µg/mL. QC samples consisted of blank 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 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).

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 µm (50 x 4.6 mm id) |
| Column temperature: | Set at 50°C |
| Mobile phase gradient elution: | Eluent A: 2mM ammonium acetate, pH 4.0<br>Eluent B: methanol:2mM ammonium acetate (pH 4.0); 80:20, v/v |

| Time (min) | %B |
|---|---|
| 0.0 | 70 |
| 3.5 | 70 |

| | |
|---|---|
| Flow rate: | 1.0 mL/min |
| Injection volume: | 5 µL |
| 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: | AB Sciex API 4000 |
| Data capture system: | AB 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 | ~2.3 | 200 | -40 | -5 | -13 | -15 |
| PFHxA-1,2-$^{13}$C2 | 315.0 | 270.0 | ~2.3 | 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 ≤ 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 AB Sciex.

Statistical analyses included quadratic regression with 1/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 phase report will be transferred to the scientific archives of PCS-MTL for a period of approximately 1 year from finalization.

## 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, 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.

There were no re-assay samples in the study.

**Table 1 Serum Concentrations of Perfluorohexanoic Acid (PFH)**

| Subject | Gender/Generation | Subject Group | Study Day | Nominal Time | Concentration (µg/mL) |
|---|---|---|---|---|---|
| 9002 | Male / F1 | 1 | 42 | OD42 Terminal | < LLOQ |
| 9003 | Male / F1 | 1 | 42 | OD42 Terminal | < LLOQ |
| 9004 | Male / F1 | 1 | 42 | OD42 Terminal | < LLOQ |
| 9005 | Male / F1 | 1 | 42 | OD42 Terminal | < LLOQ |
| 9006 | Male / F1 | 1 | 42 | OD42 Terminal | < LLOQ |
| 9082 | Female / F1 | 1 | 42 | OD42 Terminal | < LLOQ |
| 9083 | Female / F1 | 1 | 42 | OD42 Terminal | < LLOQ |
| 9084 | Female / F1 | 1 | 42 | OD42 Terminal | < LLOQ |
| 9085 | Female / F1 | 1 | 42 | OD42 Terminal | < LLOQ |
| 9086 | Female / F1 | 1 | 42 | OD42 Terminal | < LLOQ |
| 9022 | Male / F1 | 2 | 42 | OD42 Terminal | < LLOQ |
| 9023 | Male / F1 | 2 | 42 | OD42 Terminal | < LLOQ |
| 9024 | Male / F1 | 2 | 42 | OD42 Terminal | < LLOQ |
| 9025 | Male / F1 | 2 | 42 | OD42 Terminal | < LLOQ |
| 9026 | Male / F1 | 2 | 42 | OD42 Terminal | < LLOQ |
| 9103 | Female / F1 | 2 | 42 | OD42 Terminal | < LLOQ |
| 9104 | Female / F1 | 2 | 42 | OD42 Terminal | < LLOQ |
| 9105 | Female / F1 | 2 | 42 | OD42 Terminal | < LLOQ |
| 9106 | Female / F1 | 2 | 42 | OD42 Terminal | < LLOQ |
| 9107 | Female / F1 | 2 | 42 | OD42 Terminal | < LLOQ |
| 9043 | Male / F1 | 3 | 42 | OD42 Terminal | < LLOQ |
| 9044 | Male / F1 | 3 | 42 | OD42 Terminal | < LLOQ |
| 9045 | Male / F1 | 3 | 42 | OD42 Terminal | < LLOQ |
| 9046 | Male / F1 | 3 | 42 | OD42 Terminal | < LLOQ |
| 9047 | Male / F1 | 3 | 42 | OD42 Terminal | < LLOQ |
| 9124 | Female / F1 | 3 | 42 | OD42 Terminal | < LLOQ |
| 9125 | Female / F1 | 3 | 42 | OD42 Terminal | < LLOQ |
| 9126 | Female / F1 | 3 | 42 | OD42 Terminal | < LLOQ |
| 9127 | Female / F1 | 3 | 42 | OD42 Terminal | < LLOQ |
| 9128 | Female / F1 | 3 | 42 | OD42 Terminal | < LLOQ |
| 9063 | Male / F1 | 4 | 42 | OD42 Terminal | < LLOQ |
| 9064 | Male / F1 | 4 | 42 | OD42 Terminal | < LLOQ |
| 9065 | Male / F1 | 4 | 42 | OD42 Terminal | < LLOQ |
| 9066 | Male / F1 | 4 | 42 | OD42 Terminal | < LLOQ |
| 9067 | Male / F1 | 4 | 42 | OD42 Terminal | < LLOQ |
| 9143 | Female / F1 | 4 | 42 | OD42 Terminal | < LLOQ |
| 9144 | Female / F1 | 4 | 42 | OD42 Terminal | < LLOQ |
| 9145 | Female / F1 | 4 | 42 | OD42 Terminal | < LLOQ |
| 9146 | Female / F1 | 4 | 42 | OD42 Terminal | < LLOQ |
| 9147 | Female / F1 | 4 | 42 | OD42 Terminal | < LLOQ |

LLOQ – lower limit of quantitation (theoretical concentration 1.00 µg/mL)

**Table 2 Calibration Standard Statistics**

| Analytical Run[a] | Concentration (µg/mL) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 1.00 | 2.00 | 5.00 | 25.0 | 50.0 | 100 | 200 | 400 | 800 | 1000 |
| 2 | 1.01 | 2.01 | 4.78 | 22.3 | 51.1 | 99.4 | 223 | 288[b] | 893 | 887 |
| Mean | NC | NC | NC | NC | NC | NC | NC | NC | NC | NC |
| S.D. | NC | NC | NC | NC | NC | NC | NC | NC | NC | NC |
| % CV | NC | NC | NC | NC | NC | NC | NC | NC | NC | NC |
| % Bias | 0.9 | 0.5 | -4.4 | -10.8 | 2.1 | -0.6 | 11.7 | NC | 11.7 | -11.3 |
| n | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 |

a = Run 01 was a qualification batch, no study samples were analyzed, data not included in summary.
b = Outside of acceptance criteria
NC - Not calculated for sample set where n < 3

**Table 3 Quality Control Sample Statistics**

| Analytical Run[a] | Concentration (µg/mL) | | |
|---|---|---|---|
| | 3.00 | 60.0 | 700 |
| 2 | 3.08 | 52.3 | 649 |
| | 2.93 | 55.1 | 670 |
| | 3.09 | 53.9 | 623 |
| | 2.96 | 55.5 | 684 |
| Mean | 3.016 | 54.18 | 656.7 |
| S.D. | 0.0785 | 1.447 | 26.56 |
| % CV | 2.6 | 2.7 | 4.0 |
| % bias | 0.5 | -9.7 | -6.2 |
| n | 4 | 4 | 4 |

a = Run 01 was a qualification batch, no study samples were analyzed, data not included in statistical calculation.

**Figure 1** **Representative Calibration Line (Theoretical Concentration 1.00 to 1000 µg/mL)**

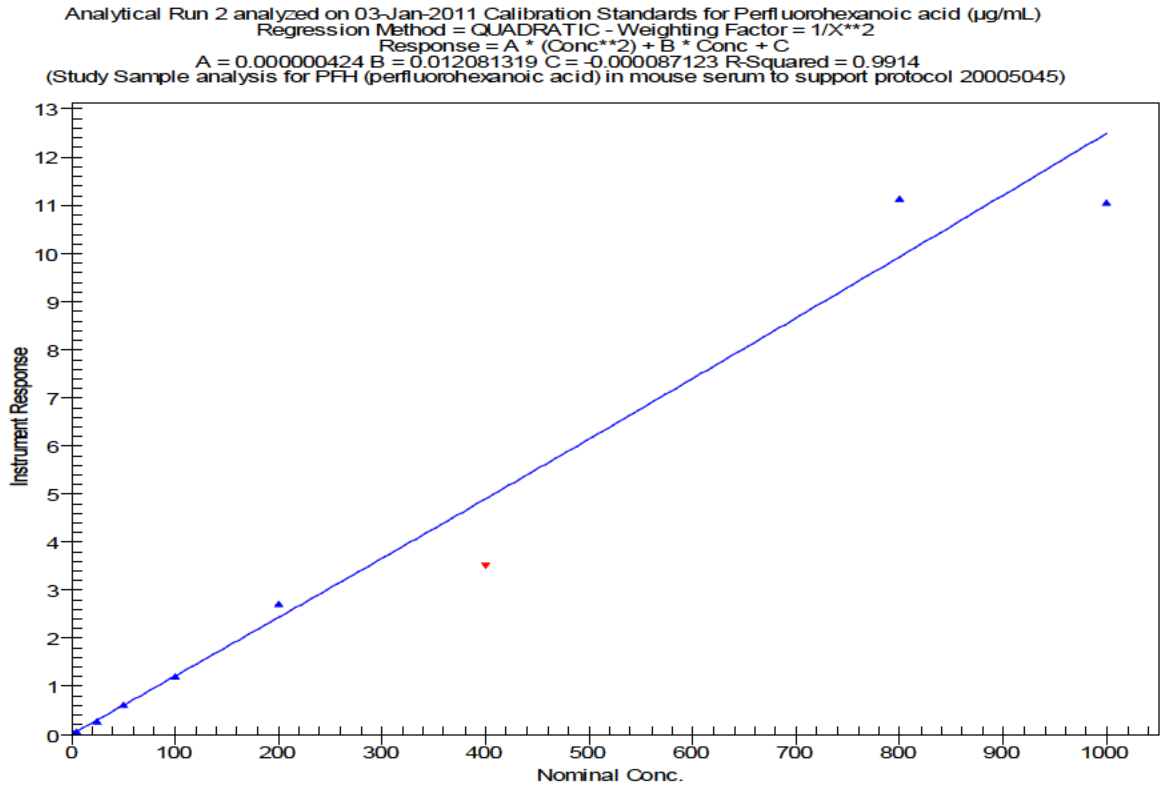


**Figure 2** **Representative LLOQ Standard Chromatogram (Theoretical Concentration 1.00 µg/mL)**

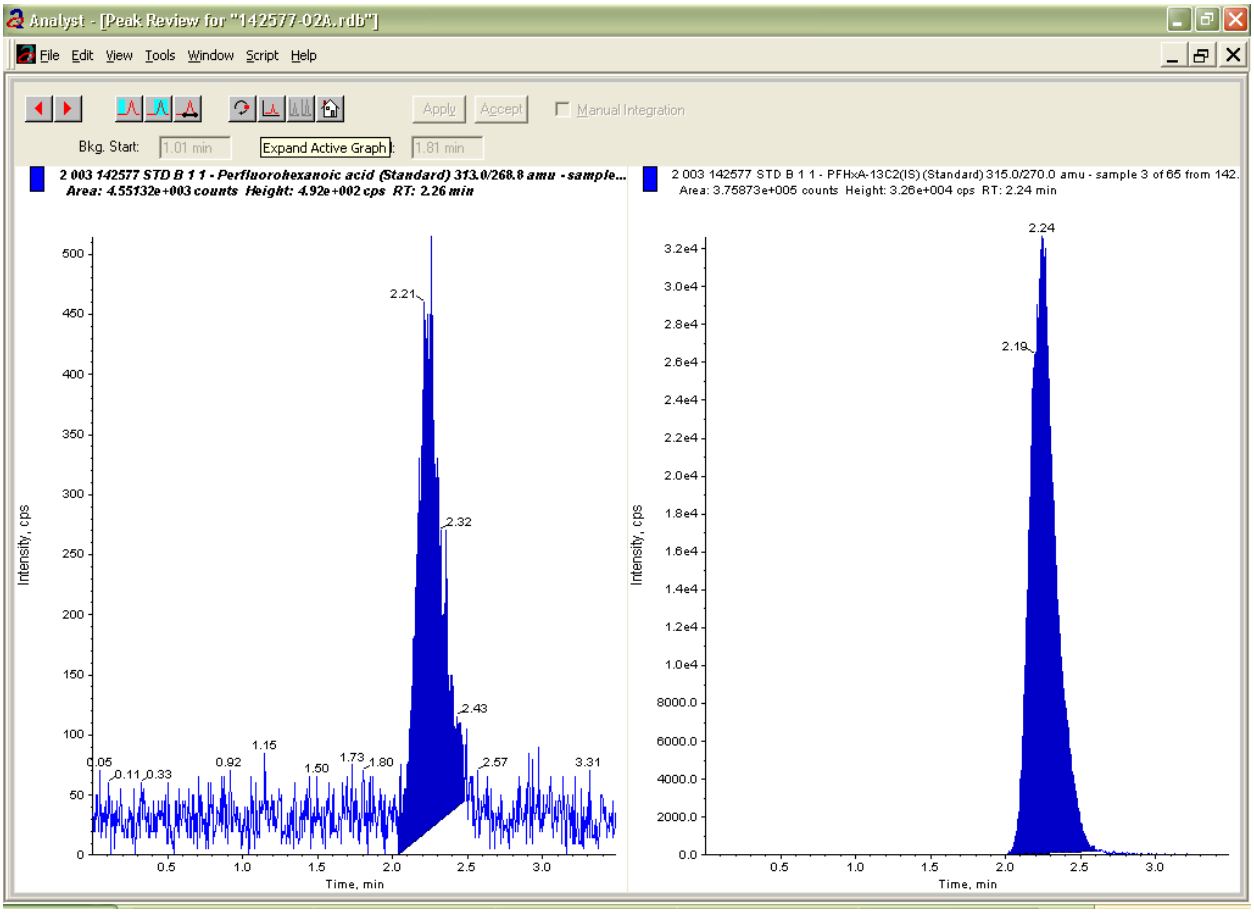


**Figure 3** **Representative ULOQ Standard Chromatogram (Theoretical Concentration 1000 µg/mL)**

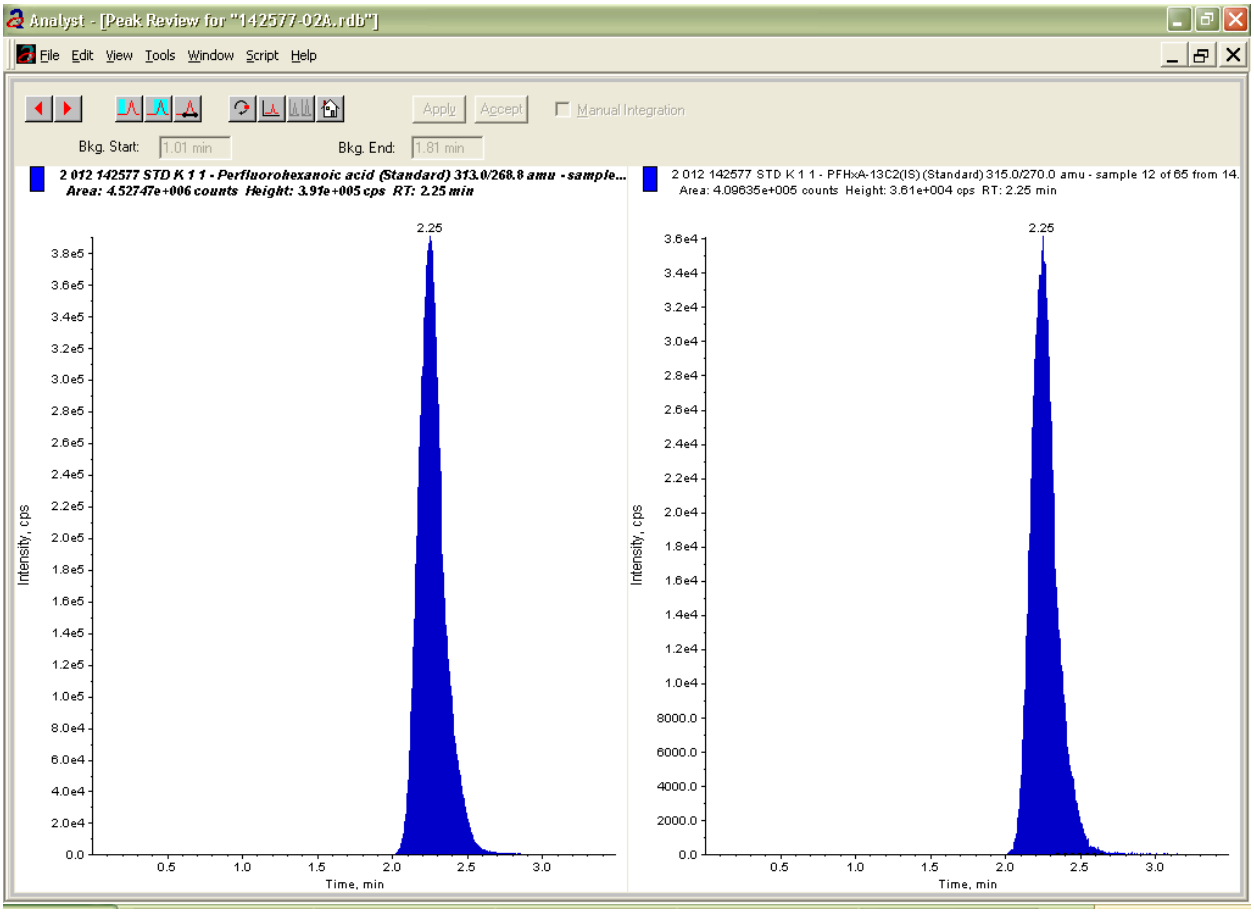


**Figure 4 Representative Double Blank Chromatogram**

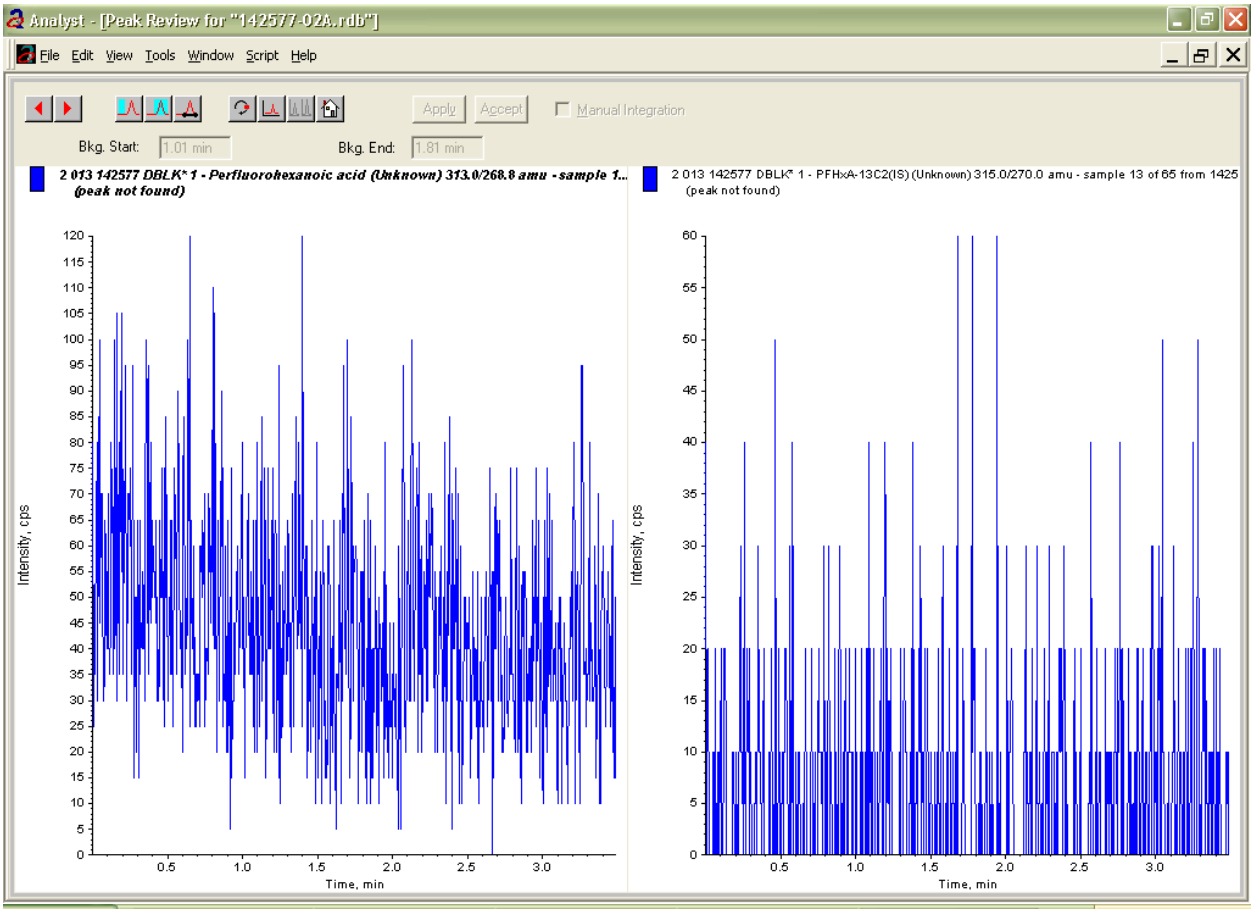


**Figure 5 Representative Sample Chromatogram (Group 1, Animal No. 9002)**

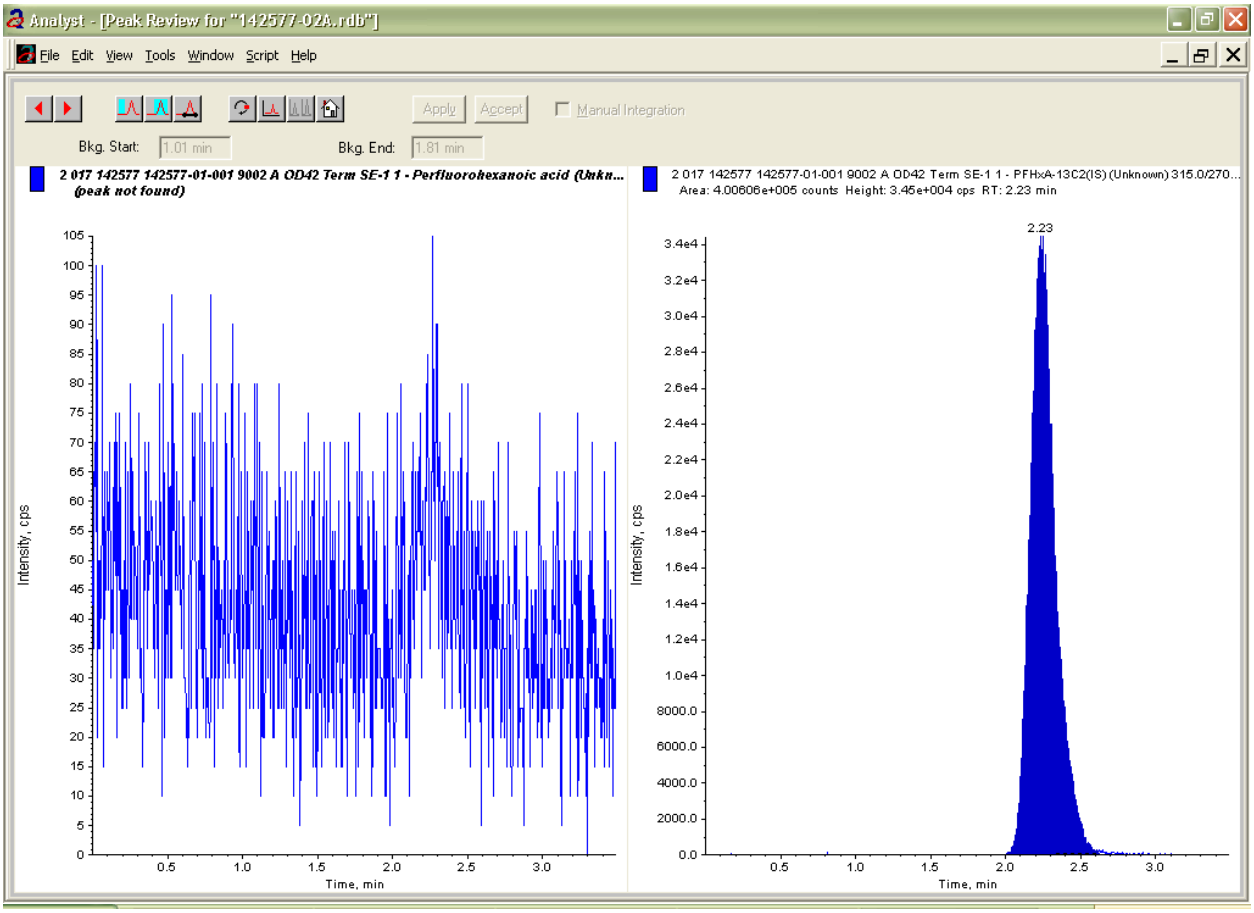


**Figure 6 Representative Sample Chromatogram (Group 2, Animal No. 9103)**

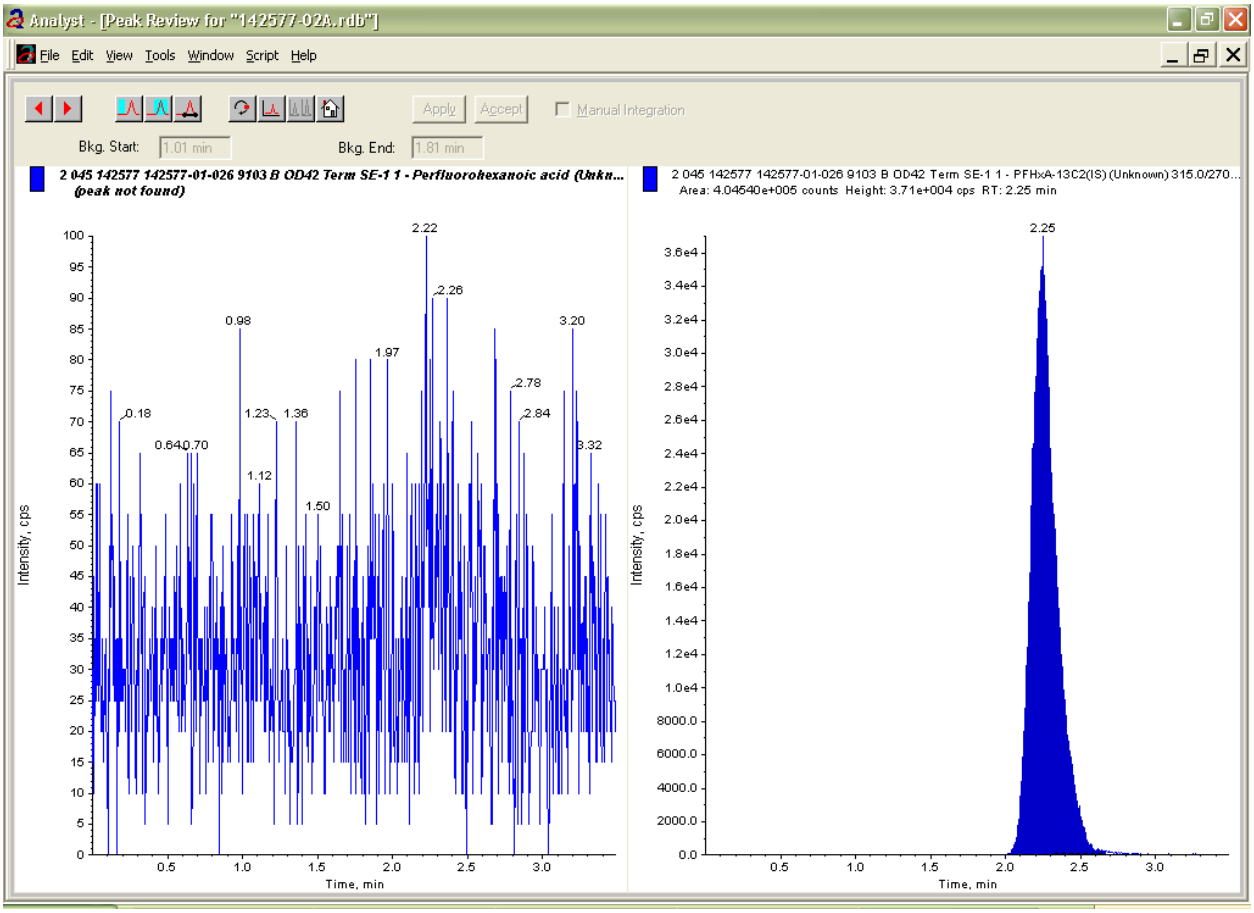


**Figure 7 Representative Sample Chromatogram (Group 3, Animal No. 9124)**

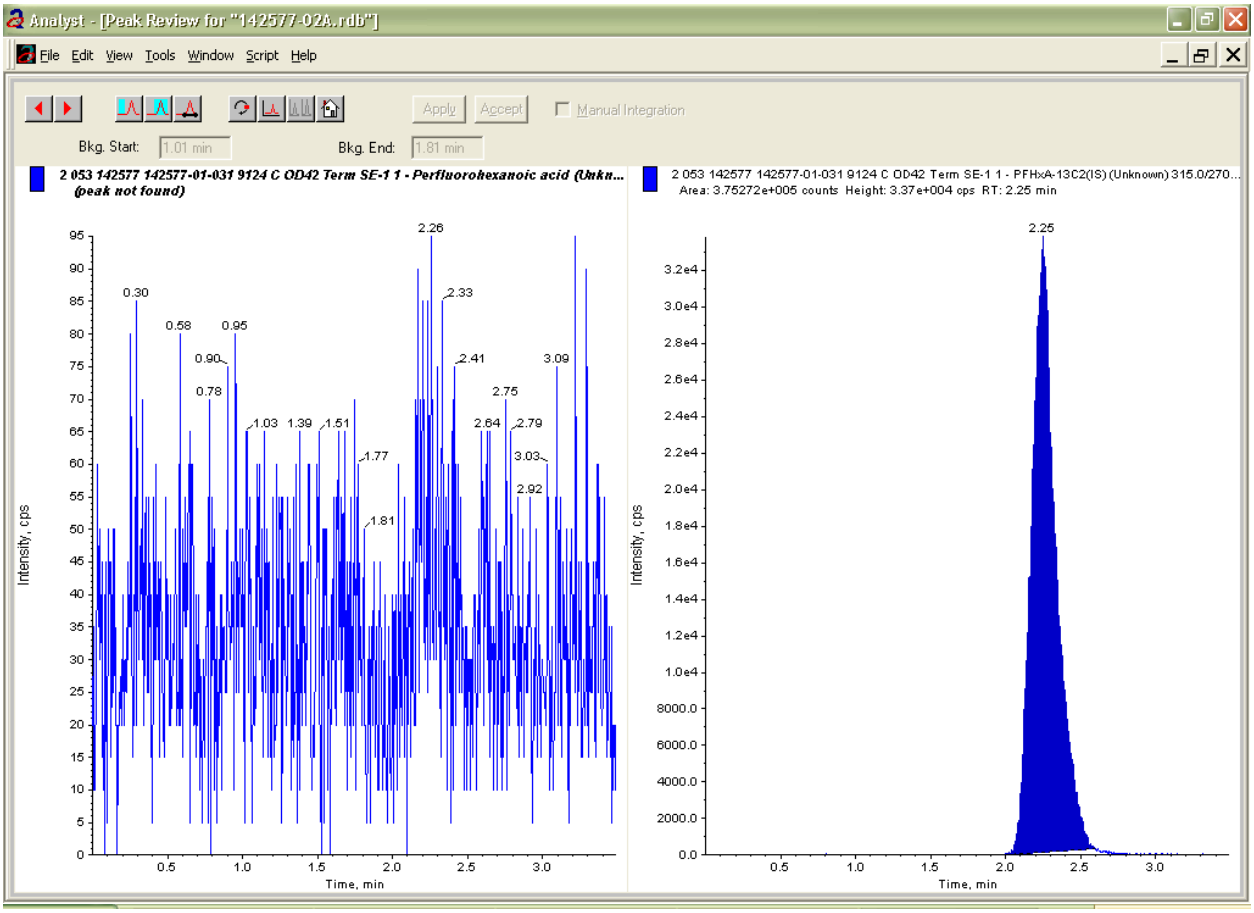
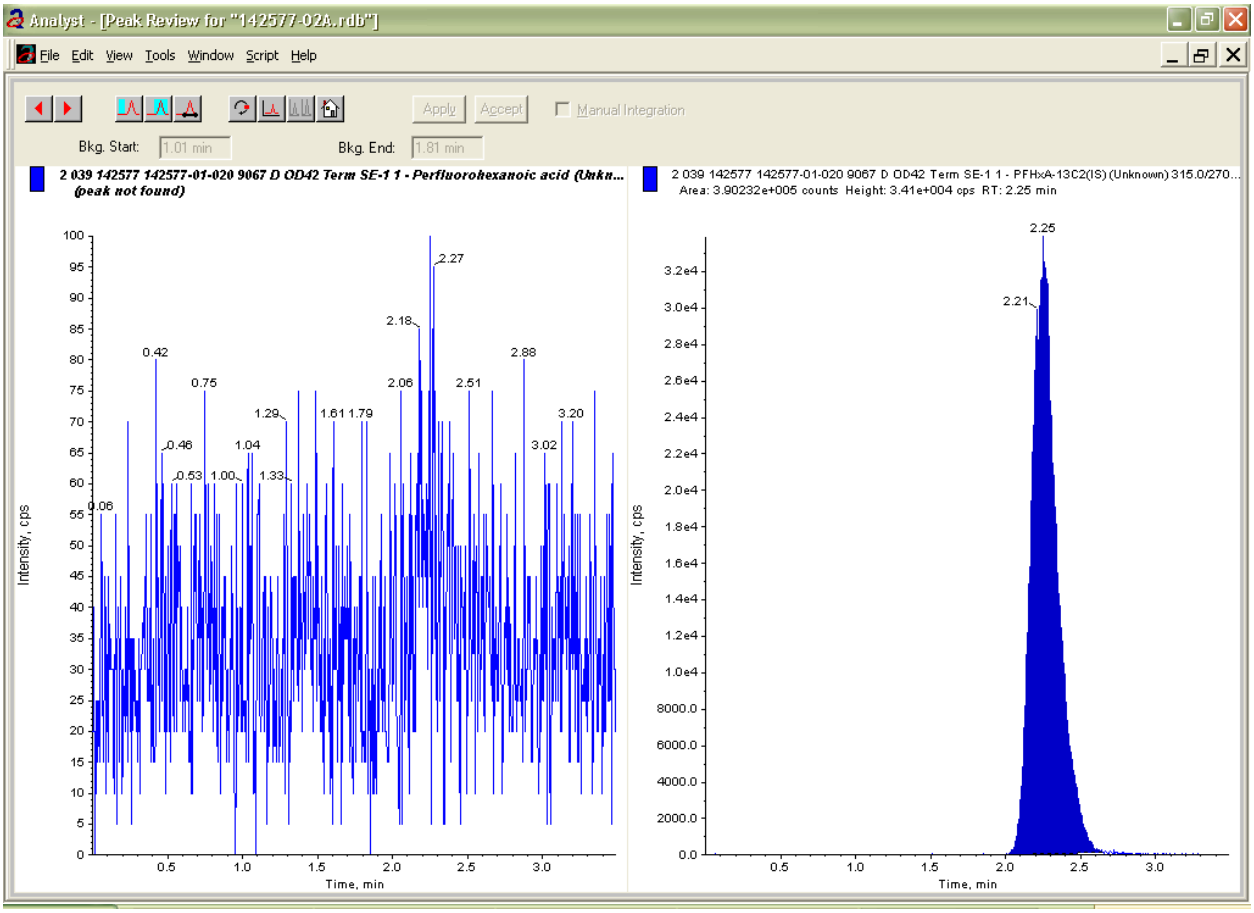


**Figure 8 Representative Sample Chromatogram (Group 4, Animal No. 9067)**



**Appendix 1 Certificates 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*

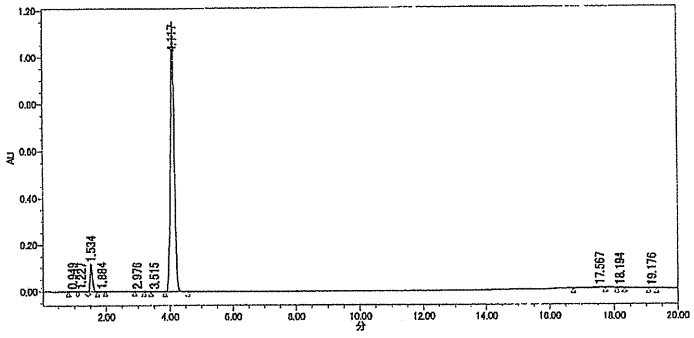
| | |
|---|---|
| *Column* | *: TOSOH TSKGel ODS120T 4.6mm×150mm* |
| *Temp.* | *: 40 ℃* |
| *Mobile phase* | *: A=acetonitrile 、 B=Solution of 0.6% perchloric acid in water* |
| *Gradient* | *: A:B=50:50(mass%) (0-10min.) →90:10(mass%) (15-20min.)* |
| *Injection volume* | *: 20μL* |
| *Injection Concentration* | *: 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 | 分析担当者： | System |
| サンプルの種類： | 未知試料 | 分析日： | 2009/05/14 11:49:44 |
| バイアル： | 82 | 取り込みメソッドセット： | 090514S |
| 注入#： | 1 | 解析日： | 2009/05/14 13:55:17 |
| 注入量： | 20.00 μl | 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 (μVsec.) | Area (%) | Height (μV) | | |
|---|---|---|---|---|---|---|---|
| 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 | 3861 | 0.04 | 592 | | |

1/1 ページ

DAIKIN

**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

**FINAL REPORT**

**Test Site Ref. No. 142578**
**Testing Facility Study No. 20005045**

# Determination of Perfluorohexanoic Acid (PFH) in Mouse Liver Homogenate (CD1) by Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS) in Support of Toxicology Study No. 20005045

**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**
**United States**

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

**10 June 2011**

## TABLE OF CONTENTS

## LIST OF TABLES

## LIST OF FIGURES

## LIST OF APPENDICES

## 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.

10 Jun 2011
Date

Bioanalytical Principal Investigator
Research Scientist, Bioanalysis
Laboratory Sciences
Charles River Laboratories

## 2. QUALITY ASSURANCE STATEMENT

In compliance with the Good Laboratory Practice Regulations, Reference No. 142578 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 | 15 November 2010 | 15 November 2010 | 14 February 2011 |
| SOP Review - In-life | 15 November 2010 | 15 November 2010 | 14 February 2011 |
| Bioanalysis Data<br>Sample Management/Shipping Records - Data Review<br>Bioanalysis Report Tabulation<br>Bioanalysis Matrix Report | 03 February 2011 to 04 February 2011 | 04 February 2011 | 14 February 2011 |
| Final Report Review | 27 May 2011 to 30 May 2011 | 30 May 2011 | 08 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.

10/Jun/2011

Date

Inspector
Quality Assurance
Charles River Laboratories

## 3. SUMMARY

The concentrations of Perfluorohexanoic Acid (PFH) in Mouse Liver Homogenate samples in support of Testing Facility Study No. 20005045, 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: The reference standard is identified as perfluorohexanoic acid in the analytical procedure and bioanalytical phase report. This is the same as the test substance used in the study which is identified in the study protocol as PFH ammonium salt (ammonium salt of perfluorinated hexanoic acid) or ammonium perfluorohexanoate.

## 4. INTRODUCTION

The concentrations of Perfluorohexanoic Acid (PFH) 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.142578.LI.04, was previously validated (Study No. 141659).

For the work detailed in this report, the experimental start date was 18 November 2010 and the experimental end date was 23 December 2010. The study 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) |
| Lot number: | 7005 |
| Purity: | 93.4% (correction factor: 0.474, corrected for effective component in solution) |
| Expiry date: | 31 July 2012 |
| 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 (identified in raw data 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 |
| | |
| Identity: | Perfluoro-n-[1, 2-$^{13}C_2$] hexanoic acid (identified in raw data as PFHxA-1, 2-$^{13}C_2$) |
| Lot number: | MPFHxA0910 |
| Purity: | > 98% (50 µg/mL certified solution) |
| Expiry date: | 23 September 2013 |
| Storage condition: | In a refrigerator set at 4°C, dark |

The reference standard characterization was the responsibility of the Sponsor who provided Certificates 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.

### 5.3. Blank Matrix

| | |
|---|---|
| Identity: | Mouse liver |
| Species: | *Mus musculus* |
| Strain: | CD1 |

## 6. EXPERIMENTAL PROCEDURES

### 6.1. Blank Liver Homogenate

Blank mouse liver homogenate was prepared by homogenizing blank 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 mouse liver homogenate covering the theoretical concentration range of 0.0200 to 10.0 µg/mL. Calibration standards consisted of blank 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 mouse liver homogenate at theoretical concentrations of 0.0600, 1.50 and 8.00 µg/mL. QC samples consisted of blank 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, until sample homogenization, in a freezer set to maintain at -80°C. Once homogenized, study liver sample homogenates were stored frozen in a freezer set to maintain at -80°C prior to analysis. Samples above the ULOQ on initial analysis were diluted with blank mouse liver homogenate prior to re-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 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 µg/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; ~0°C, ~10 minutes). The samples were stored for at least 1 hour (~4°C) and then centrifuged (~14000 rpm; ~0°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 (~4°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 |

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: AB Sciex API 4000
Data capture system: AB 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 | ~6.9 | 200 | -40 | -5 | -13 | -15 |
| PFHxA-1,2-$^{13}C_2$ | 315.0 | 270.0 | ~6.9 | 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 ≤ 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 AB Sciex.

Statistical analyses included quadratic regression with 1/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 2003).

Tables were prepared from retrospective manual entry on computer (Microsoft Word, version 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. Stock solution stability was also performed under validation Study No. 141658 and validation Study No. 141837.

### 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, together with the final phase 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.

## 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, 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, Table 2, Table 3 and Table 4. The calibration standard and quality control sample statistics are presented in Table 5 and Table 6, respectively. The study sample re-assay history results are presented in Table 7.

Sample “Animal No. 8316” was initially analyzed in run 02 which had concentration above the lower limit of detection. This was considered an anomalous sample value as the sample was from a control dosing group and was not expected to have quantifiable concentration. The sample was repeated in duplicate in run 04. Both repeated values were within 20% of each other and the initial value. The initial value is reported in the table. The impact of this anomalous sample value will be assessed in the final report of the study.

**Table 1 Group 1 Liver Homogenate Concentrations of Perfluorohexanoic Acid (PFH)**

| Subject | Subject Group | Gender/Generation | Liver Homogenate Concentration (µg/mL)[a] |
|---|---|---|---|
| 8311 | 1 | Female / F0 | < LLOQ |
| 8312 | 1 | Female / F0 | < LLOQ |
| 8313 | 1 | Female / F0 | < LLOQ |
| 8314 | 1 | Female / F0 | < LLOQ |
| 8315 | 1 | Female / F0 | < LLOQ |
| 8316 | 1 | Female / F0 | 0.118 |
| 8317 | 1 | Female / F0 | < LLOQ |
| 8318 | 1 | Female / F0 | < LLOQ |
| 8328 | 1 | Female / F0 | < LLOQ |
| 8329 | 1 | Female / F0 | < LLOQ |
| 9002 | 1 | Male / F1 | < LLOQ |
| 9003 | 1 | Male / F1 | < LLOQ |
| 9004 | 1 | Male / F1 | < LLOQ |
| 9005 | 1 | Male / F1 | < LLOQ |
| 9006 | 1 | Male / F1 | < LLOQ |
| 9082 | 1 | Female / F1 | < LLOQ |
| 9083 | 1 | Female / F1 | < LLOQ |
| 9084 | 1 | Female / F1 | < LLOQ |
| 9085 | 1 | Female / F1 | < LLOQ |
| 9086 | 1 | Female / F1 | < LLOQ |

LLOQ - lower limit of quantitation (theoretical concentration 0.0200 µg/mL liver homogenate)
a = 1.00 µg/mL of PFH in liver homogenate is equivalent to 10.0 µg/mL of PFH in liver sample

**Table 2 Group 2 Liver Homogenate Concentrations of Perfluorohexanoic Acid (PFH)**

| Subject | Subject Group | Gender/Generation | Liver Homogenate Concentration (µg/mL)[a] |
|---|---|---|---|
| 8331 | 2 | Female / F0 | < LLOQ |
| 8332 | 2 | Female / F0 | < LLOQ |
| 8333 | 2 | Female / F0 | < LLOQ |
| 8334 | 2 | Female / F0 | < LLOQ |
| 8335 | 2 | Female / F0 | < LLOQ |
| 8336 | 2 | Female / F0 | < LLOQ |
| 8343 | 2 | Female / F0 | < LLOQ |
| 8344 | 2 | Female / F0 | < LLOQ |
| 8345 | 2 | Female / F0 | < LLOQ |
| 8346 | 2 | Female / F0 | < LLOQ |
| 8347 | 2 | Female / F0 | < LLOQ |
| 8348 | 2 | Female / F0 | < LLOQ |
| 9022 | 2 | Male / F1 | < LLOQ |
| 9023 | 2 | Male / F1 | < LLOQ |
| 9024 | 2 | Male / F1 | < LLOQ |
| 9025 | 2 | Male / F1 | < LLOQ |
| 9026 | 2 | Male / F1 | < LLOQ |
| 9103 | 2 | Female / F1 | < LLOQ |
| 9104 | 2 | Female / F1 | < LLOQ |
| 9105 | 2 | Female / F1 | < LLOQ |
| 9106 | 2 | Female / F1 | < LLOQ |
| 9107 | 2 | Female / F1 | < LLOQ |

LLOQ - lower limit of quantitation (theoretical concentration 0.0200 µg/mL liver homogenate)
a = 1.00 µg/mL of PFH in liver homogenate is equivalent to 10.0 µg/mL of PFH in liver sample

**Table 3 Group 3 Liver Homogenate Concentrations of Perfluorohexanoic Acid (PFH)**

| Subject | Subject Group | Gender/Generation | Liver Homogenate Concentration (µg/mL)[a] |
|---|---|---|---|
| 8351 | 3 | Female / F0 | < LLOQ |
| 8352 | 3 | Female / F0 | < LLOQ |
| 8353 | 3 | Female / F0 | < LLOQ |
| 8354 | 3 | Female / F0 | 0.0213 |
| 8355 | 3 | Female / F0 | < LLOQ |
| 8356 | 3 | Female / F0 | < LLOQ |
| 8358 | 3 | Female / F0 | 0.0477 |
| 8361 | 3 | Female / F0 | 87.5 |
| 9043 | 3 | Male / F1 | < LLOQ |
| 9044 | 3 | Male / F1 | < LLOQ |
| 9045 | 3 | Male / F1 | < LLOQ |
| 9046 | 3 | Male / F1 | < LLOQ |
| 9047 | 3 | Male / F1 | < LLOQ |
| 9124 | 3 | Female / F1 | < LLOQ |
| 9125 | 3 | Female / F1 | < LLOQ |
| 9126 | 3 | Female / F1 | < LLOQ |
| 9127 | 3 | Female / F1 | < LLOQ |
| 9128 | 3 | Female / F1 | < LLOQ |

LLOQ - lower limit of quantitation (theoretical concentration 0.0200 µg/mL liver homogenate)
a = 1.00 µg/mL of PFH in liver homogenate is equivalent to 10.0 µg/mL of PFH in liver sample

**Table 4 Group 4 Liver Homogenate Concentrations of Perfluorohexanoic Acid (PFH)**

| Subject | Subject Group | Gender/Generation | Liver Homogenate Concentration (µg/mL)[a] |
|---|---|---|---|
| 8371 | 4 | Female / F0 | < LLOQ |
| 8372 | 4 | Female / F0 | < LLOQ |
| 8373 | 4 | Female / F0 | < LLOQ |
| 8374 | 4 | Female / F0 | < LLOQ |
| 8375 | 4 | Female / F0 | < LLOQ |
| 8376 | 4 | Female / F0 | < LLOQ |
| 8377 | 4 | Female / F0 | < LLOQ |
| 8378 | 4 | Female / F0 | 1.295702 |
| 8381 | 4 | Female / F0 | 0.037621 |
| 8383 | 4 | Female / F0 | 0.063321 |
| 8384 | 4 | Female / F0 | < LLOQ |
| 8385 | 4 | Female / F0 | 0.486 |
| 8386 | 4 | Female / F0 | 98.4 |
| 8387 | 4 | Female / F0 | < LLOQ |
| 8388 | 4 | Female / F0 | < LLOQ |
| 8389 | 4 | Female / F0 | < LLOQ |
| 9063 | 4 | Male / F1 | < LLOQ |
| 9064 | 4 | Male / F1 | < LLOQ |
| 9065 | 4 | Male / F1 | < LLOQ |
| 9066 | 4 | Male / F1 | < LLOQ |
| 9067 | 4 | Male / F1 | < LLOQ |
| 9143 | 4 | Female / F1 | < LLOQ |
| 9144 | 4 | Female / F1 | < LLOQ |
| 9145 | 4 | Female / F1 | < LLOQ |
| 9146 | 4 | Female / F1 | < LLOQ |
| 9147 | 4 | Female / F1 | < LLOQ |

LLOQ - lower limit of quantitation (theoretical concentration 0.0200 µg/mL liver homogenate)
a = 1.00 µg/mL of PFH in liver homogenate is equivalent to 10.0 µg/mL of PFH in liver sample

**Table 5 Calibration Standard Statistics**

| Analytical Run[a] | Concentration in Liver Homogenate (µg/mL) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 0.0200 | 0.0400 | 0.100 | 0.250 | 1.00 | 2.50 | 4.50 | 6.50 | 8.50 | 10.0 |
| 2 | 0.0196 | 0.0412 | 0.103 | 0.242 | 1.01 | 2.57 | 4.39 | 6.12 | 8.46 | 10.5 |
| 4 | 0.0198 | 0.0420 | 0.0945 | 0.240 | 1.02 | 2.55 | 4.63 | 6.61 | 8.38 | 9.82 |
| 5 | 0.0204 | 0.0393 | 0.0940 | 0.259 | 1.00 | 2.52 | 4.60 | 6.64 | 8.24 | 9.96 |
| | | | | | | | | | | |
| Mean | 0.01992 | 0.04084 | 0.09705 | 0.2471 | 1.011 | 2.548 | 4.541 | 6.458 | 8.362 | 10.081 |
| S.D. | 0.000380 | 0.001380 | 0.004862 | 0.009988 | 0.0097 | 0.0231 | 0.1326 | 0.2937 | 0.1094 | 0.3394 |
| % CV | 1.907726 | 3.4 | 5.0 | 4.0 | 1.0 | 0.9 | 2.9 | 4.5 | 1.3 | 3.4 |
| % Bias | -0.405 | 2.1 | -3.0 | -1.2 | 1.1 | 1.9 | 0.9 | -0.6 | -1.6 | 0.8 |
| n | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

a = Run 01 was a qualification batch, no study samples were analyzed, data not included in statistical calculation. Run 03 was rejected due to a technical error, data not included in statistical calculation. Run 06 was used for investigation of internal standard response, no study samples were analyzed, data not included in statistical calculation.

**Table 6 Quality Control Sample Statistics**

| Analytical Run[a] | Concentration in Liver Homogenate (µg/mL) | | |
|---|---|---|---|
| | 0.0600 | 1.50 | 8.00 |
| 2 | 0.0633 | 1.51 | 7.46 |
| | 0.0596 | 1.59 | 7.83 |
| | 0.0602 | 1.51 | 8.40 |
| | 0.0590 | 1.57 | 8.04 |
| 4 | 0.0624 | 1.64 | 8.05 |
| | 0.0627 | 1.58 | 7.84 |
| | 0.0628 | 1.56 | 8.14 |
| | 0.0635 | 1.58 | 8.03 |
| 5 | 0.0616 | 1.57 | 8.66 |
| | 0.0594 | 1.63 | 8.30 |
| | 0.0598 | 1.62 | 8.30 |
| | 8.11[b] | 1.65 | 0.0595[b] |
| Mean | 0.0613 | 1.586 | 8.095 |
| S.D. | 0.00171 | 0.0454 | 0.3235 |
| % CV | 2.8 | 2.9 | 4.0 |
| % bias | 2.2 | 5.7 | 1.2 |
| n | 11 | 12 | 11 |

a = Run 01 was a qualification batch, no study samples were analyzed, data not included in statistical calculation. Run 03 was rejected due to a technical error, data not included in statistical calculation. Run 06 was used for investigation of internal standard response, no study samples were analyzed, data not included in statistical calculation.

b = Outside of acceptance criteria; suspected a sample mix up between low and high QC; not included in statistical calculation

**Table 7 Study Sample Re-assay History**

| Subject | Custom ID | Original Liver Homogenate Conc. (µg/mL) | Original Curve Number | Reason for Reassay | Reassay Liver Homogenate Conc. (µg/mL) | Reassay Curve Number | Reported Liver Homogenate Conc. (µg/mL) | Reason for Reported Conc. |
|---|---|---|---|---|---|---|---|---|
| 8316 | 429600000017 | 0.118 | 2 | 1 | 0.105, 0.110 | 4, 4 | 0.118 | 1 |
| 8361 | 429600000006 | > ULOQ | 2 | 2 | 87.5 | 4 | 87.5 | 2 |
| 8386 | 429600000014 | > ULOQ | 2 | 2 | 98.4 | 4 | 98.4 | 2 |

ULOQ - upper limit of quantitation (theoretical concentration 10.0 µg/mL in liver homogenate)

Reasons for re-assay:

1) Anomalous sample value
2) Initial sample value above >ULOQ

Reasons for reported concentration:

1) Both repeated values within 20% of the initial value; initial value reported
2) Sample was diluted and repeated, repeated value within analytical range

**Figure 1** **Representative Calibration Line (Theoretical Liver Homogenate Concentration 0.0200 to 10.0 µg/mL)**

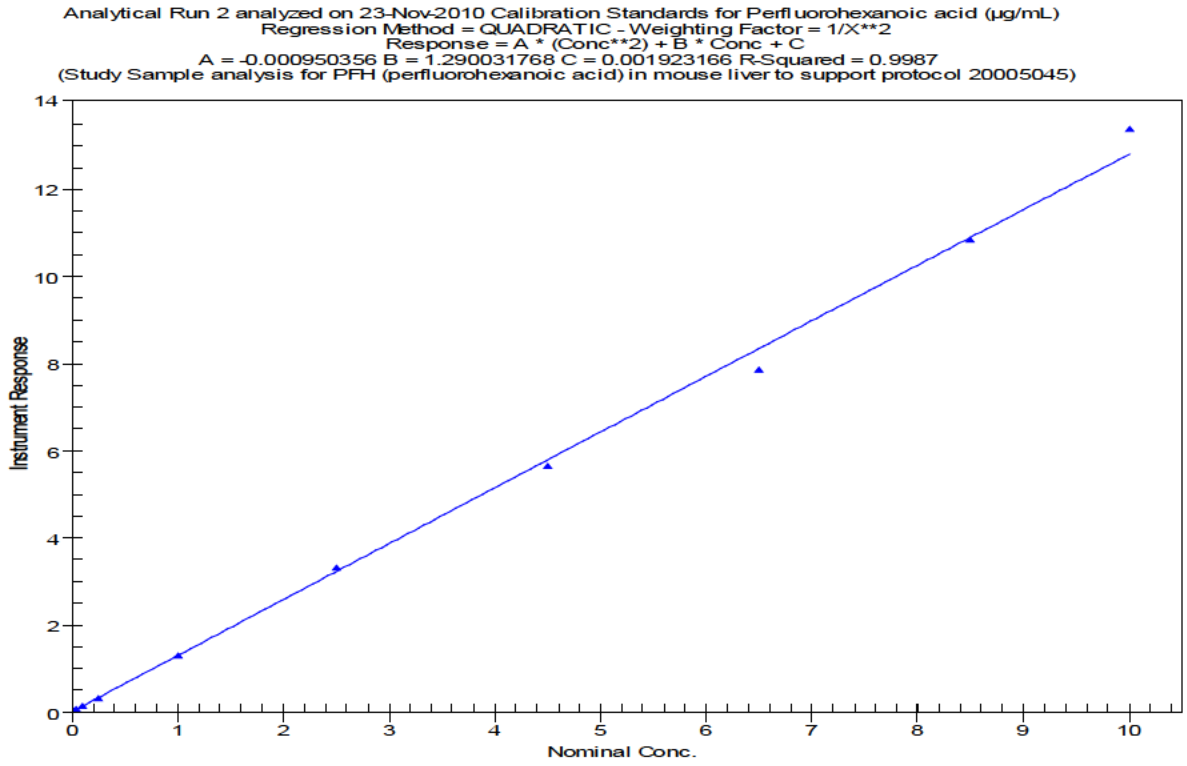


**Figure 2** **Representative LLOQ Standard Chromatogram (Theoretical Concentration in Liver Homogenate 0.0200 µg/mL)**

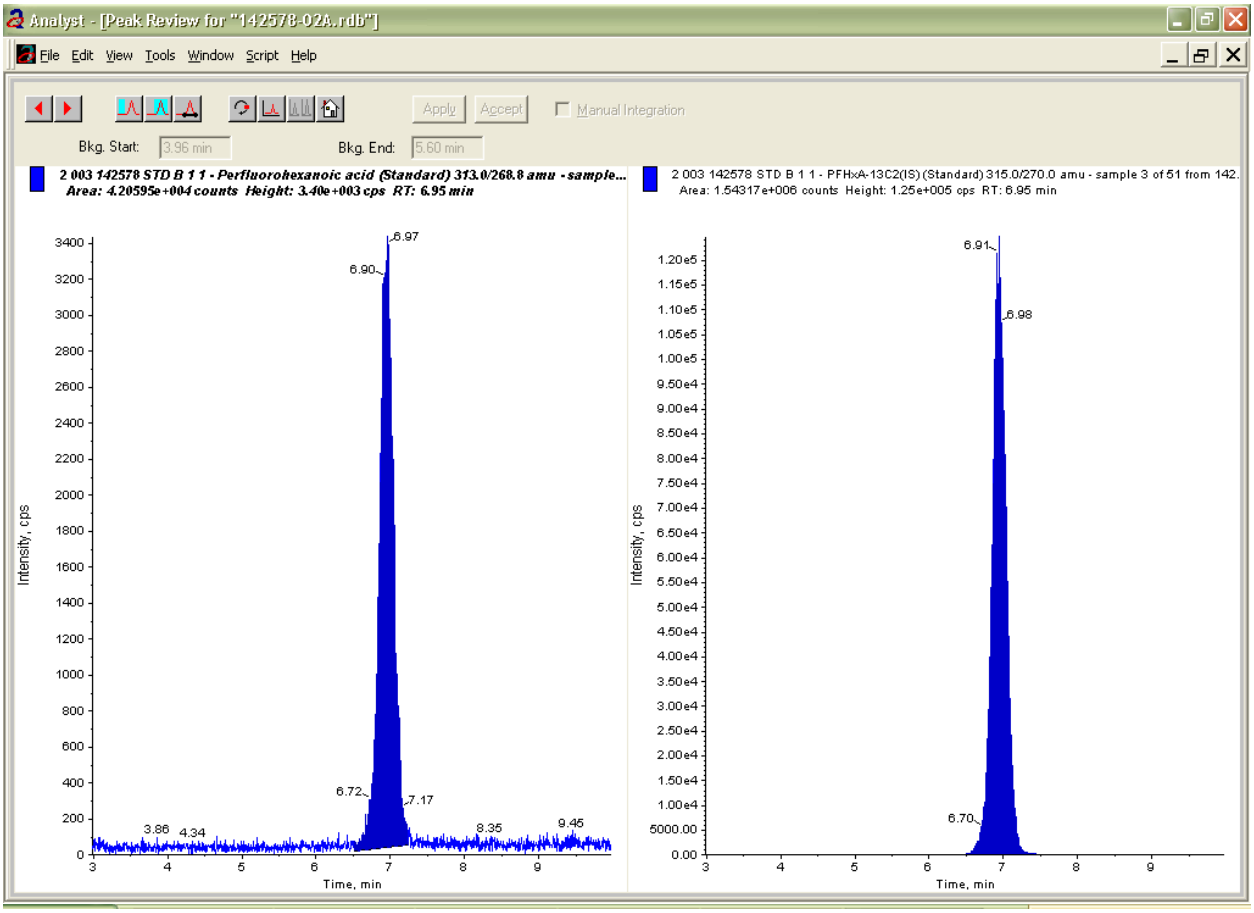


**Figure 3** **Representative ULOQ Standard Chromatogram (Theoretical Concentration in Liver Homogenate 10.0 µg/mL)**

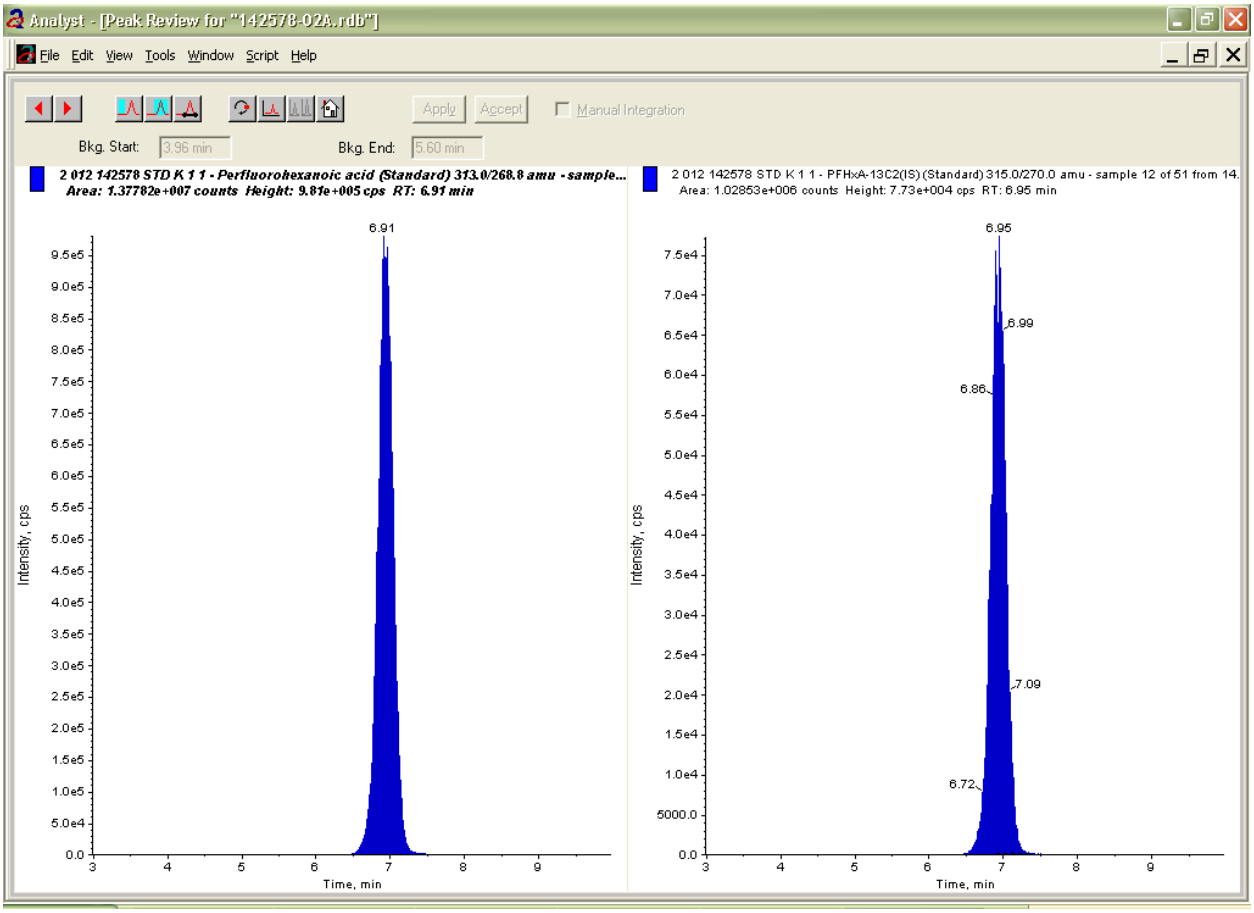


**Figure 4 Representative Double Blank Chromatogram**

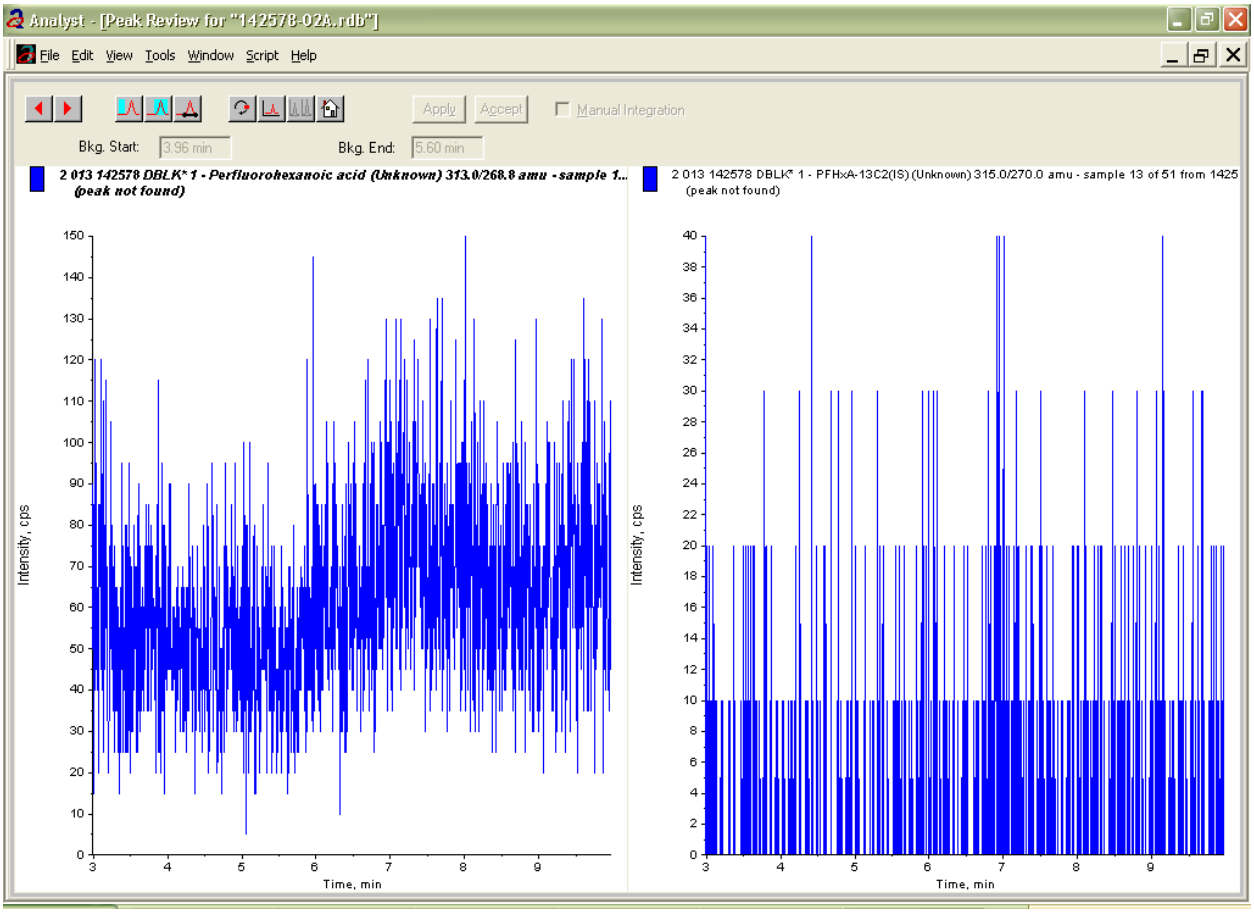


**Figure 5 Representative Sample Chromatogram (Group 1, Animal No. 8313)**

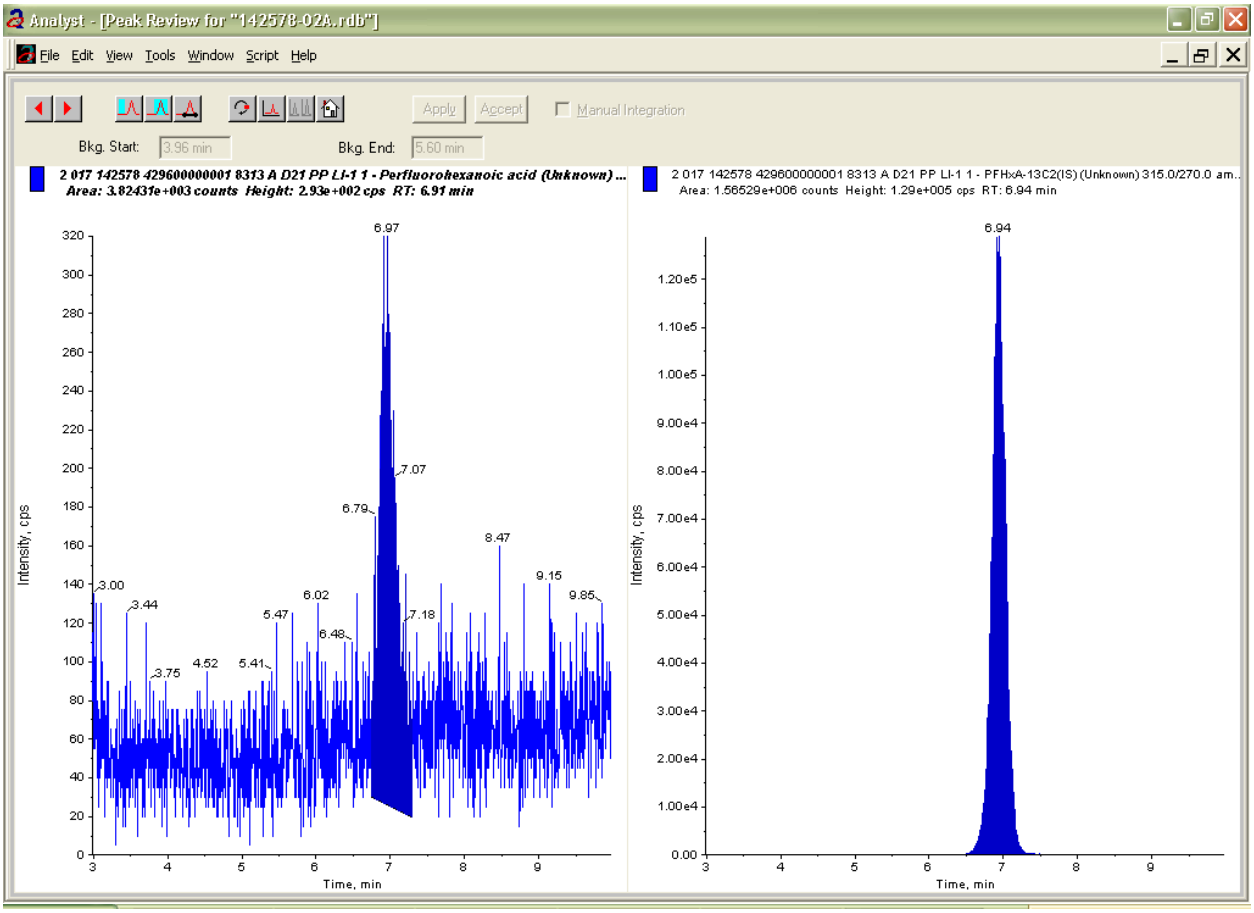


**Figure 6 Representative Sample Chromatogram (Group 2, Animal No. 8333)**

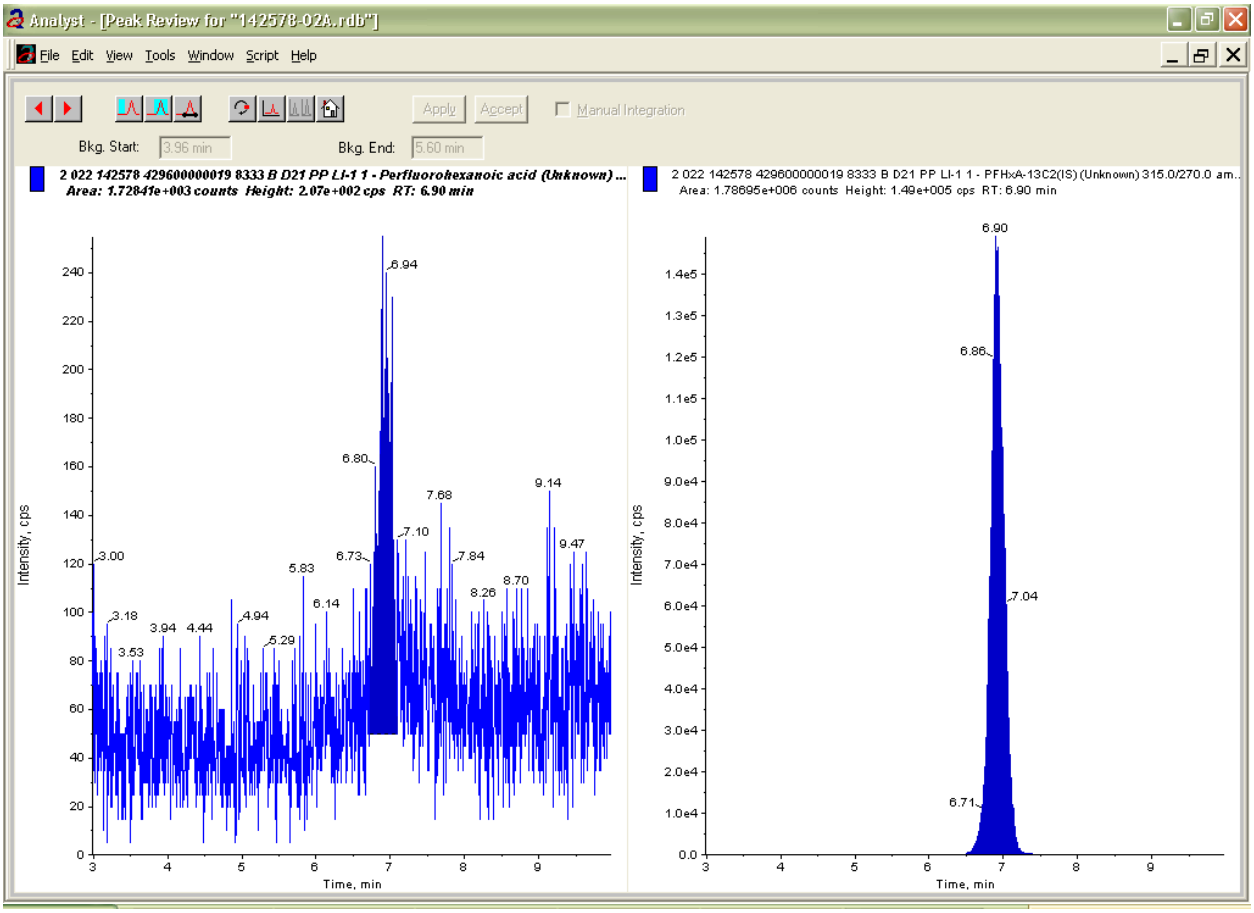


**Figure 7 Representative Sample Chromatogram (Group 3, Animal No. 8354)**

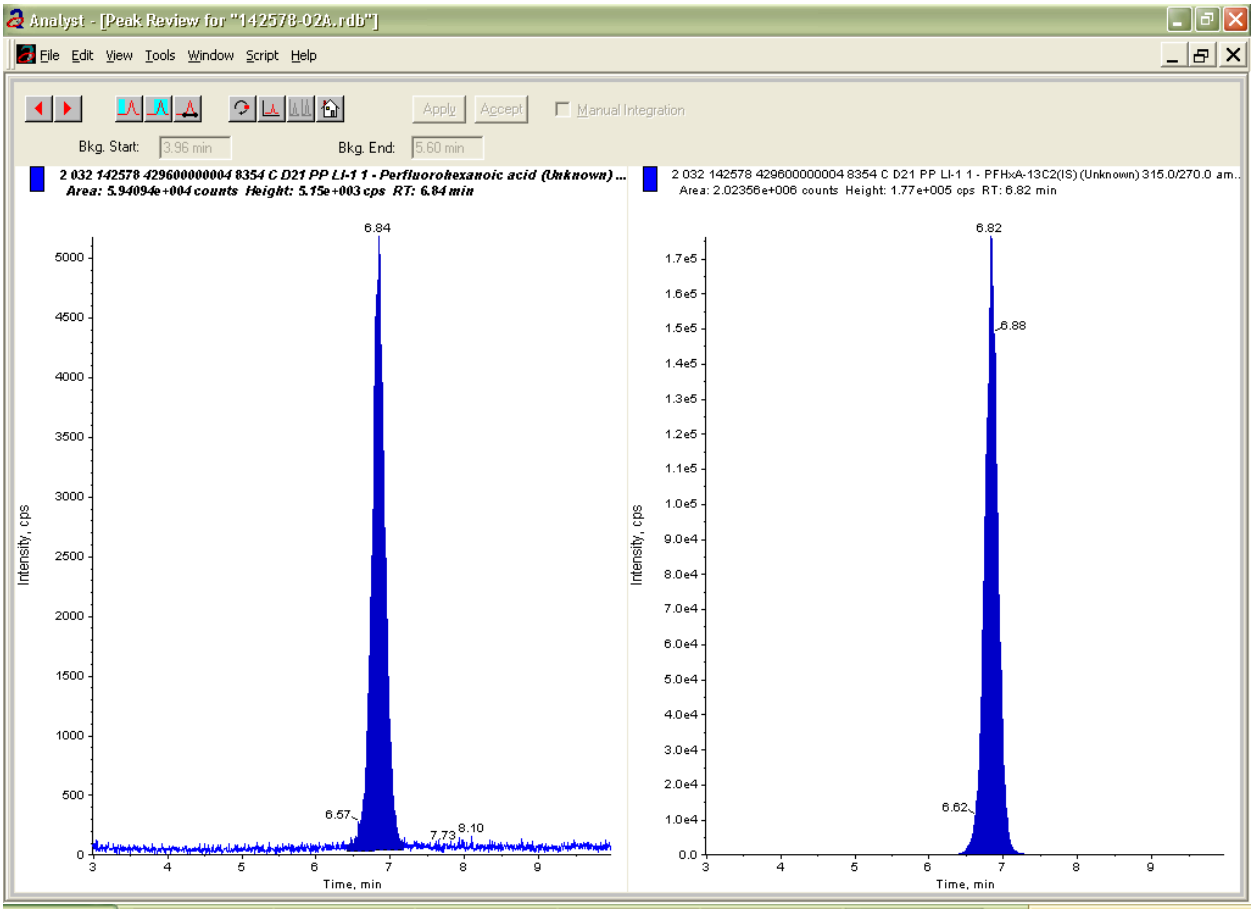
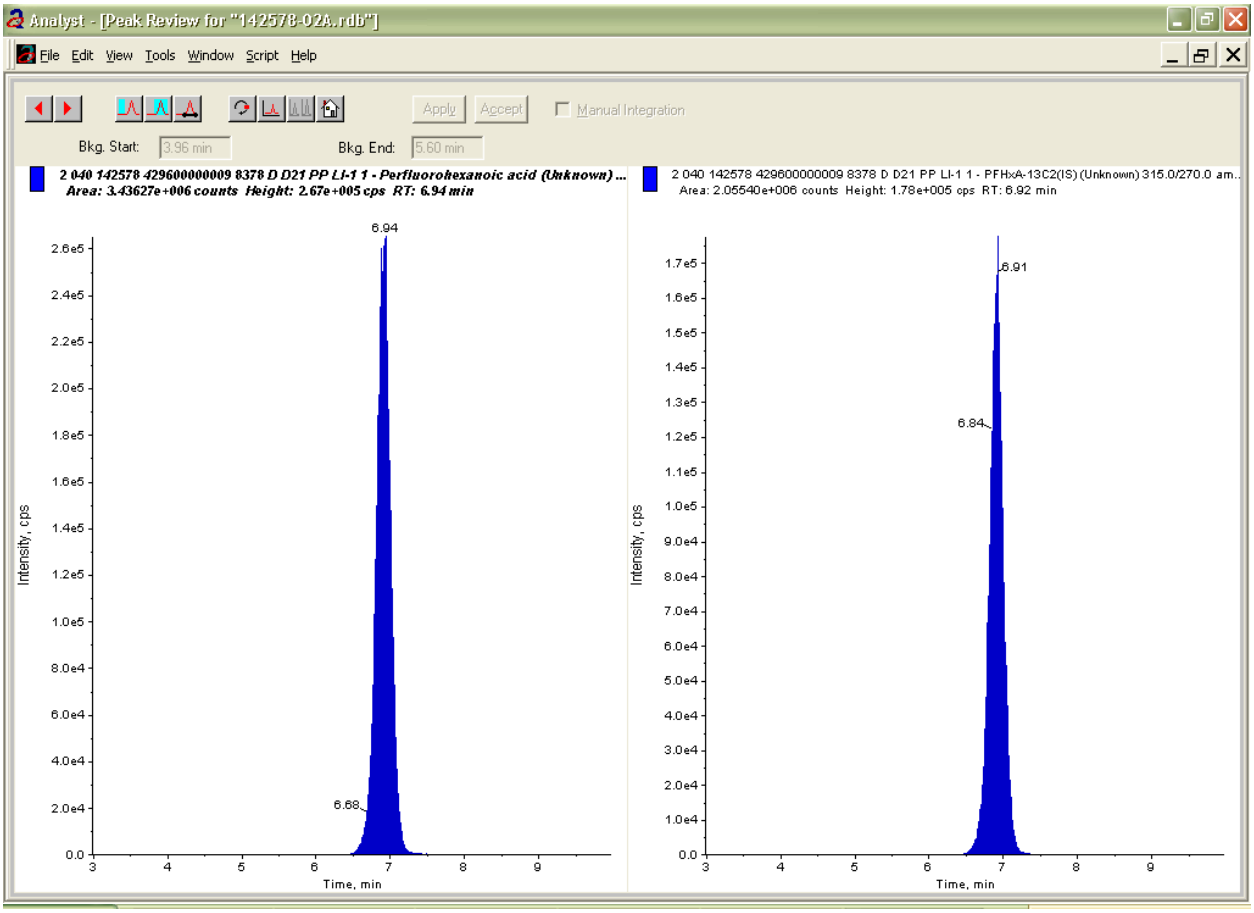


**Figure 8 Representative Sample Chromatogram (Group 4, Animal No. 8378)**



**Appendix 1 Certificates of Analysis**

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*<br>*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*

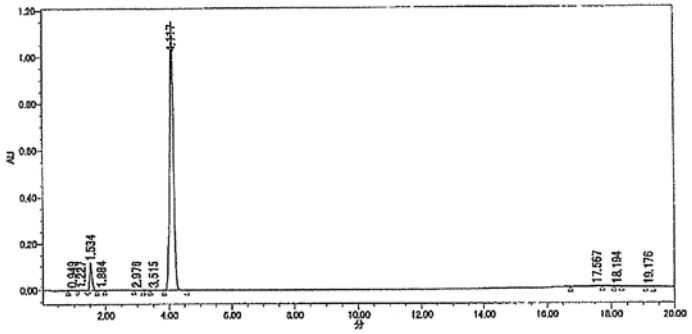
| | |
|---|---|
| *Column* | *: TOSOH TSKGel ODS120T 4.6mm×150mm* |
| *Temp.* | *: 40 ℃* |
| *Mobile phase* | *: A=acetonitrile、B=Solution of 0.6% perchloric acid in water* |
| *Gradient* | *: A:B=50:50(mass%) (0-10min.) →90:10(mass%) (15-20min.)* |
| *Injection volume* | *: 20μL* |
| *Injection Concentration* | *: 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 | 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： | 090514S |
| 注入#： | 1 | 解析日： | 2009/05/14 13:55:17 |
| 注入量： | 20.00 μl | 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 (μVsec.) | Area (%) | Height (μV) | | |
|---|---|---|---|---|---|---|---|
| 1 | | 0.949 | 17034 | 0.18 | 2554 | | |
| 2 | | 1.227 | 20551 | 0.20 | 1927 | | |
| 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 | 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 | | |

1/1 ページ

DAIKIN

**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 6 - ENVIRONMENTAL AND HUSBANDRY REPORTS

**Temperature and Relative Humidity**

**ARGUS**

**Temperature and Relative Humidity Report**
**Location: Room 04**

**Protocol Number: 20005045**

**Range of Dates: 21-Sep-2010 14:26 to 03-Dec-2010 08:59**

| | Temperature | | Relative Humidity | |
|---|---|---|---|---|
| **Target Range:** | 64°F to 79°F | | 30% to 70% | |
| **Species:** Mouse | | | | |
| **Total Number of Days:** | 74 | | 74 | |
| **Total Number of Hours:** | 1746.25 | | 1746.25 | |
| **Total Number of Data Points:** | 1746 | | 1746 | |
| **Mean (± SD):** | 72.4 | (± 0.8) | 46.1 | (± 8.7) |
| **Maximum:** | 74.4 | | 73.3 | |
| **Median:** | 72.5 | | 43.0 | |
| **Minimum:** | 69.7 | | 19.6 | |
| **Number of Points in Range (%):** | 1746 | (100.0) | 1710 | (97.9) |
| **Number of Points High (%):** | 0 | (0.0) | 15 | (0.9) |
| **Number of Points Low (%):** | 0 | (0.0) | 21 | (1.2) |

**Report Generated:** 03-Dec-2010 at 15:51

**COMMENTS:** _____

**REVIEWED BY:** _____ **DATE:** 03 Dec 2010

**ARGUS**

## Relative Humidity Deviations Report
## Location: Room 04

## Protocol Number: 20005045

### Range of Dates: 21-Sep-2010 14:26 to 03-Dec-2010 08:59

**Humidity Target Range:** 30% to 70%
**Species:** Mouse

| Date | Time | R.H. | Date | Time | R.H. |
|---|---|---|---|---|---|
| 24-Sep-2010 | 11:00 | 71.0 H | 10-Oct-2010 | 03:00 | 25.8 L |
| 24-Sep-2010 | 20:00 | 70.6 H | 10-Oct-2010 | 04:00 | 26.7 L |
| 25-Sep-2010 | 02:00 | 70.4 H | 10-Oct-2010 | 05:00 | 26.1 L |
| 27-Sep-2010 | 17:00 | 71.0 H | 10-Oct-2010 | 06:00 | 26.4 L |
| 28-Sep-2010 | 22:00 | 70.3 H | 10-Oct-2010 | 07:00 | 24.9 L |
| 30-Sep-2010 | 08:00 | 70.9 H | 10-Oct-2010 | 08:00 | 22.3 L |
| 30-Sep-2010 | 13:00 | 71.0 H | 10-Oct-2010 | 09:00 | 24.0 L |
| 30-Sep-2010 | 14:00 | 73.3 H | 10-Oct-2010 | 10:00 | 19.6 L |
| 30-Sep-2010 | 17:00 | 72.8 H | 10-Oct-2010 | 11:00 | 19.9 L |
| 30-Sep-2010 | 18:00 | 72.1 H | 10-Oct-2010 | 12:00 | 25.0 L |
| 01-Oct-2010 | 01:00 | 72.6 H | 13-Oct-2010 | 05:00 | 28.2 L |
| 09-Oct-2010 | 19:00 | 29.1 L | 13-Oct-2010 | 06:00 | 28.2 L |
| 09-Oct-2010 | 20:00 | 26.5 L | 13-Oct-2010 | 07:00 | 28.8 L |
| 09-Oct-2010 | 21:00 | 26.5 L | 13-Oct-2010 | 08:00 | 29.8 L |
| 09-Oct-2010 | 22:00 | 29.2 L | 27-Oct-2010 | 12:00 | 70.2 H |
| 10-Oct-2010 | 00:00 | 29.2 L | 27-Oct-2010 | 14:00 | 71.8 H |
| 10-Oct-2010 | 01:00 | 29.1 L | 27-Oct-2010 | 15:00 | 70.5 H |
| 10-Oct-2010 | 02:00 | 27.5 L | 27-Oct-2010 | 17:00 | 70.1 H |

**H = Value out of range - High  L = Value out of range - Low**
**R.H. = Relative Humidity (%)**

**Report Generated:** 03-Dec-2010 at 15:51

✓ 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: 18 Feb 2011

**Feed Analysis**

LabDiet PMI NUTRITION

Return to Certified Analysis Retrieval

Product Code: 5002
Product Desc: CERTIFIED RODENT DIET
Lab Number: L1019781-1
Lot Code: JUL 30 10 1A
Entered: 8/18/2010

| Assay | Analysis | Units |
|---|---|---|
| PROTEIN | 21.0 | % |
| FAT (ACID HYDRO) | 5.55 | % |
| FIBER (CRUDE) | 5.02 | % |
| ARSENIC | 0.227 | PPM |
| CADMIUM | 0.100 | PPM |
| CALCIUM | 0.8124 | % |
| LEAD | 0.224 | PPM |
| MERCURY | LESS THAN 0.025 | PPM |
| PHOSPHORUS | 0.6678 | % |
| SELENIUM | 0.388 | 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 | | |

| AFLATOXIN | PPB Aflatoxins | LESS THAN 5 |
|---|---|---|

EXACT COPY

Approved 29 Sep 2010

No notes.

Approved by: Angela Crutcher

Angela Crutcher

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

Approved
29 sep 2010

LabDiet PMI NUTRITION

Product Code: 5002
Product Desc: CERTIFIED RODENT DIET
Lab Number: L1018820-2
Lot Code: JUL 10 10 1B
Entered: 07/27/10

| Assay | Analysis | Units |
|---|---|---|
| PROTEIN | 21.2 | % |
| FAT (ACID HYDRO) | 5.5 | % |
| FIBER (CRUDE) | 4.78 | % |
| ARSENIC | LESS THAN 0.2 | PPM |
| CADMIUM | 0.072 | PPM |
| CALCIUM | 0.730 | % |
| LEAD | 0.159 | PPM |
| MERCURY | LESS THAN 0.025 | PPM |
| PHOSPHORUS | 0.614 | % |
| SELENIUM | 0.390 | 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 | | |

| AFLATOXIN | PPB Aflatoxins | LESS THAN 5 |
|---|---|---|

EXACT COPY

Approved by: Angela Crutcher

Angela Crutcher

Approved

29 SEP 2010

Bio Serv

Delivering Solutions...

Nutritional • Enrichment • Medicated • Special Needs

**Certificate Issue Date:** 6/8/10

# Certificate of Analysis

**Product#** F05682 BUNNY BLOCKS, 50 GM, VERY BERRY, CERTIFIED (CONTAMINANT SCREENED) (100/BOX)

Approved 18 Jun 2010

**Lot#** 123754.00
**Exp Date Cool Dry:** 3/11

## Proximate Profile

| | Theoretical(%) | Actual (%) |
|---|---|---|
| Protein | 0.00% | 0.00% |
| Fat | 1.00% | 0.80% |
| Fiber | 0.00% | 0.00% |
| Ash | 0.00% | 0.00% |
| Moisture | < 5.00% | 4.80% |
| Carbohydrate | 94.00% | 94.40% |

## Micronutrient Assay

## Caloric Profile

| | Actual(Kcal/gm) |
|---|---|
| Protein | 0.000 |
| Fat | 0.080 |
| Carbohydrate | 3.816 |
| **Total** | **3.896** |

## Aflatoxin Analysis

| | Results | Limits |
|---|---|---|
| Aflatoxins **(Total)** | < 0.005 ppm | 0.005 ppm |

## Heavy Metal Analysis

| | Results | Limits |
|---|---|---|
| Arsenic | < 0.100 ppm | 1.000 ppm |
| Cadmium | < 0.100 ppm | 0.500 ppm |
| Lead | < 0.100 ppm | 1.500 ppm |
| Mercury | < 0.100 ppm | 0.200 ppm |
| Selenium | < 0.100 ppm | 0.500 ppm |

## Organochlorine Analysis

| | Results |
|---|---|
| Aldrin | < 0.010 ppm |
| a-BHC | < 0.010 ppm |
| ß-BHC | < 0.010 ppm |
| Δ-BHC | < 0.010 ppm |
| y-BHC | < 0.010 ppm |
| Chlordane **(Total)** | < 0.020 ppm |
| 4,4'-DDT | < 0.010 ppm |
| 4,4'-DDD | < 0.010 ppm |
| 4,4'-DDE | < 0.010 ppm |
| Dieldrin | < 0.010 ppm |
| Endosulfan | < 0.010 ppm |
| Endrin | < 0.010 ppm |
| Heptachlor | < 0.010 ppm |
| Heptachlor Epoxide | < 0.010 ppm |
| Hexachlorobenzene | < 0.010 ppm |
| Methoxychlor | < 0.010 ppm |
| Mirex | < 0.010 ppm |
| Toxaphen | < 0.100 ppm |
| PCB's **(Total)** | < 0.100 ppm |

## Organophosphorus Analysis

| | Results |
|---|---|
| Carbophenothion | < 0.100 ppm |
| Diasulfoton | < 0.100 ppm |
| Diazinon | < 0.100 ppm |
| Ethion | < 0.100 ppm |
| Malathion | < 0.100 ppm |
| Methyl Parathion | < 0.100 ppm |
| Ethyl Parathion | < 0.100 ppm |
| Phorate | < 0.100 ppm |

Results have been reviewed by our Quality Assurance Department to ensure product results do not exceed maximum acceptable limits for each contaminant. All tests are performed by an independant laboratory registered with the EPA and member of the AOAC International and AOCS. The results reported represent the analysis performed on each batch of base meal in compliance with Quality Assurance procedures.

Judy Drake
Quality Assurance Manager

EXACT COPY
SD 20Dec10

ISO 9001:2008 Certified

One 8th Street, Suite 1, Frenchtown, NJ 08825 • Toll-Free: 800-996-9908 (U.S. & Canada)
Phone: 908-996-2155 • Fax: 908-996-4123 • Web: www.bio-serv.com

**Water Analysis**

# QC Laboratories

# Analytical Report

09/07/10 05:32pm

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. P.O. No: 6600061155 Inv. No: 1240501
Project No: W05899, CHARLES RIVER LABORATORIES, INC. PWSID No:

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3474282-1 | DRINKING WATER - IN VITRO<br>Received Temp: 40 F Iced (Y/N): Y | 09/03/10 11:50am NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM COLILERT P/A | SM 9223B | NEG col/100ml | 1. col/100ml | 09/04/10 01:56PM ARD |
| E. COLI COLILERT P/A | SM 9223B | NEG col/100ml | 1. col/100ml | 09/04/10 01:56PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 09/04/10 06:40AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | < 0.02 mg/l | | 09/03/10 11:53AM JCN |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3474282-2 | DRINKING WATER - ANALYTICAL<br>Received Temp: 40 F Iced (Y/N): Y | 09/03/10 12:06pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM COLILERT P/A | SM 9223B | NEG col/100ml | 1. col/100ml | 09/04/10 01:57PM ARD |
| E. COLI COLILERT P/A | SM 9223B | NEG col/100ml | 1. col/100ml | 09/04/10 01:57PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 09/04/10 06:40AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | < 0.02 mg/l | | 09/03/10 12:08PM JCN |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3474282-3 | DRINKING WATER - FILL STATION<br>Received Temp: 40 F Iced (Y/N): Y | 09/03/10 12:04pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM COLILERT P/A | SM 9223B | NEG col/100ml | 1. col/100ml | 09/04/10 01:56PM ARD |

Approved
Thomas J. Hines, President
13-OCT 2010



Serial Number: 1542413

1205 Industrial Blvd., P.O. Box 514, Southampton, PA 18966-0514 Phone: 215-355-3900 Fax: 215-355-7231 www.qclaboratories.com

EXACT COPY

# QC Laboratories

# Analytical Report

09/07/10 05:32pm

Account No: W05899, CHARLES RIVER LABORATORIES, INC. P.O. No: 6600061155 Inv. No: 1240501
Project No: W05899, CHARLES RIVER LABORATORIES, INC. PWSID No:

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3474282-3 | DRINKING WATER - FILL STATION | 09/03/10 12:04pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| E. COLI COLILERT P/A | SM 9223B | NEG col/100ml | 1. col/100ml | 09/04/10 01:56PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 09/04/10 06:40AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL | SM 4500CL G | 0.76 mg/l | 0.02 mg/l | 09/03/10 12:09PM JCN |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3474282-4 | DRINKING WATER - FORMULATION<br>Received Temp: 40 F Iced (Y/N): Y | 09/03/10 12:08pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM COLILERT P/A | SM 9223B | NEG col/100ml | 1. col/100ml | 09/04/10 01:56PM ARD |
| E. COLI COLILERT P/A | SM 9223B | NEG col/100ml | 1. col/100ml | 09/04/10 01:56PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 09/04/10 06:40AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | < 0.02 mg/l | | 09/03/10 12:10PM JCN |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3474282-5 | DRINKING WATER - ROOM 55 RACK 012<br>Received Temp: 40 F Iced (Y/N): Y | 09/03/10 12:11pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM COLILERT P/A | SM 9223B | NEG col/100ml | 1. col/100ml | 09/04/10 01:57PM ARD |
| E. COLI COLILERT P/A | SM 9223B | NEG col/100ml | 1. col/100ml | 09/04/10 01:57PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 09/04/10 06:40AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL | SM 4500CL G | 0.48 mg/l | 0.02 mg/l | 09/03/10 12:12PM JCN |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3474282-6 | DRINKING WATER - ROOM 27 RACK 1184<br>Received Temp: 40 F Iced (Y/N): Y | 09/03/10 12:14pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM COLILERT P/A | SM 9223B | NEG col/100ml | 1. col/100ml | 09/04/10 01:59PM ARD |
| E. COLI COLILERT P/A | SM 9223B | NEG col/100ml | 1. col/100ml | 09/04/10 01:59PM ARD |

Approved
13-OCT-2010
Thomas J. Hines, President



Serial Number: 1542413

EXACT COPY
ANN 11NOV10

# QC Laboratories

# Analytical Report

09/07/10 05:32pm

Account No: W05899, CHARLES RIVER LABORATORIES, INC. P.O. No: 6600061155 Inv. No: 1240501
Project No: W05899, CHARLES RIVER LABORATORIES, INC. PWSID No:

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3474282-6 | DRINKING WATER - ROOM 27 RACK 1184 | 09/03/10 12:14pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| STANDARD PLATE COUNT | SM 9215B | 2 col/ml | 1. col/ml | 09/04/10 06:40AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL | SM 4500CL G | 0.46 mg/l | 0.02 mg/l | 09/03/10 12:16PM JCN |

L3474282-1:
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.

L3474282-2:
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.

L3474282-3:
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.

L3474282-4:
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.

L3474282-5:
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.

L3474282-6:
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.

- 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

Approved
13-OCT-2010
Thomas J. Hines, President



Serial Number: 1542413

EXACT COPY
Date 11/9/10

# QC Laboratories

# Analytical Report

09/07/10 05:32pm

Account No: WO5899, CHARLES RIVER LABORATORIES, INC. P.O. No: 6600061155 Inv. No: 1240501
Project No: WO5899, CHARLES RIVER LABORATORIES, INC. PWSID No:

- 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.
- 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.
- 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
13 OCT 2010



Serial Number: 1542413

Thomas J. Hines, President

EXACT COPY

QC Laboratories

# Analytical Report

10/04/10 11:16am

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. P.O. No: 6600061155 Inv. No: 1249368
Project No: W05899, CHARLES RIVER LABORATORIES, INC. PWSID No:

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3503244-1 | DRINKING WATER - IN VITRO<br>Received Temp: 34 F Iced (Y/N): Y | 10/01/10 11:03am NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | 1. col/100ml | 10/01/10 06:52PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 10/01/10 05:15PM ARD |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | < 0.02 mg/l | | 10/01/10 11:06AM JCN |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3503244-2 | DRINKING WATER - FORMULATION<br>Received Temp: 34 F Iced (Y/N): Y | 10/01/10 11:13am NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | 1. col/100ml | 10/01/10 06:52PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 10/01/10 05:15PM ARD |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | < 0.02 mg/l | | 10/01/10 11:15AM JCN |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3503244-3 | DRINKING WATER - FILL STATION<br>Received Temp: 34 F Iced (Y/N): Y | 10/01/10 11:16am NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | 1. col/100ml | 10/01/10 06:52PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 10/01/10 05:15PM ARD |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | 0.60 mg/l | | 10/01/10 11:21AM JCN |

Approved
11 OCT 2010
Thomas J. Hines, President



Serial Number: 1559896

1205 Industrial Blvd., P.O. Box 514, Southampton, PA 18966-0514 Phone: 215-355-3900 Fax: 215-355-7231 www.qclaboratories.com

exact copy
of original

# QC Laboratories

# Analytical Report

10/04/10 11:16am

Account No: W05899, CHARLES RIVER LABORATORIES, INC. P.O. No: 6600061155 Inv. No: 1249368
Project No: W05899, CHARLES RIVER LABORATORIES, INC. PWSID No:

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3503244-4 | DRINKING WATER - ANALYTICAL<br>Received Temp: 34 F Iced (Y/N): Y | 10/01/10 11:18am NA F | Customer Sampled |

| Parameter | Method | Result | | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | | 1. col/100ml | 10/01/10 06:52PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | | 1. col/ml | 10/01/10 05:15PM ARD |
| **FIELD SERVICES** | | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | < 0.02 | mg/l | | 10/01/10 11:23AM JCN |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3503244-5 | DRINKING WATER - ROOM 13 RACK 126<br>Received Temp: 34 F Iced (Y/N): Y | 10/01/10 11:24am NA F | Customer Sampled |

| Parameter | Method | Result | | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | | 1. col/100ml | 10/01/10 06:52PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | | 1. col/ml | 10/01/10 05:15PM ARD |
| **FIELD SERVICES** | | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | 0.17 | mg/l | | 10/01/10 11:27AM JCN |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3503244-6 | DRINKING WATER - ROOM T-2 RACK 1761<br>Received Temp: 34 F Iced (Y/N): Y | 10/01/10 11:30am NA F | Customer Sampled |

| Parameter | Method | Result | | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | | 1. col/100ml | 10/01/10 06:52PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | | 1. col/ml | 10/01/10 05:15PM ARD |
| **FIELD SERVICES** | | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | 0.87 | mg/l | | 10/01/10 11:35AM JCN |

L3503244-1:

Approved
11 OCT 2010
Thomas J. Hines, President



Serial Number: 1559896

exact copy
omw 11Nov10

# QC Laboratories

## Analytical Report

10/04/10 11:16am

Account No: W05899, CHARLES RIVER LABORATORIES, INC. P.O. No: 6600061155 Inv. No: 1249368
Project No: W05899, CHARLES RIVER LABORATORIES, INC. PWSID No:

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.

L3503244-2:
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.

L3503244-3:
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.

L3503244-4:
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.

L3503244-5:
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.

L3503244-6:
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.

- 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.
- 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.
- The report shall not be reproduced except in full without the written consent of the laboratory.

Approved
11 OCT 2010
Thomas J. Hines, President



Serial Number: 1559896

Exact copy
on 11/4/10

# QC Laboratories

# Analytical Report

10/04/10 11:16am

Account No: W05899, CHARLES RIVER LABORATORIES, INC. P.O. No: 6600061155 Inv. No: 1249368
Project No: W05899, CHARLES RIVER LABORATORIES, INC. PWSID No:

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
11 OCT 2010



Serial Number: 1559896

exact copy
OMW 11Nov10

Thomas J. Hines, President

QC Laboratories

# Analytical Report

ACCREDITED IN ACCORDANCE WITH nelac
11/10/10 11:35am

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. P.O. No: 6600061155 Inv. No: 1258935
Project No: W05899, CHARLES RIVER LABORATORIES, INC. PWSID No:

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3539696-1 | DRINKING WATER - IN VITRO<br>Received Temp: 40 F Iced (Y/N): Y | 11/05/10 12:45pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | 1. col/100ml | 11/06/10 01:12PM AMD |
| STANDARD PLATE COUNT | SM 9215B | 14 col/ml | 1. col/ml | 11/06/10 06:26AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | < 0.02 mg/l | | 11/05/10 12:50PM JCN |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3539696-2 | DRINKING WATER - FORMULATION<br>Received Temp: 40 F Iced (Y/N): Y | 11/05/10 12:58pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | 1. col/100ml | 11/06/10 01:12PM AMD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 11/06/10 06:26AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | < 0.02 mg/l | | 11/05/10 01:03PM JCN |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3539696-3 | DRINKING WATER - FILL STATION<br>Received Temp: 40 F Iced (Y/N): Y | 11/05/10 01:03pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | 1. col/100ml | 11/06/10 01:12PM AMD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 11/06/10 06:26AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | 0.84 mg/l | | 11/05/10 01:05PM JCN |



This report is a revision of report number 1583799
Serial Number: 1584209

Approved

Thomas J. Hines, President

17DEC10

EXACT COPY
SD 29DEC10

1205 Industrial Blvd., P.O. Box 514, Southampton, PA 18966-0514 Phone: 215-355-3900 Fax: 215-355-7231 www.qclaboratories.com

# QC Laboratories

# Analytical Report

ACCREDITED IN ACCORDANCE WITH nelac
11/10/10 11:35am

Account No: W05899, CHARLES RIVER LABORATORIES, INC. P.O. No: 6600061155 Inv. No: 1258935
Project No: W05899, CHARLES RIVER LABORATORIES, INC. PWSID No:

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3539696-4 | DRINKING WATER - ANALYTICAL<br>Received Temp: 40 F Iced (Y/N): Y | 11/05/10 01:07pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | 1. col/100ml | 11/06/10 01:12PM AMD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 11/06/10 06:26AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | < 0.02 mg/l | | 11/05/10 01:09PM JCN |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3539696-5 | DRINKING WATER - ROOM 36 RACK 289<br>Received Temp: 40 F Iced (Y/N): Y | 11/05/10 01:11pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | 1. col/100ml | 11/06/10 01:12PM AMD |
| STANDARD PLATE COUNT | SM 9215B | 1 col/ml | 1. col/ml | 11/06/10 06:26AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | 0.76 mg/l | | 11/05/10 01:14PM JCN |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3539696-6 | DRINKING WATER - ROOM 47 RACK 666<br>Received Temp: 40 F Iced (Y/N): Y | 11/05/10 01:15pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | 1. col/100ml | 11/06/10 01:12PM AMD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 11/06/10 06:26AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL LOW LEVEL-FIELD | SM 4500CL G | 0.80 mg/l | | 11/05/10 01:17PM JCN |

L3539696-1:



This report is a revision of report number 1583799
Serial Number: 1584209

Thomas J. Hines, President

EXACT COPY
SD 29 Dec 10

Approved
17 Dec 2010

# QC Laboratories

# Analytical Report

11/10/10 11:35am

Account No: W05899, CHARLES RIVER LABORATORIES, INC. P.O. No: 6600061155 Inv. No: 1258935
Project No: W05899, CHARLES RIVER LABORATORIES, INC. PWSID No:

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.

L3539696-2:
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.

L3539696-3:
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.

L3539696-4:
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.

L3539696-5:
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.

L3539696-6:
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.

- 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.
- 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 89021001.
- 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.
- The report shall not be reproduced except in full without the written consent of the laboratory.

This report is a revision of report number 1583799
Serial Number: 1584209

Thomas J. Hines, President

Approved
17 Dec 2010



EXACT COPY
SD 29Dec10

# QC Laboratories

# Analytical Report

ACCREDITED IN ACCORDANCE WITH nelac
11/10/10 11:35am

Account No: W05899, CHARLES RIVER LABORATORIES, INC. P.O. No: 6600061155 Inv. No: 1258935
Project No: W05899, CHARLES RIVER LABORATORIES, INC. PWSID No:

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 MM Date 17 Dec 2010

This report is a revision of report number 1583799
Serial Number: 1584209

Thomas J. Hines, President



EXACT COPY
SD 29 Dec 10

QC Laboratories

# Analytical Report

ACCREDITED IN ACCORDANCE WITH nelac
12/06/10 04:24pm

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. P.O. No: 6600061155 Inv. No: 1265104
Project No: W05899, CHARLES RIVER LABORATORIES, INC. PWSID No:

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3566980-1 | INVITRO<br>Received Temp: 39 F Iced (Y/N): Y | 12/03/10 12:02pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | 1. col/100ml | 12/04/10 01:10PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 12/04/10 06:25AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL | SM 4500CL G | < 0.02 mg/l | 0.02 mg/l | 12/03/10 12:05PM CU |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3566980-2 | FORMULATION<br>Received Temp: 39 F Iced (Y/N): Y | 12/03/10 12:13pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | 1. col/100ml | 12/04/10 01:10PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 12/04/10 06:25AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL | SM 4500CL G | < 0.02 mg/l | 0.02 mg/l | 12/03/10 12:15PM CU |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3566980-3 | FILL STATION<br>Received Temp: 39 F Iced (Y/N): Y | 12/03/10 12:20pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | 1. col/100ml | 12/04/10 01:10PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 12/04/10 06:25AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL | SM 4500CL G | 0.75 mg/l | 0.02 mg/l | 12/03/10 12:25PM CU |

Approved
Thomas J. Hines, President
27 Jan 2011



Serial Number: 1598663

1205 Industrial Blvd., P.O. Box 514, Southampton, PA 18966-0514 Phone: 215-355-3900 Fax: 215-355-7231 www.qclaboratories.com

EXACT COPY
Feb 11

# QC Laboratories

# Analytical Report

12/06/10 04:24pm

Account No: W05899, CHARLES RIVER LABORATORIES, INC. P.O. No: 6600061155 Inv. No: 1265104
Project No: W05899, CHARLES RIVER LABORATORIES, INC. PWSID No:

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3566980-4 | ANALYTICAL<br>Received Temp: 39 F Iced (Y/N): Y | 12/03/10 12:19pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | 1. col/100ml | 12/04/10 01:10PM ARD |
| STANDARD PLATE COUNT | SM 9215B | 3 col/ml | 1. col/ml | 12/04/10 06:25AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL | SM 4500CL G | < 0.02 mg/l | 0.02 mg/l | 12/03/10 12:23PM CU |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3566980-5 | ROOM 3 RACK 66<br>Received Temp: 39 F Iced (Y/N): Y | 12/03/10 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 | 12/04/10 01:10PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 12/04/10 06:25AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL | SM 4500CL G | 0.67 mg/l | 0.02 mg/l | 12/03/10 12:44PM CU |

| Sample Number | Sample Description | Samp. Date/Time/Temp | Sampled by |
|---|---|---|---|
| L3566980-6 | ROOM 56 RACK 09405<br>Received Temp: 39 F Iced (Y/N): Y | 12/03/10 12:29pm NA F | Customer Sampled |

| Parameter | Method | Result | RLs | Test Date, Time, Analyst |
|---|---|---|---|---|
| **ENVIRONMENTAL MICROBIOLOGY** | | | | |
| COLIFORM-MF | SM 9222B | <1 col/100ml | 1. col/100ml | 12/04/10 01:10PM ARD |
| STANDARD PLATE COUNT | SM 9215B | <1 col/ml | 1. col/ml | 12/04/10 06:25AM CAS |
| **FIELD SERVICES** | | | | |
| CHLORINE RESIDUAL | SM 4500CL G | 1.18 mg/l | 0.02 mg/l | 12/03/10 12:31PM CU |

L3566980-1:
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.

L3566980-2:

Approved
27 JAN 2011



Serial Number: 1598663

Thomas J. Hines, President

EXACT COPY
Feb 11

# QC Laboratories

# Analytical Report

12/06/10 04:24pm

Account No: W05899, CHARLES RIVER LABORATORIES, INC. P.O. No: 6600061155 Inv. No: 1265104
Project No: W05899, CHARLES RIVER LABORATORIES, INC. PWSID No:

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.

L3566980-3:
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.

L3566980-4:
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.

L3566980-5:
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.

L3566980-6:
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.

- 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.
- 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 89021001.
- 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.
- 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
JAN 2011

Page 3 of 3 Serial Number: 1598663

Thomas J. Hines, President

EXACT COPY
Feb 11

Lancaster Laboratories

2425 New Holland Pike, PO Box 12425, Lancaster, PA 17605-2425 • 717-656-2300 Fax: 717-656-2681 • www.lancasterlabs.com

# Analysis Report



**Sample Description:** #1 905 Analytical Lab Grab Water Sample
Semi-Annual

LLI Sample # WW 6036580
LLI Group # 1203845
Account # 02423

**Project Name:** Semi-Annual

Collected: 07/20/2010 10:55 by EA

Charles River Laboratories
905 Sheehy Dr.
Horsham PA 19044-1297

Submitted: 07/20/2010 16:00
Reported: 07/29/2010 12:02
Discard: 08/13/2010

1905-

| CAT No. | Analysis Name | CAS Number | As Received Result | As Received Method Detection Limit* | As Received Limit of Quantitation | Dilution Factor |
|---|---|---|---|---|---|---|
| **Herbicides** | **SW-846 8151A** | | 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. | 0.081 | 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. | 0.20 | 0.50 | 1 |
| 01856 | MCPA | 94-74-6 | N.D. | 300 | 1,000 | 1 |
| 01856 | MCPP | 93-65-2 | N.D. | 50 | 200 | 1 |
| 01856 | Pentachlorophenol | 87-86-5 | N.D. | 0.060 | 0.060 | 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. | 0.030 | 0.050 | 1 |
| | Due to interfering peaks on the chromatogram, the values reported for various compounds represent the lowest reporting limits attainable. | | | | | |
| **Pesticides/PCBs** | **EPA 608** | | 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. | 0.011 | 0.029 | 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 | 959-98-8 | 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. | 0.0048 | 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. | 0.14 | 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 |
| **Metals** | **EPA 200.7 rev 4.4** | | mg/l | mg/l | mg/l | |
| 07035 | Arsenic | 7440-38-2 | N.D. | 0.0098 | 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 |

*=This limit was used in the evaluation of the final result

EXACT COPY

Approved 06 Aug 2010

Lancaster Laboratories

2425 New Holland Pike, PO Box 12425, Lancaster, PA 17605-2425 • 717-656-2300 Fax: 717-656-2681 • www.lancasterlabs.com

# Analysis Report



**Sample Description:** #1 905 Analytical Lab Grab Water Sample
Semi-Annual

LLI Sample # WW 6036580
LLI Group # 1203845
Account # 02423

**Project Name:** Semi-Annual

Collected: 07/20/2010 10:55 by EA

Submitted: 07/20/2010 16:00
Reported: 07/29/2010 12:02
Discard: 08/13/2010

Charles River Laboratories
905 Sheehy Dr.
Horsham PA 19044-1297

1905-

| 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 | |
| 07072 | Zinc | | 7440-66-6 | N.D. | 0.0081 | 0.0200 | 1 |
| | | **EPA 245.1 rev 3** | | mg/l | mg/l | mg/l | |
| 00259 | 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 | N.D. | 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 |

## 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.

Approved MW 06 Aug 2010

## 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 | 102040037A | 07/26/2010 22:54 | John W Perkins | 1 |
| 00178 | Pesticides/PCB's in Water | EPA 608 | 1 | 102030016A | 07/23/2010 18:13 | Lisa A Reinert | 1 |
| 10241 | Method 608 Water Extraction | EPA 608 | 1 | 102030016A | 07/23/2010 02:40 | Sherry L Morrow | 1 |
| 00816 | Water Sample Herbicide Extract | SW-846 8151A | 1 | 102040037A | 07/23/2010 02:30 | Karen L Beyer | 1 |
| 07035 | Arsenic | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/23/2010 03:52 | Tara L Snyder | 1 |
| 07046 | Barium | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/23/2010 03:52 | Tara L Snyder | 1 |
| 07049 | Cadmium | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/23/2010 03:52 | Tara L Snyder | 1 |
| 07051 | Chromium | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/23/2010 03:52 | Tara L Snyder | 1 |
| 07055 | Lead | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/23/2010 03:52 | Tara L Snyder | 1 |
| 07036 | Selenium | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/23/2010 03:52 | Tara L Snyder | 1 |
| 07066 | Silver | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/24/2010 01:34 | John W Yanzuk II | 1 |
| 07072 | Zinc | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/23/2010 03:52 | Tara L Snyder | 1 |
| 00259 | Mercury | EPA 245.1 rev 3 | 1 | 102025714001 | 07/22/2010 06:52 | Damary Valentin | 1 |
| 05716 | EPA 600 ICP Digest (tot rec) | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/22/2010 09:05 | Denise K Conners | 1 |
| 05714 | PW/WW Hg Digest | EPA 245.1 rev 3 | 1 | 102025714001 | 07/21/2010 15:15 | Nelli S Markaryan | 1 |
| 01505 | Bromide | EPA 300.0 | 1 | 10202196601A | 07/21/2010 18:56 | Ashley M Adams | 5 |
| 00224 | Chloride | EPA 300.0 | 1 | 10202196601A | 07/21/2010 18:56 | Ashley M Adams | 5 |

*=This limit was used in the evaluation of the final result

EXACT COPY
DMW 11/9/10

Lancaster Laboratories

# Analysis Report

2425 New Holland Pike, PO Box 12425, Lancaster, PA 17605-2425 • 717-656-2300 Fax: 717-656-2681 • www.lancasterlabs.com



**Sample Description:** #1 905 Analytical Lab Grab Water Sample
Semi-Annual

LLI Sample # WW 6036580
LLI Group # 1203845
Account # 02423

**Project Name:** Semi-Annual

Collected: 07/20/2010 10:55 by EA

Submitted: 07/20/2010 16:00
Reported: 07/29/2010 12:02
Discard: 08/13/2010

Charles River Laboratories
905 Sheehy Dr.
Horsham PA 19044-1297

1905-

## Laboratory Sample Analysis Record

| CAT No. | Analysis Name | Method | Trial# | Batch# | Analysis Date and Time | Analyst | Dilution Factor |
|---|---|---|---|---|---|---|---|
| 01504 | Fluoride | EPA 300.0 | 1 | 10202196601A | 07/21/2010 18:56 | Ashley M Adams | 5 |
| 00368 | Nitrate Nitrogen | EPA 300.0 | 1 | 10202196601A | 07/21/2010 18:56 | Ashley M Adams | 5 |
| 01506 | Nitrite Nitrogen | EPA 300.0 | 1 | 10202196601A | 07/21/2010 18:56 | Ashley M Adams | 5 |
| 00228 | Sulfate | EPA 300.0 | 1 | 10202196601A | 07/21/2010 18:56 | Ashley M Adams | 5 |
| 00226 | Ortho-Phosphate as P | EPA 365.3 | 1 | 10202022601A | 07/21/2010 00:20 | Daniel S Smith | 1 |

Approved
MWJ
06 Aug 2010

*=This limit was used in the evaluation of the final result

EXACT COPY

Lancaster Laboratories

2425 New Holland Pike, PO Box 12425, Lancaster, PA 17605-2425 • 717-656-2300 Fax: 717-656-2681 • www.lancasterlabs.com

# Analysis Report



Sample Description: #2 Formulation Lab (905) Grab Water Sample
Semi-Annual

LLI Sample # WW 6036579
LLI Group # 1203845
Account # 02423

Project Name: Semi-Annual

Collected: 07/20/2010 10:45 by EA

Submitted: 07/20/2010 16:00
Reported: 07/29/2010 12:02
Discard: 08/13/2010

Charles River Laboratories
905 Sheehy Dr.
Horsham PA 19044-1297

2FRM-

| CAT No. | Analysis Name | CAS Number | As Received Result | As Received Method Detection Limit* | As Received Limit of Quantitation | Dilution Factor |
|---|---|---|---|---|---|---|
| **Herbicides** | **SW-846 8151A** | | **ug/l** | **ug/l** | **ug/l** | |
| 01856 | 2,4-D | 94-75-7 | N.D. | 0.15 | 0.48 | 1 |
| 01856 | Dalapon | 75-99-0 | N.D. | 0.24 | 1.2 | 1 |
| 01856 | 2,4-DB | 94-82-6 | N.D. | 0.29 | 0.97 | 1 |
| 01856 | Dicamba | 1918-00-9 | N.D. | 0.077 | 0.29 | 1 |
| 01856 | Dinoseb | 88-85-7 | N.D. | 0.097 | 0.48 | 1 |
| 01856 | 2,4-DP (Dichlorprop) | 120-36-5 | N.D. | 0.15 | 0.48 | 1 |
| 01856 | MCPA | 94-74-6 | N.D. | 290 | 970 | 1 |
| 01856 | MCPP | 93-65-2 | N.D. | 180 | 190 | 1 |
| 01856 | Pentachlorophenol | 87-86-5 | N.D. | 0.040 | 0.048 | 1 |
| 01856 | 2,4,5-T | 93-76-5 | N.D. | 0.014 | 0.048 | 1 |
| 01856 | 2,4,5-TP | 93-72-1 | N.D. | 0.030 | 0.048 | 1 |
| | Due to interfering peaks on the chromatogram, the values reported for various compounds represent the lowest reporting limits attainable. | | | | | |
| **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. | 0.0026 | 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. | 0.068 | 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. | 0.0098 | 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 |

*=This limit was used in the evaluation of the final result

Approved 06 Aug 2010

EXACT COPY

Lancaster Laboratories

2425 New Holland Pike, PO Box 12425, Lancaster, PA 17605-2425 • 717-656-2300 Fax: 717-656-2681 • www.lancasterlabs.com

# Analysis Report



Sample Description: #2 Formulation Lab (905) Grab Water Sample
Semi-Annual

LLI Sample # WW 6036579
LLI Group # 1203845
Account # 02423

Project Name: Semi-Annual

Collected: 07/20/2010 10:45 by EA

Submitted: 07/20/2010 16:00
Reported: 07/29/2010 12:02
Discard: 08/13/2010

Charles River Laboratories
905 Sheehy Dr.
Horsham PA 19044-1297

2FRM-

| 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 | |
| 07072 | Zinc | | 7440-66-6 | N.D. | 0.0081 | 0.0200 | 1 |
| | | **EPA 245.1 rev 3** | | mg/l | mg/l | mg/l | |
| 00259 | 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 | N.D. | 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 |

## 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 | 102040037A | 07/26/2010 22:26 | John W Perkins | 1 |
| 00178 | Pesticides/PCB's in Water | EPA 608 | 1 | 102030016A | 07/23/2010 18:01 | Lisa A Reinert | 1 |
| 10241 | Method 608 Water Extraction | EPA 608 | 1 | 102030016A | 07/23/2010 02:40 | Sherry L Morrow | 1 |
| 00816 | Water Sample Herbicide Extract | SW-846 8151A | 1 | 102040037A | 07/23/2010 02:30 | Karen L Beyer | 1 |
| 07035 | Arsenic | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/23/2010 03:42 | Tara L Snyder | 1 |
| 07046 | Barium | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/23/2010 03:42 | Tara L Snyder | 1 |
| 07049 | Cadmium | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/23/2010 03:42 | Tara L Snyder | 1 |
| 07051 | Chromium | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/23/2010 03:42 | Tara L Snyder | 1 |
| 07055 | Lead | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/23/2010 03:42 | Tara L Snyder | 1 |
| 07036 | Selenium | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/23/2010 03:42 | Tara L Snyder | 1 |
| 07066 | Silver | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/24/2010 01:31 | John W Yanzuk II | 1 |
| 07072 | Zinc | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/23/2010 03:42 | Tara L Snyder | 1 |
| 00259 | Mercury | EPA 245.1 rev 3 | 1 | 102025714001 | 07/22/2010 06:48 | Damary Valentin | 1 |
| 05716 | EPA 600 ICP Digest (tot rec) | EPA 200.7 rev 4.4 | 1 | 102025716002 | 07/22/2010 09:05 | Denise K Conners | 1 |
| 05714 | PW/WW Hg Digest | EPA 245.1 rev 3 | 1 | 102025714001 | 07/21/2010 15:15 | Nelli S Markaryan | 1 |
| 01505 | Bromide | EPA 300.0 | 1 | 10202196601A | 07/21/2010 18:38 | Ashley M Adams | 5 |
| 00224 | Chloride | EPA 300.0 | 1 | 10202196601A | 07/21/2010 18:38 | Ashley M Adams | 5 |

*=This limit was used in the evaluation of the final result

EXACT COPY

Approved
06 Aug 2010

Lancaster Laboratories

# Analysis Report

2425 New Holland Pike, PO Box 12425, Lancaster, PA 17605-2425 • 717-656-2300 Fax: 717-656-2681 • www.lancasterlabs.com



Sample Description: #2 Formulation Lab (905) Grab Water Sample
Semi-Annual

LLI Sample # WW 6036579
LLI Group # 1203845
Account # 02423

Project Name: Semi-Annual

Collected: 07/20/2010 10:45 by EA

Submitted: 07/20/2010 16:00
Reported: 07/29/2010 12:02
Discard: 08/13/2010

Charles River Laboratories
905 Sheehy Dr.
Horsham PA 19044-1297

2FRM-

## Laboratory Sample Analysis Record

| CAT No. | Analysis Name | Method | Trial# | Batch# | Analysis Date and Time | Analyst | Dilution Factor |
|---|---|---|---|---|---|---|---|
| 01504 | Fluoride | EPA 300.0 | 1 | 10202196601A | 07/21/2010 18:38 | Ashley M Adams | 5 |
| 00368 | Nitrate Nitrogen | EPA 300.0 | 1 | 10202196601A | 07/21/2010 18:38 | Ashley M Adams | 5 |
| 01506 | Nitrite Nitrogen | EPA 300.0 | 1 | 10202196601A | 07/21/2010 18:38 | Ashley M Adams | 5 |
| 00228 | Sulfate | EPA 300.0 | 1 | 10202196601A | 07/21/2010 18:38 | Ashley M Adams | 5 |
| 00226 | Ortho-Phosphate as P | EPA 365.3 | 1 | 10202022601A | 07/21/2010 00:20 | Daniel S Smith | 1 |

Approved
06 Aug 2010

*=This limit was used in the evaluation of the final result

EXACT COPY

**Bedding Analysis**

Lancaster Laboratories

# Analysis Report

2425 New Holland Pike, PO Box 12425, Lancaster, PA 17605-2425 • 717-656-2300 Fax: 717-656-2681 • www.lancasterlabs.com



Sample Description: Bedding Sample Lot# 051310
2307 grams

LLI Sample # G5 6008909
LLI Group # 1199196
Account # 02423

Project Name: Analysis of Bedding

Collected: 06/15/2010

Charles River Laboratories
905 Sheehy Dr.
Horsham PA 19044-1297

Submitted: 06/16/2010 17:00
Reported: 07/01/2010 16:41
Discard: 07/16/2010

51310

| CAT No. | Analysis Name | CAS Number | As Received Result | As Received Method Detection Limit* | As Received Limit of Quantitation | Dilution Factor |
|---|---|---|---|---|---|---|
| **Herbicides** | | **SW-846 8151A** | ug/kg | ug/kg | ug/kg | |
| 01863 | 2,4-D | 94-75-7 | N.D. | 120 | 360 | 10 |
| 01863 | Dinoseb | 88-85-7 | N.D. | 80 | 240 | 10 |
| 01863 | 2,4,5-T | 93-76-5 | N.D. | 8.2 | 17 | 10 |
| 01863 | 2,4,5-TP | 93-72-1 | 10 (1) J | 7.5 (1) | 17 | 10 |
| | Due to the nature of the sample extract matrix, a dilution was used for the analysis. The reporting limits were raised accordingly. | | | | | |
| **Pesticides/PCBs** | | **SW-846 8081A** | ug/kg | ug/kg | ug/kg | |
| 10738 | Aldrin | 309-00-2 | N.D. | 0.51 | 2.5 | 1 |
| 10738 | Alpha BHC | 319-84-6 | N.D. | 0.51 | 2.5 | 1 |
| 10738 | Beta BHC | 319-85-7 | N.D. | 2.9 | 5.7 | 1 |
| 10738 | Gamma BHC - Lindane | 58-89-9 | N.D. | 0.51 | 2.5 | 1 |
| 10738 | Chlordane | 57-74-9 | N.D. | 12 | 51 | 1 |
| 10738 | p,p-DDD | 72-54-8 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | p,p-DDE | 72-55-9 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | p,p-DDT | 50-29-3 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | Delta BHC | 319-86-8 | N.D. | 1.4 | 2.5 | 1 |
| 10738 | Dieldrin | 60-57-1 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | Endosulfan I | 959-98-8 | N.D. | 0.66 | 2.5 | 1 |
| 10738 | Endosulfan II | 33213-65-9 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | Endosulfan Sulfate | 1031-07-8 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | Endrin | 72-20-8 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | Endrin Aldehyde | 7421-93-4 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | Heptachlor | 76-44-8 | N.D. | 0.51 | 2.5 | 1 |
| 10738 | Heptachlor Epoxide | 1024-57-3 | N.D. | 0.51 | 2.5 | 1 |
| 10738 | Methoxychlor | 72-43-5 | N.D. | 5.1 | 25 | 1 |
| 10738 | Toxaphene | 8001-35-2 | N.D. | 33 | 99 | 1 |
| | Due to the nature of the sample matrix, a reduced aliquot was used for analysis. The reporting limits were raised accordingly. | | | | | |
| **Pesticides/PCBs** | | **SW-846 8082** | ug/kg | ug/kg | ug/kg | |
| 10885 | PCB-1016 | 12674-11-2 | N.D. | 9.9 | 51 | 1 |
| 10885 | PCB-1221 | 11104-28-2 | N.D. | 9.9 | 51 | 1 |
| 10885 | PCB-1232 | 11141-16-5 | N.D. | 9.9 | 51 | 1 |
| 10885 | PCB-1242 | 53469-21-9 | N.D. | 9.9 | 51 | 1 |
| 10885 | PCB-1248 | 12672-29-6 | N.D. | 9.9 | 51 | 1 |
| 10885 | PCB-1254 | 11097-69-1 | N.D. | 9.9 | 51 | 1 |
| 10885 | PCB-1260 | 11096-82-5 | N.D. | 9.9 | 51 | 1 |
| **Metals** | | **SW-846 6010B** | mg/kg | mg/kg | mg/kg | |
| 06935 | Arsenic | 7440-38-2 | N.D. | 0.941 | 1.98 | 1 |
| 06946 | Barium | 7440-39-3 | 1.14 | 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** | mg/kg | mg/kg | mg/kg | |

EXACT COPY

*=This limit was used in the evaluation of the final result

(1) Result is below EPA MCL of 50mg/L and bedding is not intended for ingestion which limits exposure. MW 06 Aug 2010

Lancaster Laboratories

# Analysis Report

2425 New Holland Pike, PO Box 12425, Lancaster, PA 17605-2425 • 717-656-2300 Fax:717-656-2681 • www.lancasterlabs.com



Sample Description: Bedding Sample Lot# 051310
2307 grams

LLI Sample # G5 6008909
LLI Group # 1199196
Account # 02423

Project Name: Analysis of Bedding

Collected: 06/15/2010

Charles River Laboratories
905 Sheehy Dr.
Horsham PA 19044-1297

Submitted: 06/16/2010 17:00
Reported: 07/01/2010 16:41
Discard: 07/16/2010

51310

| CAT No. | Analysis Name | CAS Number | As Received Result | As Received Method Detection Limit* | As Received Limit of Quantitation | Dilution Factor |
|---|---|---|---|---|---|---|
| **Metals** | | **SW-846 7471A** | mg/kg | mg/kg | mg/kg | |
| 00159 | Mercury | 7439-97-6 | N.D. | 0.0111 | 0.0965 | 1 |

## 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 | 101720010A | 06/28/2010 11:55 | John W Perkins | 10 |
| 10738 | Pesticides in Soil (microwave) | SW-846 8081A | 1 | 101700009A | 06/29/2010 12:22 | Jamie L Brillhart | 1 |
| 10885 | PCBs w/ Pesticides (microwave) | SW-846 8082 | 1 | 101690000A | 06/21/2010 14:13 | Lindsey K Lafferty | 1 |
| 10497 | PCB Microwave Soil Extraction | SW-846 3546 | 1 | 101690000A | 06/18/2010 12:30 | Wanda F Oswald | 1 |
| 10496 | PPL Pest. Microwave Extraction | SW-846 3546 | 2 | 101700009A | 06/21/2010 10:30 | Olivia Arosemena | 1 |
| 04181 | Herbicide Soil Extraction | SW-846 3550B/SW-846 8151A | 1 | 101720010A | 06/22/2010 01:00 | Sherry L Morrow | 1 |
| 06935 | Arsenic | SW-846 6010B | 1 | 101685708002 | 06/22/2010 19:04 | John P Hook | 1 |
| 06946 | Barium | SW-846 6010B | 1 | 101685708002 | 06/22/2010 19:04 | John P Hook | 1 |
| 06949 | Cadmium | SW-846 6010B | 1 | 101685708002 | 06/22/2010 19:04 | John P Hook | 1 |
| 06951 | Chromium | SW-846 6010B | 1 | 101685708002 | 06/22/2010 19:04 | John P Hook | 1 |
| 06955 | Lead | SW-846 6010B | 1 | 101685708002 | 06/22/2010 19:04 | John P Hook | 1 |
| 06936 | Selenium | SW-846 6010B | 1 | 101685708002 | 06/22/2010 19:04 | John P Hook | 1 |
| 06966 | Silver | SW-846 6010B | 1 | 101685708002 | 06/22/2010 19:04 | John P Hook | 1 |
| 00159 | Mercury | SW-846 7471A | 1 | 101685711002 | 06/18/2010 11:54 | Damary Valentin | 1 |
| 05708 | SW SW846 ICP Digest | SW-846 3050B | 1 | 101685708002 | 06/17/2010 20:22 | Annamaria Stipkovits | 1 |
| 05711 | SW SW846 Hg Digest | SW-846 7471A modified | 1 | 101685711002 | 06/18/2010 01:05 | Annamaria Stipkovits | 1 |

EXACT COPY

Approved
06 Aug 2010

*=This limit was used in the evaluation of the final result

Lancaster Laboratories

2425 New Holland Pike, PO Box 12425, Lancaster, PA 17605-2425 • 717-656-2300 Fax: 717-656-2681 • www.lancasterlabs.com

# Analysis Report



**Sample Description: Bedding Sample Lot# 092210**
**1,912**

LLI Sample # G5 6103632
LLI Group # 1214913
Account # 02423

**Project Name: Analysis of Bedding**

Collected: 10/04/2010

Submitted: 10/05/2010 17:45
Reported: 10/14/2010 16:13
Discard: 10/29/2010

Charles River Laboratories
905 Sheehy Dr.
Horsham PA 19044-1297

BED22

| CAT No. | Analysis Name | CAS Number | As Received Result | As Received Method Detection Limit* | As Received Limit of Quantitation | Dilution Factor |
|---|---|---|---|---|---|---|
| **Herbicides** | **SW-846 8151A** | | ug/kg | ug/kg | ug/kg | |
| 10401 | 2,4-D | 94-75-7 | N.D. | 12 | 36 | 1 |
| 10401 | 2,4,5-TP | 93-72-1 | N.D. | 0.75 | 1.7 | 1 |
| **Pesticides/PCBs** | **SW-846 8081A** | | ug/kg | ug/kg | ug/kg | |
| 10738 | Aldrin | 309-00-2 | N.D. | 0.51 | 2.5 | 1 |
| 10738 | Alpha BHC | 319-84-6 | N.D. | 0.51 | 2.5 | 1 |
| 10738 | Beta BHC | 319-85-7 | N.D. | 2.9 | 5.7 | 1 |
| 10738 | Gamma BHC - Lindane | 58-89-9 | N.D. | 0.51 | 2.5 | 1 |
| 10738 | Chlordane | 57-74-9 | N.D. | 12 | 51 | 1 |
| 10738 | p,p-DDD | 72-54-8 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | p,p-DDE | 72-55-9 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | p,p-DDT | 50-29-3 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | Delta BHC | 319-86-8 | N.D. | 1.4 | 2.5 | 1 |
| 10738 | Dieldrin | 60-57-1 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | Endosulfan I | 959-98-8 | N.D. | 0.66 | 2.5 | 1 |
| 10738 | Endosulfan II | 33213-65-9 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | Endosulfan Sulfate | 1031-07-8 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | Endrin | 72-20-8 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | Endrin Aldehyde | 7421-93-4 | N.D. | 0.99 | 5.1 | 1 |
| 10738 | Heptachlor | 76-44-8 | N.D. | 0.51 | 2.5 | 1 |
| 10738 | Heptachlor Epoxide | 1024-57-3 | N.D. | 0.51 | 2.5 | 1 |
| 10738 | Methoxychlor | 72-43-5 | N.D. | 5.1 | 25 | 1 |
| 10738 | Toxaphene | 8001-35-2 | N.D. | 33 | 99 | 1 |

The sample was injected numerous times. Each time the responses for various analytes in the calibration check standard injected after the sample were outside the acceptance criteria. Therefore, this effect is attributed to the sample matrix and the data is reported.

Reporting limits were raised due to interference from the sample matrix.

Approved 17 Dec 2010

| | | | | | | |
|---|---|---|---|---|---|---|
| **Pesticides/PCBs** | **SW-846 8082** | | ug/kg | ug/kg | ug/kg | |
| 10885 | PCB-1016 | 12674-11-2 | N.D. | 20 | 100 | 1 |
| 10885 | PCB-1221 | 11104-28-2 | N.D. | 20 | 100 | 1 |
| 10885 | PCB-1232 | 11141-16-5 | N.D. | 20 | 100 | 1 |
| 10885 | PCB-1242 | 53469-21-9 | N.D. | 20 | 100 | 1 |
| 10885 | PCB-1248 | 12672-29-6 | N.D. | 20 | 100 | 1 |
| 10885 | PCB-1254 | 11097-69-1 | N.D. | 20 | 100 | 1 |
| 10885 | PCB-1260 | 11096-82-5 | N.D. | 20 | 100 | 1 |

Reporting limits were raised due to interference from the sample matrix.

| | | | | | | |
|---|---|---|---|---|---|---|
| **Metals** | **SW-846 6010B** | | mg/kg | mg/kg | mg/kg | |
| 06935 | Arsenic | 7440-38-2 | N.D. | 0.950 | 2.00 | 1 |
| 06946 | Barium | 7440-39-3 | 0.626 | 0.0400 | 0.500 | 1 |
| 06949 | Cadmium | 7440-43-9 | N.D. | 0.140 | 0.500 | 1 |
| 06951 | Chromium | 7440-47-3 | N.D. | 0.590 | 1.50 | 1 |
| 06955 | Lead | 7439-92-1 | N.D. | 0.600 | 1.50 | 1 |
| 06936 | Selenium | 7782-49-2 | N.D. | 0.980 | 2.00 | 1 |
| 06966 | Silver | 7440-22-4 | N.D. | 0.180 | 0.500 | 1 |

*=This limit was used in the evaluation of the final result

EXACT COPY
SD 29Dec10

Lancaster Laboratories

2425 New Holland Pike, PO Box 12425, Lancaster, PA 17605-2425 •717-656-2300 Fax:717-656-2681• www.lancasterlabs.com

# Analysis Report



**Sample Description: Bedding Sample Lot# 092210 1,912**

**LLI Sample # G5 6103632**
**LLI Group # 1214913**
**Account # 02423**

**Project Name: Analysis of Bedding**

Collected: 10/04/2010

Submitted: 10/05/2010 17:45
Reported: 10/14/2010 16:13
Discard: 10/29/2010

Charles River Laboratories
905 Sheehy Dr.
Horsham PA 19044-1297

BED22

| CAT No. | Analysis Name | CAS Number | As Received Result | As Received Method Detection Limit* | As Received Limit of Quantitation | Dilution Factor |
|---|---|---|---|---|---|---|
| **Metals** | | **SW-846 7471A** | mg/kg | mg/kg | mg/kg | |
| 00159 | Mercury | 7439-97-6 | N.D. | 0.0028 | 0.0985 | 1 |

## 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 |
|---|---|---|---|---|---|---|---|
| 10401 | Herbicide soils 8151A Master | SW-846 8151A | 1 | 102850009A | 10/14/2010 00:33 | John W Perkins | 1 |
| 10738 | Pesticides in Soil (microwave) | SW-846 8081A | 1 | 102810005A | 10/12/2010 09:17 | Jamie L Brillhart | 1 |
| 10885 | PCBs w/ Pesticides (microwave) | SW-846 8082 | 1 | 102820003A | 10/13/2010 11:23 | Lindsey K Lafferty | 1 |
| 10497 | PCB Microwave Soil Extraction | SW-846 3546 | 1 | 102820003A | 10/10/2010 14:00 | Wanda F Oswald | 1 |
| 10496 | PPL Pest. Microwave Extraction | SW-846 3546 | 1 | 102810005A | 10/08/2010 18:45 | Sally L Appleyard | 1 |
| 04181 | Herbicide Soil Extraction | SW-846 3550B/SW-846 8151A | 1 | 102850009A | 10/13/2010 01:30 | Sherry L Morrow | 1 |
| 06935 | Arsenic | SW-846 6010B | 1 | 102795708002 | 10/12/2010 17:22 | Eric L Eby | 1 |
| 06946 | Barium | SW-846 6010B | 1 | 102795708002 | 10/12/2010 17:22 | Eric L Eby | 1 |
| 06949 | Cadmium | SW-846 6010B | 1 | 102795708002 | 10/12/2010 17:22 | Eric L Eby | 1 |
| 06951 | Chromium | SW-846 6010B | 1 | 102795708002 | 10/12/2010 17:22 | Eric L Eby | 1 |
| 06955 | Lead | SW-846 6010B | 1 | 102795708002 | 10/12/2010 17:22 | Eric L Eby | 1 |
| 06936 | Selenium | SW-846 6010B | 1 | 102795708002 | 10/12/2010 17:22 | Eric L Eby | 1 |
| 06966 | Silver | SW-846 6010B | 1 | 102795708002 | 10/12/2010 17:22 | Eric L Eby | 1 |
| 00159 | Mercury | SW-846 7471A | 1 | 102795711001 | 10/06/2010 18:27 | Nelli S Markaryan | 1 |
| 05708 | SW SW846 ICP Digest | SW-846 3050B | 1 | 102795708002 | 10/06/2010 13:25 | James L Mertz | 1 |
| 05711 | SW SW846 Hg Digest | SW-846 7471A modified | 1 | 102795711001 | 10/06/2010 14:44 | James L Mertz | 1 |

Approved
17 Dec 2010

*=This limit was used in the evaluation of the final result

EXACT COPY
SD 29Dec10

# APPENDIX 7 - HEALTH ANALYSIS REPORTS

*Printed: Tuesday, September 28, 2010 at 16:0*

**Charles River Research Animal Diagnostic Services**
251 Ballardvale Street, Wilmington, MA 01887 USA
Tel: 800-338-9680 Fax: 978-658-7698

**Sponsor: Charles River Preclin Srvs Pennsylvania** **Accession #: 2010-042108**

## *Diagnostic Summary Report*

905 Sheehy Drive
Horsham, PA 19044 USA

**Attn:** Dena Lebo

**Received:** 24 Sep 2010
**Approved:** 28 Sep 2010, 14:54
**Bill Method:** No PO Required
**Test Specimen:** 2000504-5 pooled feces Mouse

| Sample Set | Service (# Tested) | Profile | Assay | Tested | + | +/- | ? |
|---|---|---|---|---|---|---|---|
| #1 | Infectious Disease PCR (2) | All Results Negative | | | | | |

+ = Positive, +/- = Equivocal, ? = Indeterminate

### Service Approvals

| Service | Approved By* | Date |
|---|---|---|
| Infectious Disease PCR | DiAnne L. Peck | 28 Sep 2010, 14:54 |

To assure the SPF status of your research animal colonies, it is essential that you understand the sources, pathobiology, diagnosis and control of pathogens and other adventitious infectious agents that may cause research interference. We have summarized this important information in infectious agent **Technical Sheets**, which you can view by visiting http://www.criver.com/info/disease_sheets.

Dena Lebo 28 Sept 2010

**This report has been electronically signed by laboratory personnel. The name of the individual who approved these results appears in the header of this service report. All services are performed in accordance with and subject to General Terms and Conditions of Sale found in the Charles River Laboratories-Research Models and Services catalogue and on the back of invoices.*

*Printed: Tuesday, September 28, 2010 at 16:0*

***Charles River Research Animal Diagnostic Services***
251 Ballardvale Street, Wilmington, MA 01887
Tel: 800-338-9680 Fax: 978-658-7

**Sponsor: Charles River Preclin Srvs Pennsylvania** **Accession #: 2010-042108**

**Product:** Not Indicated **Test Specimen:** 2000504-5 pooled feces Mouse **Received:** 24 Sep 2010

## *Molecular Diagnostics Infectious Disease PCR Results Report*

**Department Review:** Approved by DiAnne L. Peck, 28 Sep 2010, 14:54*

### *MVM/MPV PCR*

| Sample #: | 1 | 2 |
|---|---|---|
| Code : | 1, 10, 20, 30, 40, 5 | 100 |
| *MVM/MPV PCR* | - | - |

**Remarks:** - = Negative; I = Inhibition, +/- = Equivocal; + = Positive.

Sample Suitability/Detection of PCR Inhibition:
Sample DNA or RNA is spiked with a low-copy number of a exogenous DNA or RNA template respectively. A spike template-specific PCR assay is used to test for the spike template for the purpose of determining the presence of PCR inhibitors. The RNA spike control is also used to evaluate the reverse-transcription of RNA. Amplification of spike template indicates that there is no detectable inhibition and the assay is valid.

Sample IDs: 1-(1, 10, 20, 30, 40, 50, 60, 70, 80, 90); 2-(100). DLP 28SEP2010

28 Sept 2010

*This report has been electronically signed by laboratory personnel. The name of the individual who approved these results appears in the header of this service report.

ZOOLOGIX
Molecular diagnostic testing for animals.

Assay Results Report **11011303**

☐ **Fax to:**

☒ **E-mail to:** alan.hoberman@crl.com
**Cc to:** dena.lebo@crl.com

☐ **Hard copy to:**

**Date results transmitted:** 17jan11

| Client: Charles River Preclinical Services - PA | Client #: 607311 |
|---|---|
| Contact name: Alan Hoberman | PO #: 6600083204 |
| Date samples received: 13jan11 | |

Initials _____



| Client sample ID | Zoologix accession ID | Sample type | Assay | Assay result |
|---|---|---|---|---|
| 20005045/#8314 | 1101130088 | Feces | B0042 | **Negative** |
| 20005045/#8316 | 1101130089 | Feces | B0042 | **Negative** |
| 20005045/#8328 | 1101130090 | Feces | B0042 | **Negative** |
| 20005045/#8333 | 1101130091 | Feces | B0042 | **Negative** |
| 20005045/#8343 | 1101130092 | Feces | B0042 | **Negative** |
| 20005045/#8344 | 1101130093 | Feces | B0042 | **Negative** |
| 20005045/#8346 | 1101130094 | Feces | B0042 | **Negative** |
| 20005045/#8347 | 1101130095 | Feces | B0042 | **Negative** |
| 20005045/#8348 | 1101130096 | Feces | B0042 | **Negative** |
| 20005045/#8387 | 1101130097 | Feces | B0042 | **Negative** |
| 20005045/#8388 | 1101130098 | Feces | B0042 | **Negative** |

Assay descriptions and notes

Assay B0042: Ultrasensitive qualitative detection of *Clostridium perfringens* by real time PCR

*Zoologix has verified the performance characteristics of these tests. However, diagnosis and management of the animal patient should not rely solely upon the results of these tests, as unusual genetic variations of the pathogen can affect results. Correlation with other clinical data is recommended. Specimens will be held for six months by Zoologix to facilitate followup testing, after which time specimens will be disposed of at the discretion of Zoologix unless otherwise directed by client.*

Zoologix, Inc. 9811 Owensmouth Avenue, Suite 4 Chatsworth CA 91311 USA
Phone 818-717-8880 www.zoologix.com Fax 818-717-8881