FINAL REPORT

PROTOCOL 418-015

ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS

SPONSOR'S STUDY NUMBER: T-6295.14

FINAL REPORT DATE: 23 JULY 1999

PROTOCOL 418-015

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ARGUS RESEARCH LABORATORIES, INC.
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I. SUMMARY AND CONCLUSION

A. Methods[a]

Twenty-four presumed pregnant Crl:CD®BR VAF/Plus® (Sprague-Dawley) rats were assigned to three dosage groups (Groups I through III), eight rats per dosage group. The rats were administered the test article, PFOS (FC-95), or the vehicle, 0.5% Tween® 80 in reverse osmosis membrane processed deionized water (R.O. deionized water), orally (via gavage), once daily beginning 43 days prior to cohabitation until confirmed evidenced of mating. Dosages of 0 (Vehicle), 0.1 and 1.6 mg/kg/day were administered at a dosage volume of 5 mL/kg.

A.1. Fo Generation Rats:

The female rats were observed for viability at least twice each day of the study. The rats were examined for clinical observations of effects of the test article, abortions, premature deliveries and deaths before and approximately one hour after dosage. Rats were observed for clinical observations and general appearance once daily during all other periods of study. Body weights were recorded daily during the dosage and postdosage periods and at sacrifice. Feed consumption values were recorded weekly prior to cohabitation, daily during gestation and on days 1, 4, 7, 10 and 14 of lactation (DLs 1, 4, 7, 10 and 14).

The female rats were evaluated for duration of gestation, litter sizes and pup viability at birth. Pups that either appeared stillborn or that died before initial examination of the litters for viability were examined for vital status at birth. Maternal behavior of the dams was evaluated daily when the pups were examined during the 21-day postpartum period. Observed maternal behavior was recorded on DLs 1, 4, 7, 10, 14 and 21.

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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 C (PROTOCOL AND AMENDMENT).

Urine and fecal sample were collected from female rats for the following intervals: one day prior to initiation of cohabitation to the following morning, days 6 to 7, 14 to 15 and 20 to 21 of presumed gestation (DGs 6 to 7, 14 to 15 and 20 to 21), and DLs 21 to 22. Following each 24-hour collection interval, samples were shipped to the Sponsor for analysis. Blood samples were collected from each of the maternal rats on the day cohabitation was initiated (prior to cohabitation), DGs 7, 15 and 21, and DLs 14 and 22. Serum samples were shipped to the Sponsor for analysis.

All surviving rats assigned to the study were sacrificed on DL 22 following the final collection interval for urine and fecal samples and blood sample collection and a gross necropsy of the thoracic, abdominal and pelvic viscera was performed. Tissues with gross lesions were retained. The number and distribution of implantation sites was recorded. A liver section from each dam was collected and shipped to the Sponsor for analysis.

A.2. F1 Generation Litters:

Day 1 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. The litters were observed for viability at least twice each day during the postpartum period. Litters were observed for clinical observations and general appearance once daily during the postpartum period. The pups in each litter were counted once daily. Body weights were recorded on DLs 1 (birth), 4, 7, 14 and 21.

Pups found dead were examined for gross lesions and for the cause of death. For all pups found dead on DLs 2 to 4, all lungs were preserved.

On DL 4, litters were culled to five male pups and five female pups per litter, where possible. The lungs and the livers were collected from the first ten pups culled determined to be at DL 4 from each dosage group (irrespective of litter). The lungs and the livers were individually retained. Remaining culled pups were sacrificed and discarded without evaluation.

All remaining pups on study were sacrificed and examined for gross lesions on DL 21. Gross lesions were retained. The liver from each pup was collected, pooled (per litter) and shipped to the Sponsor for analysis. Blood samples were collected and pooled (per litter). Serum samples were shipped to the Sponsor for analysis.

B. Results

No deaths or premature deliveries were attributed to PFOS treatment. One vehicle control group rat was injured and died after orbital sinus bleeding on DG 15. All other rats survived to scheduled sacrifice. All adverse clinical observations during the precohabitation, gestation and lactation periods were considered unrelated to the test article. A red substance was found in the thoracic cavity of the rat that died. All other rats appeared normal at necropsy.

Rats administered the 1.6 mg/kg/day dosage of the test article had reduced body weight gains or body weight losses in each week of the precohabitation period. Dams in the 1.6 mg/kg/day dosage group had reduced body weight gains during the first week of the gestation period (DGs 0 to 7). Body weight gains were then increased as compared to the control group value on DGs 7 to 10, 13 to 15 and 15 to 18. Reflecting this rebound effect, body weight gains were increased for the entire gestation period (DGs 0 to 20) in the 1.6 mg/kg/day dosage group, as compared to the control group value. Body weight gains for dams administered the 1.6 mg/kg/day dosage of the test article during the precohabitation period generally continued to be increased during the lactation period.

Absolute (g/day) and relative (g/kg/day) feed consumption values were reduced in the 1.6 mg/kg/day dosage group in each week of the precohabitation period. Dams in the 1.6 mg/kg/day dosage group had reduced absolute and relative feed consumption values during the first week of the gestation period (DGs 0 to 7). Feed consumption values were then generally comparable to control group values for the remainder of the gestation period. Absolute and relative feed consumption values in this dosage group were slightly reduced, as compared to control group values, for the entire gestation period (DGs 0 to 20). Absolute and relative feed consumption values during the lactation period were reduced in the groups administered 0.1 or 1.6 mg/kg/day of the test article during the precohabitation period, however the reductions were not strictly dosage-dependent.

Administration of the test article at dosages as high as 1.6 mg/kg/day did not adversely affect any parameter evaluated at natural delivery or during the 22-day lactation period. No clinical or necropsy observations in the F1 generation pups were attributable to dosages of the test article as high as 1.6 mg/kg/day.

C. Conclusion

The purpose of the study, as stated in the protocol, was to evaluate the pharmacokinetics of PFOS in Fo generation pregnant female rats following PFOS treatment during the pre-cohabitation period. This report includes study data from the in-life portion which was conducted at Argus Research laboratories, Inc. The pharmacokinetic samples that were collected during the in-life portion of the study were sent to the Sponsor for analysis and will be reported separately. It is the responsibility of the Sponsor, 3M Corporate Toxicology, to combine the in-life results with the analytical results into a final pharmacokinetic report.

23 JUL 99

Mildred S. Christian, Ph.D., Fellow, ATS Date
Executive Director of Research

23 JUL 99

Alan M. Hoberman, Ph.D., DABT Date
Director of Research

23 JUL 99

Raymond G. York, Ph.D., DABT Date
Associate Director of Research and
Study Director

II. DESCRIPTION OF TEST PROCEDURES

A. Conduct of Study:

A.1. Sponsor:

3M Corporate Toxicololgy, 3M Center, Building 220-2E-02, St. Paul, Minnesota 55144-1000

A.2. Testing Facility:

Argus Research Laboratories, Inc., 905 Sheehy Drive, Building A, Horsham, Pennsylvania 19044-1297

A.3. Study Number:

418-015

A.4. Sponsor's Study Number:

T-6295.14

A.5. Purpose of the Study:

The purpose of this study was to evaluate the pharmacokinetics of PFOS in Fo generation and F1 generation rats during gestation and lactation following cessation of PFOS treatment of Crl:CD®BR VAF/Plus® female rats at confirmed mating.

A.6. Study Design:

The requirements of the U.S. Food and Drug Administration (FDA)[1] were used as the basis of study design.

A.7. Regulatory Compliance:

The study was conducted in compliance with Good Laboratory Practice (GLP) regulations of the U.S. Food and Drug Administration (FDA)[2], the Japanese Ministry of Health and Welfare (MHW)[3] and the European Economic Community (EEC)[4]. There were no deviations from the GLP regulations that affected the quality or integrity of the study. Quality Assurance Unit findings derived from the inspections during the conduct of this study are documented and have been provided to the Study Director and the Testing Facility Management.

A.8. Ownership of the Study:

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

A.9. Study Monitor:

Marvin T. Case, D.V.M., Ph.D.

A.10. Alternate Study Monitor:

Andrew M. Seacat, Ph.D.

A.11. Study Director:

Raymond G. York, Ph.D., DABT (Associate Director of Research)

A.12. Technical Performance:

John F. Barnett, B.S. (Director of Laboratory Operations)
Paul E. Ciotti (Team Leader)
Todd J. Killino, B.S. (Laboratory Technician)

A.13. Report Preparation:

Raymond G. York, Ph.D., DABT
Jo Ann Frazee, M.S. (Study Coordinator)
Denise P. Gasiorowski (Data Management Specialist)
Karen G. Parker, A.A. (Report Administrator)

A.14. Report Review:

Mildred S. Christian, Ph.D., Fellow, ATS (Executive Director of Research)
Alan M. Hoberman, Ph.D, DABT (Director of Research)

A.15. Date Protocol Signed:

16 November 1998

A.16. Dates of Technical Performance:

Rat Arrival Date	17 NOV 98
Dosage Period [43 days prior to the first day of cohabitation[a] until confirmed mating (DG 0)]	23 NOV 98 - 08 JAN 99
Cohabitation Period	04 JAN 99 PM - 09 JAN 99 AM
DG[b] 0	05 JAN 99 - 08 JAN 99
Delivery Period (DL[c] 1)	26 JAN 99 - 30 JAN 99
Sacrifice of Fo generation rats not selected for continued evaluation	15 JAN 99
DL 4 Culling (pups not selected for continued observation)	29 JAN 99 - 02 FEB 99
DG 25 Sacrifice (dam with no confirmed date of mating)	02 FEB 99
DL 21 Scheduled Sacrifice (F1 generation pups)	15 FEB 99 - 19 FEB 99
DL 22 Scheduled Sacrifice (Fo generation dams)	16 FEB 99 - 20 FEB 99

A.17. Records Maintained:

The original report, raw data and reserve samples of the test article and vehicle components are retained in the archives of Argus Research Laboratories, Inc. Any preserved tissues are retained in the archives of the Testing Facility for one year after the mailing of the final report, after which time the Sponsor will decide their final disposition. All unused prepared formulations were discarded at the Testing Facility. All remaining bulk test article was returned to the Study Monitor upon completion of all work with the test article.

B. Test Article Information:

B.1. Description:

PFOS (FC-95) - off-white powder

B.2. Lot/Batch Number:

217 (Expiration date: May 2000)

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a. See APPENDIX D (DEVIATIONS FROM THE PROTOCOL AND THE STANDARD OPERATING PROCEDURES OF THE TESTING FACILITY), item 1.
b. DG is used as an abbreviation for day of (presumed) gestation.
c. DL is used as an abbreviation for day of lactation or day postpartum.

B.3. Date Received and Storage Conditions:

The test article was received on 21 October 1998, and stored at room temperature.

B.4. Special Handling Instructions:

Standard safety precautions (use of protective clothing, gloves, dust-mist respirator, safety goggles or safety glasses and a face-shield) were taken when handling the bulk test article and prepared suspensions.

B.5. Analysis of Activity:

Information regarding the identity, composition, strength and purity of the test article is on file with the Sponsor.

C. Vehicle Information:

C.1. Description:

0.5% Tween® 80 in Reverse Osmosis Membrane Processed Deionized Water (R.O. Deionized Water).
Tween® 80 - a clear or yellow viscous liquid

C.2. Lot Numbers:

Tween® 80 - M29477 and M03H05

C.3. Dates Received, Source and Storage Conditions:

Tween® 80 was received from J.T. Baker, Phillipsburg, New Jersey, on 17 September 1998 (lot M29477) and 3 December 1998 (lot M03H05), and stored at room temperature. The R.O. deionized water is available from a continuous source at the Testing Facility and is maintained at room temperature.

C.4. Special Handling Instructions:

Standard safety precautions (use of protective clothing, gloves, dust-mist respirator, safety goggles or safety glasses and a face-shield) were taken when handling the vehicle.

C.5. Analysis of Purity:

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

D. Test Article Preparation and Storage Conditions:

Suspensions of PFOS (PC-95) were prepared daily at concentrations of 0, 0.02, and 0.32 mg/mL. Prepared formulations were stored at room temperature.

D.1. Sample Information:

Sample Type	Size	Date Retained	Storage Conditions	Shipped To	Date Shipped
Concentration (all levels)	2 mL[a]	22 NOV 98 07 JAN 99	Frozen	Sponsor	23 NOV 98 12 JAN 99
Bulk Test Article Reserve	1 g	19 NOV 98	Room temperature	Testing Facility Archives	27 JAN 99
Vehicle Components Reserve Tween® 80 Lot M29477 Lot M03H05 R.O. Water	 5 mL 5 mL 5 mL	 19 NOV 98 10 DEC 98 19 NOV 98	Room temperature	Testing Facility Archives	 27 JAN 99 27 JAN 99 27 JAN 99

a. Duplicate samples were taken from the first and last preparation. One sample of each set was shipped for analysis; the remaining samples were retained as backups. Backup samples were stored frozen (-70°C or below) and will be discarded at the Testing Facility upon the request of the Sponsor.

D.2. Analytical Results:

Information on the stability and homogeneity of the prepared formulations and of the stability of the bulk test article are on file with the Sponsor. Data verifying the stability of the test article in the vehicle for 48 hours under the conditions of administration are on file with the Sponsor. Records were maintained to document how the test article formulations were prepared.

Results of the concentration analyses were not available at the time of the writing of this report.

E. Test System:

E.1. Species:

Rat

E.2. Strain:

Crl:CD®BR VAF/Plus® (Sprague-Dawley)

E.3. Supplier (Source):

Charles River Laboratories, Inc., Raleigh, North Carolina

E.4. Sex:

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

E.5. Rationale for Test System:

The Crl:CD®BR VAF/Plus® (Sprague-Dawley) rat was selected as the Test System because: 1) this strain of rat was used in the reproductive and developmental toxicity studies; 2) historical data and experience exist at the Testing Facility[5-7]; and 3) the test article is pharmacologically active in the species and strain.

E.6. Test System Data:

Number of Rats	37
Approximate Date of Birth	14 SEP 98
Approximate Age at Arrival	65 days
Weight (g) on the Day After Arrival	181 - 222
Weight (g) at Study Assignment	192 - 231

E.7. Breeder Male Rat Data:

Number of Rats	112
Approximate Date of Birth	13 JAN 98
Approximate Age at Arrival	78 days
Weight (g) on the Day After Arrival	300 - 356
Weight (g) at Cohabitation	515 - 893

E.8. Method of Randomization:

Upon arrival, rats were assigned to individual housing on the basis of computer-generated random units. After acclimation, 36 virgin female rats were placed into groups on the basis of physical appearance and body weights recorded during acclimation. Female rats were assigned to three dosage groups (Groups I through III), 12 rats per dosage group, using a computer-generated (weight-ordered) randomization procedure. After these 36 rats were cohabitated,

eight mated female rats (those with confirmed evidence of mating) were selected for the study from each dosage group.

On DL 4, a table of random units was used to cull the litters to five male pups and five female pups per litter, where possible.

E.9. System of Identification:

E.9.a. Fo Generation Rats:

Male rats were given unique permanent identification numbers upon assignment to the Testing Facility's breeder male rat population. Female rats were assigned temporary numbers at receipt and given unique permanent identification numbers before cohabitation. Each rat was individually identified with a Monel® self-piercing ear tag (Gey Band and Tag Co., Inc., No. MSPT 20101).

E.9.b. F1 Generation Pups:

Pups were not individually identified during lactation; all parameters were evaluated in terms of the litter.

F. Husbandry:

F.1. Research Facility Registration:

USDA Registration No. 23-R-099 under the Animal Welfare Act, 7 U.S.C. 2131 *et seq.*

F.2. Study Rooms:

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

F.3. Housing:

All cage sizes and housing conditions were in compliance with the *Guide for the Care and Use of Laboratory Animals*[8]. Fo generation rats were individually housed in stainless steel, wire-bottomed cages, except during the cohabitation and postpartum periods. During cohabitation, each pair of rats was housed in the male rat's cage. Beginning no later than DG 20, Fo generation female rats

were individually housed in nesting boxes, except during collection intervals for urine and fecal samples. During these collection intervals, the female rats were housed individually in metabolism cages. Each dam and delivered litter were housed in a common nesting box during the postpartum period.

F.4. Lighting:

An automatically-controlled fluorescent light cycle was maintained at 12-hours light:12-hours dark, with each dark period beginning at 1900 hours EST.

F.5. Sanitization:

Cage pan liners were changed approximately three times each week. Cages were changed approximately every other week.

F.6. Feed:

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

F.7. Feed Analysis:

Analyses were routinely performed by the feed supplier. No contaminants at levels exceeding the maximum concentration or deviations from expected nutritional requirements were detected by these analyses. Copies of the results of the feed analyses are available 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.

F.8. Water:

Local water that had been processed by passage through a reverse osmosis membrane (R.O. water) was available to the rats *ad libitum* from an automatic watering access system and/or individual water bottles. Chlorine was added to the processed water as a bacteriostat.

F.9. Water Analysis:

The processed water is analyzed twice annually for possible chemical contamination (Lancaster Laboratories, Lancaster, Pennsylvania) and monthly for possible bacterial contamination (Analytical Laboratories, Inc., Chalfont, Pennsylvania). Copies of the results of the water analyses are available in the raw data.

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

F.10. Bedding:

Bed-o'cobs® was used as the nesting material (The Andersons' Industrial Products Groups, Maumee, Ohio).

F.11. Bedding Analysis:

Bedding was changed as often as necessary to keep the animals dry and clean. Analyses for possible contamination were conducted annually and documented in the raw data.

Neither the Study Director nor the Sponsor was aware of any agent present in the bedding that was known to interfere with the results of this study.

G. Methods:

G.1. Dosage Administration:

Dosage Group	Dosage (mg/kg/day)[a]	Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Female Rats	Assigned Rat Numbers
I	0 (Vehicle)	0	5	8	13726 - 13728, 13731, 13734 – 13737
II	0.1	0.02	5	8	13739 - 13741, 13744 – 13746, 13748 – 13749
III	1.6	0.32	5	8	13751 - 13756, 13758 – 13859

a. The test article was considered 100% pure for the purpose of dosage calculations.

G.2. Rationale for Dosage Selection:

Dosages were selected on the basis of a previous study conducted with the test article (Argus Research Laboratories, Inc., Protocol 418-008). In this study the Fo generation maternal and paternal no-observable-effect-level (NOEL) of PFOS was 0.1 mg/kg/day (0.4 mg/kg/day and higher dosages caused reductions in body weight gain and reduced feed consumption values).

The Fo generation reproductive NOEL was greater than 3.2 mg/kg/day; no effects on mating, fertility or estrous cycling occurred. The NOEL for viability and growth in the F1 generation offspring was 0.4 mg/kg/day (1.6 mg/kg/day and higher dosages caused preimplantation loss and reductions in litter size, pup viability, growth and survival).

The F1 generation maternal and paternal NOEL of PFOS was 0.1 mg/kg/day (0.4 mg/kg/day dosage caused reductions in body weight gain and reduced feed consumption values). The F1 generation reproductive NOEL was greater than a dosage of 0.4 mg/kg/day; no effects on mating or fertility occurred. The NOEL for viability and growth in the F2 generation offspring was 0.1 mg/kg/day (0.4 mg/kg/day dosage caused stillbirths and reductions in litter size, pup viability, growth and survival).

G.3. Route of Administration:

Oral (gavage)

G.4. Rationale for Route of Administration:

The oral (gavage) route was selected for use because: 1) this was the route of administration in the developmental and reproductive toxicology studies; and 2) it is one of the possible routes of human exposure.

G.5. Frequency of Administration:

G.5.a. Fo Generation Female Rats:

Appropriate dosages[a] of the test article or vehicle were administered orally (via gavage) once daily to female rats beginning 43[b] days prior to cohabitation until DG 0 (confirmed evidenced of mating, such as observation of spermatozoa in a smear of the vaginal contents or a copulatory plug *in situ*). Female rats were not given the test article or vehicle on DG 0. Dosages were adjusted daily on the basis of the individual body weights recorded before intubation. The rats were intubated once daily at approximately the same time each day.

G.5.b. F1 Generation Pups:

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

G.6. Length of Study:

Approximately 14 weeks

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a. See APPENDIX D, item 2.
b. See APPENDIX D, item 1.

G.7. Method of Study Performance:

G.7.a. Fo Generation Rats:

After acclimation and 43 days of dosage administration, 36 healthy virgin female rats were placed into cohabitation with 36 breeder male rats (one male rat per female rat in the male rat's cage). The cohabitation period consisted of a maximum of five days. Mating was evaluated daily during the cohabitation period. Female rats with spermatozoa observed in a smear of the vaginal contents or a copulatory plug *in situ* were considered to be at DG 0 and returned to individual housing. Twenty-four mated female rats, eight per dosage group, were selected for the study, as previously discussed.

The female rats were observed for viability at least twice each day of the study and for general appearance at least once during acclimation. The rats were also examined for clinical observations of effects of the test article, abortions, premature deliveries and deaths before and approximately one hour after dosage. Rats were observed for clinical observations and general appearance once daily during all other periods of study.

Body weights were recorded once during acclimation. Body weights were recorded daily during the dosage and postdosage periods and at sacrifice. Feed consumption values were recorded once during acclimation, weekly prior to cohabitation, daily during gestation and on DLs 1, 4, 7, 10 and 14. Feed consumption was not tabulated after DL 14, when it was expected that pups would begin to consume maternal feed.

The female rats were evaluated for duration of gestation (DG 0 to the day the first pup was observed), litter sizes (defined as all pups delivered), live litter size (live born pups only) and pup viability at birth. Pups that either appeared stillborn or that died before initial examination of the litters for viability were examined 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. Maternal behavior of the dams was evaluated daily when the pups were examined during the 21-day postpartum period. Observed maternal behavior was recorded on DLs 1, 4, 7, 10, 14 and 21. Deviations from expected maternal behavior were recorded, if and when present, on all other days during the postpartum period.

G.7.b. F1 Generation Rats:

Day 1 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).

The litters were observed for viability at least twice each day during the postpartum period. Dead pups observed at these times were removed from the nesting box. Litters were observed for clinical observations and general appearance once daily during the postpartum period. The pups in each litter were counted once daily. Body weights were recorded on DLs 1 (birth), 4, 7, 14 and 21.

G.8. Pharmacokinetic Sample Collection:

G.8.a. Fo Generation Rats:

Urine and fecal sample were collected from female rats for the following intervals: one day prior to initiation of cohabitation to the following morning, DGs 6 to 7, 14 to 15 and 20 to 21, and DLs 21 to 22. Following each 24-hour collection interval, samples were collected into centrifuge tubes, placed on dry ice and stored frozen (-70°C or below) and shipped, frozen on dry ice, to the Sponsor for analysis.

Blood samples were collected from each of the maternal rats following removal from metabolism caging (prior to test article or vehicle administration) on each of the following days: on the day cohabitation is initiated (prior to cohabitation), DGs 7, 15 and 21, and DLs 14 and 22.

On all days of collection except DL 22, blood samples (approximately 1 mL each) were collected from the orbital sinus. On DL 22, blood samples (approximately 4 mL each) were collected via the inferior vena cava. Blood was collected and transferred into serum separator tubes. The samples were spun in a refrigerated centrifuge. The serum was transferred into polypropylene tubes labeled with the study number, rat identification, date of collection, study day and collection timepoint. All samples were immediately frozen on dry ice and maintained frozen (-70°C or below), and shipped, frozen on dry ice, to the Sponsor for analysis.

G.8.b. F1 Generation Litters:

On DL 21, blood samples were collected from all remaining pups on study. Blood samples were collected via the inferior vena cava from each pup, pooled (per litter) and transferred into serum separator tubes. The samples were spun in a refrigerated centrifuge. The serum was transferred into polypropylene tubes labeled with the study number, rat identification, date of collection, study day and collection timepoint. All samples were immediately frozen on dry ice and maintained frozen (-70°C or below) and shipped to the Sponsor for analysis.

G.9. Gross Necropsy:

G.9.a. Fo Generation Rats:

Female rats, with or without confirmed evidence of mating, that were cohabited but not assigned to the study, were sacrificed by carbon dioxide asphyxiation and discarded without further evaluation.

All surviving rats assigned to the study were sacrificed by carbon dioxide asphyxiation on DL 22 following the final collection interval for urine and fecal samples and blood sample collection. A gross necropsy of the thoracic, abdominal and pelvic viscera was performed. Tissues with gross lesions were preserved in neutral buffered 10% formalin for possible future evaluation. Representative photographs of maternal lesions are available in the raw data. The number and distribution of implantation sites was recorded. A liver section (right lateral lobe) from each dam was collected, frozen and stored (-70°C or below) until shipment to the Sponsor for analysis. All other maternal tissues were discarded.

The rat that did not deliver a litter was sacrificed on DG 25 and examined for gross lesions. Uteri were stained with 10% ammonium sulfide to confirm the absence of implantation sites[9]. The rat that was found dead was examined for the cause of death on the day of the death. The rat was examined for gross lesions. A liver section (right lateral lobe) was collected and stored, as described above. Pregnancy status was recorded; fetuses were examined to the extent possible.

G.9.b. F1 Generation Pups:

All pups culled on DL 4 were sacrificed via decapitation. The lungs and the livers were collected from the first ten pups culled determined to be at DL 4 from each dosage group (irrespective of litter) and preserved for possible future histopathological evaluation. The lungs were individually retained in Bouin's solution, and the livers were individually retained in neutral buffered 10% formalin for possible future evaluation. Remaining culled pups were sacrificed and discarded without evaluation.

Pups found dead were examined for gross lesions and for the cause of death. For all pups found dead on DLs 2 to 4, all lungs were preserved in Bouin's solution for possible future evaluation.

All remaining pups on study were sacrificed on DL 21 by carbon dioxide asphyxiation and examined for gross lesions. Gross lesions were preserved in neutral buffered 10% formalin. The liver from each pup was collected, pooled

(per litter), frozen and stored (-70°C or below) and shipped to the Sponsor for analysis.

G.10. Statistical Analyses:

Averages and percentages were calculated. Litter values were used where appropriate.

III. RESULTS

A. Mortality, Clinical and Necropsy Observations (Summaries - Tables 1 and 2; Individual Data - Tables 19 and 20)

A.1. Mortality

No deaths or premature deliveries were attributed to PFOS treatment. One vehicle control group rat was injured and died after orbital sinus bleeding on DG `15. All other rats survived to scheduled sacrifice.

A.2. Clinical Observations

All adverse clinical observations during the precohabitation, gestation and lactation periods were considered unrelated to the test article because the incidences were not dosage-dependent and/or the observation occurred in only one rat in a group. These observations included dental problems (missing, broken and/or misaligned incisors), chromodacryorrhea, abrasion on the forepaw, localized alopecia on the head or limbs, chromorhinorrhea, exophthalmos, hemorrhagic area on the eye, urine-stained abdominal fur, missing eye, corneal opacity, swollen area on chest or around eye, red, dried perioral substance, torn ear and soft or liquid feces. A red perinasal substance, blue paws and gasping were agonal signs for the rat that died.

A.3. Necropsy Observations

A red substance was found in the thoracic cavity of the rat that died. All other rats appeared normal at necropsy.

B. Body Weights and Body Weight Changes (Figure 1; Summaries - Tables 3 through 8; Individual Data - Tables 21 through 23)

B.1. Precohabitation

Rats administered 1.6 mg/kg/day dosage of the test article had reduced body weight gains or body weight losses in each week of the precohabitation period. Reflecting these effects of the test article, body weight gains were 46.1% of the control group value for the entire precohabitation period (DSs 1 to 43) in the 1.6 mg/kg/day dosage group.

Precohabitation body weights and body weight gains were unaffected by the 0.1 mg/kg/day dosage of the test article.

B.2. Gestation

Dams administered 1.6 mg/kg/day dosage of the test article during the precohabitation period (treatment ended on DG 0) had reduced body weight gains during the first week of the gestation period (DGs 0 to 7). Body weight gains were then increased as compared to the control group value on DGs 7 to 10, 13 to 15 and 15 to 18. Reflecting this rebound effect, body weight gains were increased for the entire gestation period (DGs 0 to 20) in the 1.6 mg/kg/day dosage group, as compared to the control group value.

Gestation body weights and body weight gains were unaffected by the 0.1 mg/kg/day dosage of the test article.

B.3. Lactation

Body weight gains for dams administered the 1.6 mg/kg/day dosage of the test article during the precohabitation period generally continued to be increased during the lactation period.

Lactation body weights and body weight gains were unaffected by the 0.1 mg/kg/day dosage of the test article.

C. Absolute (g/day) and Relative (g/kg/day) Feed Consumption Values (Summaries - Tables 9 through 14; Individual Data - Tables 24 through 26)

C.1. Precohabitation

Absolute (g/day) and relative (g/kg/day) feed consumption values were reduced in the 1.6 mg/kg/day dosage group in each week of the precohabitation period. Reflecting these effects of the test article, feed consumption values were reduced for the entire precohabitation period (DSs 1 to 43) in the 1.6 mg/kg/day dosage group.

Precohabitation feed consumption values were unaffected by the 0.1 mg/kg/day dosage of the test article.

C.2. Gestation

Dams administered 1.6 mg/kg/day dosage of the test article during the precohabitation period (treatment ended on DG 0) had reduced absolute and relative feed consumption values during the first week of the gestation period (DGs 0 to 7). Feed consumption values were then generally comparable to control group values for the remainder of the gestation period. Absolute and

relative feed consumption values in this dosage group were slightly reduced, as compared to control group values, for the entire gestation period (DGs 0 to 20).

Gestation feed consumption values were unaffected by the 0.1 mg/kg/day dosage of the test article.

C.3. Lactation

Absolute and relative feed consumption values during the lactation period were reduced in the groups administered 0.1 or 1.6 mg/kg/day of the test article during the precohabitation period, however the reductions were not strictly dosage-dependent.

D. Natural Delivery and Litter Observations (Summaries - Tables 15 and 16; Individual Data - Tables 27 through 30)

Natural delivery observations were based on 7, 8 and 7 pregnant rats in each of the three respective dosage groups.

Administration of the test article at dosages as high as 1.6 mg/kg/day did not adversely affect any parameter evaluated at natural delivery or during the 22-day lactation period (duration of gestation, averages for implantations and live litter sizes, numbers of dams with no liveborn pups or all pups dying during lactation, gestation, viability and lactation indices, surviving pups per litter, litter size at weighing, pup weight per litter and pup sex ratios).

E. Clinical Observations from Birth to Day 21 Postpartum and Necropsy Observations (Summaries - Tables 17 and 18; Individual Data - Tables 31 and 32)

No clinical or necropsy observations in the F1 generation pups were attributable to maternal dosages of the test article as high as 1.6 mg/kg/day because: 1) the incidences were not dosage-dependent; and/or 2) the observation occurred in only one or two pups. The only adverse clinical observation was a black tip of tail in one 0.1 mg/kg/day dosage group pup. No milk in stomach occurred in 0, 1 and 2 pups that were found dead in the three respective dosage groups. All pups appeared normal at necropsy on DL 4 or 21.

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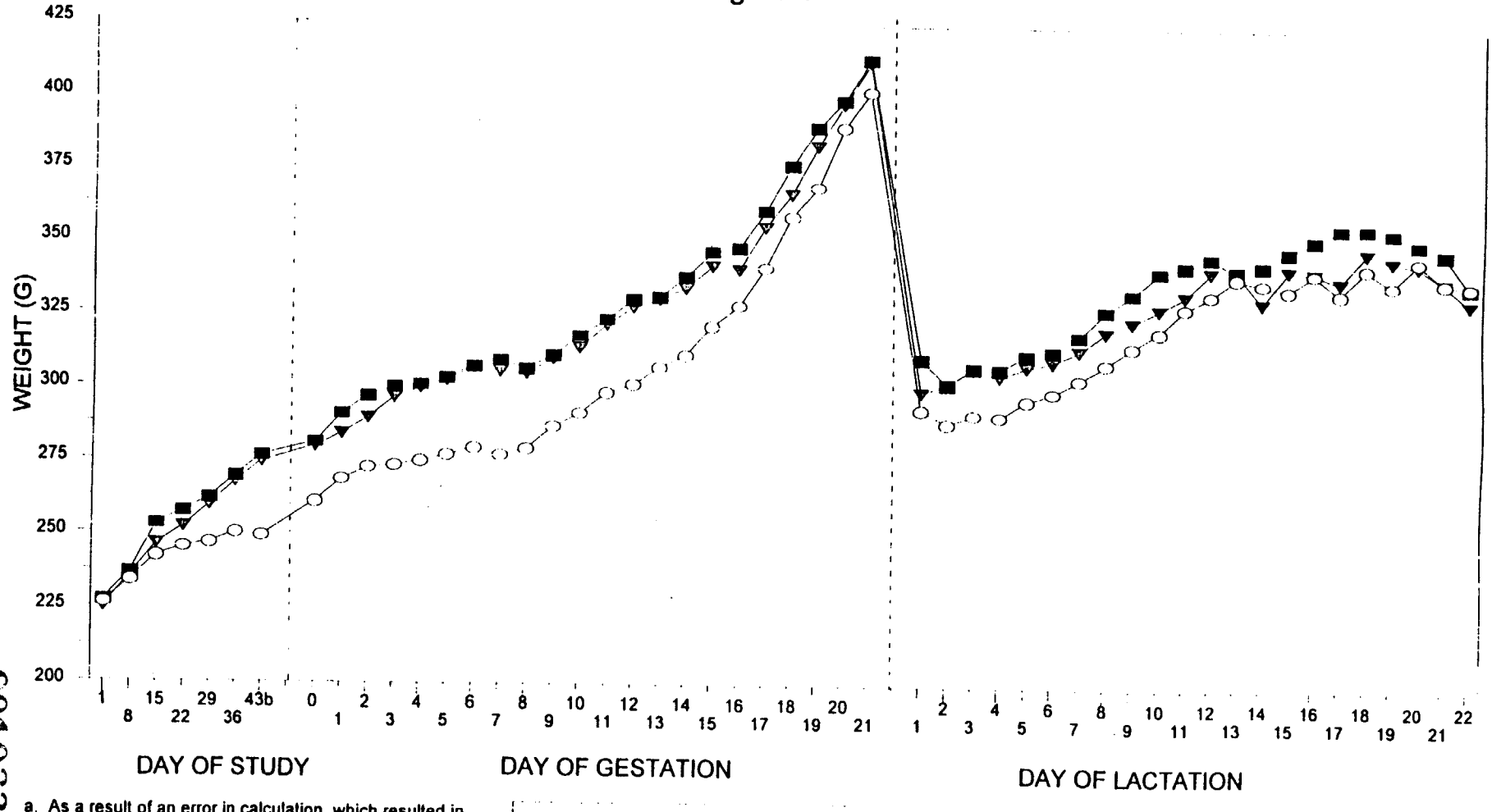
APPENDIX A

REPORT FIGURE

BODY WEIGHTS

Fo GENERATION FEMALE RATS

Figure 1



a. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
b. Last value recorded before cohabitation.

APPENDIX B

REPORT TABLES

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 1 (PAGE 1): CLINICAL OBSERVATIONS - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP DOSAGE (MG/KG/DAY)a	I 0 (VEHICLE)	II 0.1b	III 1.6b
PRECOHABITATION (DAY 1 OF STUDY TO THE DAY OF COHABITATION):			
MAXIMUM POSSIBLE INCIDENCE	516/ 12	516/ 12	516/ 12
MORTALITY	0	0	0
INCISORS: TOTAL	0/ 0	0/ 0	16/ 1
MISALIGNED	0/ 0	0/ 0	16/ 1
MISSING/BROKEN	0/ 0	0/ 0	5/ 1
CHROMODACRYORRHEA	0/ 0	0/ 0	10/ 1
RIGHT FOREPAW: ABRASION	0/ 0	0/ 0	5/ 1
LOCALIZED ALOPECIA: HEAD	0/ 0	2/ 1	0/ 0

MAXIMUM POSSIBLE INCIDENCE = (DAYS x RATS)/NUMBER OF RATS EXAMINED PER GROUP.
N/N = TOTAL NUMBER OF OBSERVATIONS/NUMBER OF RATS WITH OBSERVATION.
a. Dosage occurred on day 1 of study until day 0 of presumed gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 1 (PAGE 2): CLINICAL OBSERVATIONS - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP DOSAGE (MG/KG/DAY)a	I 0 (VEHICLE)	II 0.1b	III 1.6b
PRESUMED GESTATION: c			
MAXIMUM POSSIBLE INCIDENCE	190/ 12	192/ 11	201/ 12
ACCIDENTAL DEATH	1d	0	0
LOCALIZED ALOPECIA: LIMBS	0/ 0	5/ 2	11/ 2
CHROMODACRYORRHEA	5/ 1	12/ 3	5/ 1
CHROMORHINORRHEA	1/ 1	9/ 2	3/ 1
INCISORS: MISALIGNED	0/ 0	0/ 0	5/ 1
EXOPHTHALMOS	5/ 1	4/ 1	0/ 0
EYES: HEMORRHAGIC AREA	5/ 1	4/ 1	0/ 0
URINE-STAINED ABDOMINAL FUR	0/ 0	2/ 1	0/ 0
RIGHT EYE: REMOVED	0/ 0	1/ 1	0/ 0
GASPING	1/ 1d	0/ 0	0/ 0
PAWS: BLUE	1/ 1d	0/ 0	0/ 0
RED PERINASAL SUBSTANCE	1/ 1d	0/ 0	0/ 0

MAXIMUM POSSIBLE INCIDENCE = (DAYS x RATS)/NUMBER OF RATS EXAMINED PER GROUP.
N/N = TOTAL NUMBER OF OBSERVATIONS/NUMBER OF RATS WITH OBSERVATION.

a. Dosage occurred on day 1 of study until day 0 of presumed gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Restricted to rats with a confirmed mating date.
d. Dam 13731 had an accidental death on day 15 of gestation.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 1 (PAGE 3): CLINICAL OBSERVATIONS - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP DOSAGE (MG/KG/DAY)a	I 0 (VEHICLE)	II 0.1b	III 1.6b
LACTATION:			
MAXIMUM POSSIBLE INCIDENCE	154/ 7	176/ 8	154/ 7
MORTALITY	0	0	0
CHROMODACRYORRHEA	0/ 0	10/ 2	1/ 1
CORNEAL OPACITY	0/ 0	0/ 0	7/ 1
CHROMORHINORRHEA	0/ 0	20/ 4	0/ 0
RIGHT EYE: MISSING	0/ 0	22/ 1	0/ 0
CHEST OR AROUND RIGHT EYE: SWOLLEN	1/ 1	7/ 1	0/ 0
RED DRIED PERIORAL SUBSTANCE	0/ 0	1/ 1	0/ 0
RIGHT EAR: TORN	3/ 1	0/ 0	0/ 0
SOFT OR LIQUID FECES	3/ 1	0/ 0	0/ 0

MAXIMUM POSSIBLE INCIDENCE = (DAYS x RATS)/NUMBER OF RATS EXAMINED PER GROUP.
N/N = TOTAL NUMBER OF OBSERVATIONS/NUMBER OF RATS WITH OBSERVATION.

a. Dosage occurred on day 1 of study until day 0 of gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 2 (PAGE 1): NECROPSY OBSERVATIONS - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP		I	II	III
DOSAGE (MG/KG/DAY)a		0 (VEHICLE)	0.1b	1.6b
RATS EXAMINED c	N	8d	8d	8d
ACCIDENTAL DEATH	N	1e	0	0
APPEARED NORMAL	N	7	8	8
THORACIC CAVITY:				
RED SUBSTANCE	N	1e	0	0

a. Dosage occurred on day 1 of study until day 0 of presumed gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Refer to the individual clinical observations table (Table 19) for external observations confirmed at necropsy.
d. Excludes values for rats that were not selected for continuation on study.
e. Dam 13731 had an accidental death on day 15 of gestation.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 3 (PAGE 1): BODY WEIGHTS - PRECOHABITATION - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP DOSAGE (MG/KG/DAY)a		I 0 (VEHICLE)	II 0.1b	III 1.6b
RATS TESTED	N	12	12	12
BODY WEIGHT (G)				
DAY 1	MEAN±S.D	225.0 ± 10.2	227.2 ± 8.9	226.3 ± 12.3
DAY 8	MEAN±S.D	235.4 ± 10.8	236.6 ± 10.5	233.9 ± 13.0
DAY 15	MEAN±S.D	246.2 ± 10.9	253.1 ± 12.0	242.3 ± 14.4
DAY 22	MEAN±S.D	252.2 ± 13.4	257.5 ± 14.4	245.2 ± 15.7
DAY 29	MEAN±S.D	259.6 ± 12.7	262.0 ± 15.5	246.9 ± 14.5
DAY 36	MEAN±S.D	267.6 ± 15.8	269.6 ± 15.8	250.3 ± 18.6
DAY 43c	MEAN±S.D	274.5 ± 17.9	276.4 ± 18.6	249.2 ± 21.5

DAY = DAY OF STUDY

a. Dosage occurred on day 1 of study until day 0 of presumed gestation.

b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

c. Last value recorded before cohabitation.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 4 (PAGE 1): BODY WEIGHT CHANGES - PRECOHABITATION - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP		I	II	III
DOSAGE (MG/KG/DAY)a		0 (VEHICLE)	0.1b	1.6b
RATS TESTED	N	12	12	12
BODY WEIGHT CHANGE (G)				
DAYS 1 - 8	MEAN±S.D.	+10.4 ± 4.9	+9.4 ± 3.3	+7.6 ± 6.7
DAYS 8 - 15	MEAN±S.D.	+10.8 ± 5.6	+16.5 ± 6.8	+8.4 ± 4.4
DAYS 15 - 22	MEAN±S.D.	+6.1 ± 6.6	+4.4 ± 6.5	+2.9 ± 3.8
DAYS 22 - 29	MEAN±S.D.	+7.3 ± 6.9	+4.5 ± 6.8	+1.7 ± 3.0
DAYS 29 - 36	MEAN±S.D.	+8.0 ± 6.3	+7.6 ± 6.8	+3.4 ± 5.8
DAYS 36 - 43c	MEAN±S.D.	+6.9 ± 6.6	+6.8 ± 6.9	-1.2 ± 5.3
DAYS 1 - 43c	MEAN±S.D.	+49.5 ± 14.5	+49.2 ± 14.0	+22.8 ± 16.3

DAYS = DAYS OF STUDY

a. Dosage occurred on day 1 of study until day 0 of presumed gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Last value recorded before cohabitation.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 5 (PAGE 1): MATERNAL BODY WEIGHTS - GESTATION - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP DOSAGE (MG/KG/DAY)a		I 0 (VEHICLE)	II 0.1b	III 1.6b
RATS TESTED	N	12	12	12
INCLUDED IN ANALYSES	N	8c	8c	8c
PREGNANT	N	8	8	7
MATERNAL BODY WEIGHT (G)				
DAY 0	MEAN±S.D.	279.6 ± 20.2	281.1 ± 20.9	261.0 ± 19.7
DAY 1	MEAN±S.D.	284.1 ± 18.0	290.8 ± 18.6	268.7 ± 19.9
DAY 2	MEAN±S.D.	289.5 ± 16.7	297.2 ± 17.5	272.7 ± 21.0
DAY 3	MEAN±S.D.	296.5 ± 19.4	300.2 ± 19.0	273.6 ± 20.2
DAY 4	MEAN±S.D.	299.9 ± 19.7	301.1 ± 19.2	275.1 ± 19.4
DAY 5	MEAN±S.D.	302.6 ± 18.9	303.5 ± 17.6	277.0 ± 16.7
DAY 6	MEAN±S.D.	307.2 ± 21.3	307.6 ± 16.6	279.7 ± 15.0
DAY 7	MEAN±S.D.	305.9 ± 18.0	309.5 ± 15.5	277.1 ± 15.0
DAY 8	MEAN±S.D.	305.1 ± 21.1	306.9 ± 17.7	279.4 ± 16.2
DAY 9	MEAN±S.D.	310.2 ± 20.3	311.5 ± 17.3	287.0 ± 16.1
DAY 10	MEAN±S.D.	314.1 ± 19.2	318.1 ± 19.3	291.6 ± 17.5
DAY 11	MEAN±S.D.	322.0 ± 24.2	323.8 ± 18.9	298.8 ± 21.1
DAY 12	MEAN±S.D.	328.1 ± 20.8	330.6 ± 16.3	301.7 ± 15.9
DAY 13	MEAN±S.D.	330.8 ± 22.9	331.5 ± 18.6	307.6 ± 21.7

DAY = DAY OF GESTATION
a. Dosage occurred on day 1 of study until day 0 of gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Excludes values for rats that were not selected for continuation on study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 5 (PAGE 2): MATERNAL BODY WEIGHTS - GESTATION - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP			I	II	III
DOSAGE (MG/KG/DAY)a			0 (VEHICLE)	0.1b	1.6b
RATS TESTED		N	12	12	12
INCLUDED IN ANALYSES		N	8c	8c	8c
PREGNANT		N	8	8	7
MATERNAL BODY WEIGHT (G)					
DAY 14		MEAN±S.D.	334.5 ± 22.6	338.5 ± 17.9	311.7 ± 19.2
DAY 15		MEAN±S.D.	342.2 ± 24.1 [7]d	347.1 ± 20.9	321.8 ± 22.0
DAY 16		MEAN±S.D.	341.1 ± 23.5 [7]d	348.5 ± 18.6	328.6 ± 20.8
DAY 17		MEAN±S.D.	355.6 ± 25.8 [7]d	361.2 ± 17.2	341.6 ± 19.3
DAY 18		MEAN±S.D.	367.1 ± 27.2 [7]d	376.9 ± 21.2	359.3 ± 19.6
DAY 19		MEAN±S.D.	383.7 ± 29.5 [7]d	390.1 ± 20.5	369.4 ± 18.0
DAY 20		MEAN±S.D.	398.0 ± 31.0 [7]d	399.4 ± 21.7	390.0 ± 25.1
DAY 21		MEAN±S.D.	412.4 ± 34.5 [7]d	413.4 ± 31.2	402.3 ± 20.6

DAY = DAY OF GESTATION
[ ] = NUMBER OF VALUES AVERAGED

a. Dosage occurred on day 1 of study until day 0 of gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Excludes values for rats that were not selected for continuation on study.
d. Excludes values for dam 13731, which had an accidental death on day 15 of gestation.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 6 (PAGE 1): MATERNAL BODY WEIGHT CHANGES - GESTATION - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP		I	II	III
DOSAGE (MG/KG/DAY)a		0 (VEHICLE)	0.1b	1.6b
RATS TESTED	N	12	12	12
INCLUDED IN ANALYSES	N	8c	8c	8c
PREGNANT	N	8	8	7
MATERNAL BODY WEIGHT CHANGE (G)				
DAYS 0 - 7	MEAN±S.D.	+26.2 ± 7.0	+28.4 ± 9.4	+16.1 ± 7.0
DAYS 7 - 10	MEAN±S.D.	+8.2 ± 8.1	+8.6 ± 9.0	+14.4 ± 7.8
DAYS 10 - 13	MEAN±S.D.	+16.6 ± 6.5	+13.4 ± 8.8	+16.0 ± 7.9
DAYS 13 - 15	MEAN±S.D.	+11.5 ± 6.9	+15.6 ± 12.1	+14.3 ± 8.6
DAYS 15 - 18	MEAN±S.D.	+28.7 ± 7.4 [7]d	+29.8 ± 14.1	+37.4 ± 5.3
DAYS 18 - 20	MEAN±S.D.	+30.8 ± 6.1 [7]d	+22.5 ± 8.7	+30.7 ± 6.9
DAYS 0 - 20	MEAN±S.D.	+119.6 ± 16.3 [7]d	+118.2 ± 18.4	+129.0 ± 16.8

DAYS = DAYS OF GESTATION
[ ] = NUMBER OF VALUES AVERAGED

a. Dosage occurred on day 1 of study until day 0 of gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Excludes values for rats that were not selected for continuation on study.
d. Excludes values for dam 13731, which had an accidental death on day 15 of gestation.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 7 (PAGE 1): MATERNAL BODY WEIGHTS - LACTATION - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP			I	II	III
DOSAGE (MG/KG/DAY)a			0 (VEHICLE)	0.1b	1.6b
RATS TESTED		N	12	12	12
INCLUDED IN ANALYSES		N	8c	8c	8c
PREGNANT		N	8	8	7
DELIVERED LITTERS		N	7d	8	7
MATERNAL BODY WEIGHT (G)					
DAY 1		MEAN±S.D.	299.6 ± 20.6	311.1 ± 19.7	293.6 ± 23.8
DAY 2		MEAN±S.D.	302.6 ± 25.8	302.4 ± 23.3	289.0 ± 20.8
DAY 3		MEAN±S.D.	307.7 ± 23.5	308.1 ± 28.4	292.0 ± 15.9
DAY 4		MEAN±S.D.	305.3 ± 22.9	307.8 ± 31.7	291.4 ± 19.6
DAY 5		MEAN±S.D.	308.7 ± 23.5	312.8 ± 18.6	297.1 ± 16.7
DAY 6		MEAN±S.D.	310.4 ± 23.1	314.1 ± 16.5	299.7 ± 15.4
DAY 7		MEAN±S.D.	314.4 ± 17.9	319.2 ± 12.5	304.4 ± 17.6
DAY 8		MEAN±S.D.	321.0 ± 21.2	328.1 ± 14.4	309.8 ± 14.3
DAY 9		MEAN±S.D.	324.3 ± 20.3	333.8 ± 12.7	316.0 ± 13.3
DAY 10		MEAN±S.D.	328.8 ± 19.6	341.4 ± 13.1	321.1 ± 14.6
DAY 11		MEAN±S.D.	333.4 ± 21.4	343.6 ± 13.1	329.1 ± 11.8
DAY 12		MEAN±S.D.	341.8 ± 21.2	346.4 ± 11.5	333.6 ± 12.6

DAY = DAY OF LACTATION

a. Dosage occurred on day 1 of study until day 0 of gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Excludes values for rats that were not selected for continuation on study.
d. Excludes values for dam 13731, which had an accidental death on day 15 of gestation.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 7 (PAGE 2): MATERNAL BODY WEIGHTS - LACTATION - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP DOSAGE (MG/KG/DAY)a		I 0 (VEHICLE)	II 0.1b	III 1.6b
RATS TESTED	N	12	12	12
INCLUDED IN ANALYSES	N	8c	8c	8c
PREGNANT	N	8	8	7
DELIVERED LITTERS	N	7d	8	7
MATERNAL BODY WEIGHT (G)				
DAY 13	MEAN±S.D.	342.4 ± 23.5	342.2 ± 17.0	339.8 ± 23.5
DAY 14	MEAN±S.D.	331.4 ± 16.9	344.1 ± 20.7	337.8 ± 16.2
DAY 15	MEAN±S.D.	342.6 ± 19.2	348.9 ± 19.1	335.8 ± 17.8
DAY 16	MEAN±S.D.	341.8 ± 19.4	353.0 ± 15.5	341.4 ± 19.9
DAY 17	MEAN±S.D.	338.8 ± 21.2	356.8 ± 14.0	334.7 ± 23.1
DAY 18	MEAN±S.D.	348.8 ± 19.2	357.1 ± 16.8	343.4 ± 21.7
DAY 19	MEAN±S.D.	346.0 ± 11.1	355.5 ± 13.7	337.7 ± 19.6
DAY 20	MEAN±S.D.	344.8 ± 14.5	351.8 ± 19.4	346.0 ± 17.4
DAY 21	MEAN±S.D.	339.1 ± 14.0	348.8 ± 20.5	339.1 ± 20.9
DAY 22	MEAN±S.D.	331.7 ± 16.7	338.5 ± 22.5	337.8 ± 23.3

DAY = DAY OF LACTATION

a. Dosage occurred on day 1 of study until day 0 of presumed gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Excludes values for rats that were not selected for continuation on study.
d. Excludes values for dam 13731, which had an accidental death on day 15 of gestation.

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TABLE 8 (PAGE 1): MATERNAL BODY WEIGHT CHANGES - LACTATION - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP DOSAGE (MG/KG/DAY)a		I 0 (VEHICLE)	II 0.1b	III 1.6b
RATS TESTED	N	12	12	12
INCLUDED IN ANALYSES	N	8c	8c	8c
PREGNANT	N	8	8	7
DELIVERED LITTERS	N	7d	8	7
MATERNAL BODY WEIGHT CHANGE (G)				
DAYS 1 - 4	MEAN±S.D.	+5.7 ± 6.7	-3.4 ± 30.1	-2.1 ± 11.4
DAYS 4 - 7	MEAN±S.D.	+9.1 ± 6.3	+11.5 ± 25.5	+13.0 ± 8.8
DAYS 7 - 10	MEAN±S.D.	+14.4 ± 4.2	+22.1 ± 4.7	+16.7 ± 5.4
DAYS 10 - 14	MEAN±S.D.	+2.6 ± 12.7	+2.8 ± 13.0	+16.7 ± 5.5
DAYS 14 - 22	MEAN±S.D.	+0.3 ± 14.5	-5.6 ± 24.3	+0.0 ± 11.5
DAYS 1 - 22	MEAN±S.D.	+32.1 ± 10.0	+27.4 ± 22.2	+44.3 ± 21.7

DAYS = DAYS OF LACTATION

a. Dosage occurred on day 1 of study until day 0 of gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Excludes values for rats that were not selected for continuation on study.
d. Excludes values for dam 13731, which had an accidental death on day 15 of gestation.

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TABLE 9 (PAGE 1): ABSOLUTE FEED CONSUMPTION VALUES (G/DAY) - PRECOHABITATION - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP		I	II	III
DOSAGE (MG/KG/DAY)a		0 (VEHICLE)	0.1b	1.6b
RATS TESTED	N	12	12	12
FEED CONSUMPTION (G)				
DAYS 1 - 8	MEAN±S.D.	19.6 ± 1.2 [11]c	18.9 ± 1.2 [10]c	18.3 ± 1.7
DAYS 8 - 15	MEAN±S.D.	18.8 ± 1.5 [10]c	20.2 ± 1.9	17.8 ± 1.4
DAYS 15 - 22	MEAN±S.D.	19.6 ± 1.8 [10]c	19.2 ± 1.4 [10]c	17.5 ± 1.3 [11]c
DAYS 22 - 29	MEAN±S.D.	18.4 ± 2.2 [10]c	18.1 ± 2.1 [10]c	15.8 ± 1.5
DAYS 29 - 36	MEAN±S.D.	19.1 ± 2.0 [10]c	19.2 ± 1.6 [9]c	16.6 ± 1.6 [11]c
DAYS 36 - 43d	MEAN±S.D.	20.4 ± 1.9 [11]c	20.3 ± 2.1 [11]c	17.5 ± 2.8
DAYS 1 - 43d	MEAN±S.D.	19.4 ± 1.5 [11]c	19.6 ± 1.8 [11]c	17.4 ± 1.6

DAYS = DAYS OF STUDY
[ ] = NUMBER OF VALUES AVERAGED
a. Dosage occurred on day 1 of study until day 0 of presumed gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Excludes values that were associated with spillage.
d. Last value recorded before cohabitation.

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TABLE 10 (PAGE 1): RELATIVE FEED CONSUMPTION VALUES (G/KG/DAY) - PRECOHABITATION - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP		I	II	III
DOSAGE (MG/KG/DAY)a		0 (VEHICLE)	0.1b	1.6b
RATS TESTED	N	12	12	12
FEED CONSUMPTION (G/KG/DAY)				
DAYS 1 - 8	MEAN±S.D.	85.0 ± 5.2 [11]c	82.3 ± 3.8 [10]c	79.3 ± 4.9
DAYS 8 - 15	MEAN±S.D.	77.4 ± 5.4 [10]c	82.2 ± 5.6	74.8 ± 4.5
DAYS 15 - 22	MEAN±S.D.	78.8 ± 6.7 [10]c	76.1 ± 4.2 [10]c	71.7 ± 3.3 [11]c
DAYS 22 - 29	MEAN±S.D.	71.7 ± 7.8 [10]c	69.1 ± 5.3 [10]c	64.4 ± 5.2
DAYS 29 - 36	MEAN±S.D.	72.2 ± 5.9 [10]c	72.4 ± 4.5 [9]c	66.8 ± 4.6 [11]c
DAYS 36 - 43d	MEAN±S.D.	74.5 ± 4.5 [11]c	73.6 ± 5.8 [11]c	70.0 ± 9.2
DAYS 1 - 43d	MEAN±S.D.	76.7 ± 4.9 [11]c	76.6 ± 4.7 [11]c	71.7 ± 4.7

DAYS = DAYS OF STUDY
[ ] = NUMBER OF VALUES AVERAGED
a. Dosage occurred on day 1 of study until day 0 of presumed gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Excludes values that were associated with spillage.
d. Last value recorded before cohabitation.

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TABLE 11 (PAGE 1): MATERNAL ABSOLUTE FEED CONSUMPTION VALUES (G/DAY) - GESTATION - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP DOSAGE (MG/KG/DAY)a		I 0 (VEHICLE)	II 0.1b	III 1.6b
RATS TESTED	N	12	12	12
INCLUDED IN ANALYSES	N	8c	8c	8c
PREGNANT	N	8	8	7
MATERNAL FEED CONSUMPTION (G/DAY)				
DAYS 0 - 7	MEAN±S.D.	25.2 ± 1.2 [7]d	24.2 ± 2.0	21.1 ± 2.4
DAYS 7 - 10	MEAN±S.D.	23.8 ± 2.4	24.1 ± 2.3	22.1 ± 3.0
DAYS 10 - 13	MEAN±S.D.	26.5 ± 2.6	26.4 ± 1.4	22.5 ± 2.8
DAYS 13 - 15	MEAN±S.D.	24.9 ± 3.0	25.5 ± 2.3	26.1 ± 2.7
DAYS 15 - 18	MEAN±S.D.	26.0 ± 1.9 [7]e	27.5 ± 2.8	26.2 ± 1.6
DAYS 18 - 20	MEAN±S.D.	25.4 ± 3.3 [7]e	27.1 ± 2.4	23.8 ± 3.7
DAYS 0 - 20	MEAN±S.D.	25.2 ± 1.3 [7]e	25.4 ± 0.8	23.0 ± 2.0

DAYS = DAYS OF GESTATION
[ ] = NUMBER OF VALUES AVERAGED
a. Dosage occurred on day 1 of study until day 0 of gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Excludes values for rats that were not selected for continuation on study.
d. Excludes values that were associated with spillage.
e. Excludes values for rat 13731, which had an accidental death on day 15 of gestation.

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TABLE 12 (PAGE 1): MATERNAL RELATIVE FEED CONSUMPTION VALUES (G/KG/DAY) - GESTATION - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP DOSAGE (MG/KG/DAY)a		I 0 (VEHICLE)	II 0.1b	III 1.6b
RATS TESTED	N	12	12	12
INCLUDED IN ANALYSES	N	8c	8c	8c
PREGNANT	N	8	8	7
MATERNAL FEED CONSUMPTION (G/KG/DAY)				
DAYS 0 - 7	MEAN±S.D.	84.5 ± 6.6 [7]d	81.1 ± 7.6	77.9 ± 11.9
DAYS 7 - 10	MEAN±S.D.	76.9 ± 5.3	77.3 ± 6.2	78.1 ± 12.3
DAYS 10 - 13	MEAN±S.D.	81.9 ± 5.5	81.0 ± 6.5	75.0 ± 9.0
DAYS 13 - 15	MEAN±S.D.	74.6 ± 10.5	75.2 ± 6.1	83.4 ± 8.8
DAYS 15 - 18	MEAN±S.D.	74.1 ± 4.5 [7]e	77.0 ± 10.3	77.8 ± 5.9
DAYS 18 - 20	MEAN±S.D.	66.3 ± 5.9 [7]e	70.1 ± 8.9	63.7 ± 7.1
DAYS 0 - 20	MEAN±S.D.	78.6 ± 4.3 [7]e	77.8 ± 5.0	76.1 ± 7.8

DAYS = DAYS OF GESTATION
[ ] = NUMBER OF VALUES AVERAGED

a. Dosage occurred on day 1 of study until day 0 of gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Excludes values for rats that were not selected for continuation on study.
d. Excludes values that were associated with spillage.
e. Excludes values for rat 13731, which had an accidental death on day 15 of gestation.

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TABLE 13 (PAGE 1): MATERNAL ABSOLUTE FEED CONSUMPTION VALUES (G/DAY) - LACTATION - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP		I	II	III
DOSAGE (MG/KG/DAY)a		0 (VEHICLE)	0.1b	1.6b
RATS TESTED	N	12	12	12
INCLUDED IN ANALYSES	N	8c	8c	8c
PREGNANT	N	8	8	7
DELIVERED LITTERS	N	7d	8	7
MATERNAL FEED CONSUMPTION (G/DAY)				
DAYS 1 - 4	MEAN±S.D.	31.3 ± 5.1	30.1 ± 18.9	23.2 ± 3.5
DAYS 4 - 7	MEAN±S.D.	47.7 ± 10.7 [6]e	42.1 ± 12.4 [7]e	40.1 ± 5.6
DAYS 7 - 10	MEAN±S.D.	54.4 ± 3.1	54.8 ± 8.6	51.0 ± 6.3
DAYS 10 - 14f	MEAN±S.D.	68.1 ± 2.9 [6]e	61.4 ± 5.2 [7]e	59.5 ± 3.4
DAYS 1 - 14f	MEAN±S.D.	52.9 ± 2.8 [6]e	41.7 ± 8.3 [7]e	44.7 ± 3.9

DAYS = DAYS OF LACTATION
[ ] = NUMBER OF VALUES AVERAGED

a. Dosage occurred on day 1 of study until day 0 of gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Excludes values for rats that were not selected for continuation on study.
d. Excludes values for rat 13731, which had an accidental death on day 15 of gestation.
e. Excludes values that were associated with spillage.
f. Because it is presumed that the pups begin to consume maternal feed after day 14 of lactation, maternal feed consumption values were not tabulated on days 14 to 22 of lactation.

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TABLE 14 (PAGE 1): MATERNAL RELATIVE FEED CONSUMPTION VALUES (G/KG/DAY) - LACTATION - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP DOSAGE (MG/KG/DAY)a		I 0 (VEHICLE)	II 0.1b	III 1.6b
RATS TESTED	N	12	12	12
INCLUDED IN ANALYSES	N	8c	8c	8c
PREGNANT	N	8	8	7
DELIVERED LITTERS	N	7d	8	7
MATERNAL FEED CONSUMPTION (G/KG/DAY)				
DAYS 1 - 4	MEAN±S.D.	103.6 ± 20.3	98.7 ± 65.9	80.1 ± 14.9
DAYS 4 - 7	MEAN±S.D.	152.0 ± 33.1 [6]e	134.8 ± 44.5 [7]e	135.2 ± 23.8
DAYS 7 - 10	MEAN±S.D.	169.3 ± 12.9	166.2 ± 28.4	163.2 ± 21.1
DAYS 10 - 14f	MEAN±S.D.	202.0 ± 17.6 [6]e	178.4 ± 16.5 [7]e	179.3 ± 13.1
DAYS 1 - 14f	MEAN±S.D.	165.3 ± 16.6 [6]e	144.5 ± 28.9 [7]e	144.1 ± 16.6

DAYS = DAYS OF LACTATION
[ ] = NUMBER OF VALUES AVERAGED

a. Dosage occurred on day 1 of study until day 0 of gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Excludes values for rats that were not selected for continuation on study.
d. Excludes values for rat 13731, which had an accidental death on day 15 of gestation.
e. Excludes values that were associated with spillage.
f. Because it is presumed that the pups begin to consume maternal feed after day 14 of lactation, maternal feed consumption values were not tabulated on days 14 to 22 of lactation.

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TABLE 15 (PAGE 1): NATURAL DELIVERY OBSERVATIONS - SUMMARY - Fo GENERATION FEMALE RATS

DOSAGE GROUP DOSAGE (MG/KG/DAY)a		I 0 (VEHICLE)	II 0.1b	III 1.6b
RATS ASSIGNED TO NATURAL DELIVERY	N	8	8	8
PREGNANT	N	8	8	7
DELIVERED LITTERS	N	7c	8	7
DURATION OF GESTATION d	MEAN±S.D.	22.6 ± 0.5 [5]e	23.0 ± 0.0 [6]e	22.2 ± 0.4 [6]e
IMPLANTATION SITES	N	106	119	108
PER DELIVERED LITTER	MEAN±S.D.	15.1 ± 0.9	14.9 ± 2.0	15.4 ± 2.2
DAMS WITH STILLBORN PUPS	N(%)	1(14.3)	1(12.5)	0(0.0)
DAMS WITH NO LIVEBORN PUPS	N	0	0	0
GESTATION INDEX f	% N/N	100.0 7/ 7	100.0 8/ 8	100.0 7/ 7
DAMS WITH ALL PUPS DYING DAYS 1-4 POSTPARTUM	N	0	0	0
DAMS WITH ALL PUPS DYING DAYS 5-21 POSTPARTUM	N	0	0	0

[ ] = NUMBER OF VALUES AVERAGED

a. Dosage occurred on day 1 of study until day 0 of gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Excludes values for dam 13731, which had an accidental death on day 15 of gestation.
d. Calculated as the time (in days) elapsed between confirmed mating (arbitrarily defined as day 0) and the time (in days) the first pup was delivered.
e. Excludes values for rats that did not have delivery observations recorded.
f. Number of rats with live offspring/number of pregnant rats.

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TABLE 16 (PAGE 1): LITTER OBSERVATIONS (NATURALLY DELIVERED PUPS) - SUMMARY - F1 GENERATION LITTERS

MATERNAL DOSAGE GROUP		I	II	III
MATERNAL DOSAGE (MG/KG/DAY)a		0 (VEHICLE)	0.1b	1.6b
DELIVERED LITTERS WITH ONE OR MORE LIVEBORN PUPS	N	7	8	7
PUPS DELIVERED (TOTAL)	N	97	103	97
	MEAN±S.D.	13.8 ± 1.6	12.9 ± 3.0	13.8 ± 1.7
LIVEBORN	MEAN±S.D.	13.7 ± 1.4	12.8 ± 3.0	13.8 ± 1.7
	N(%)	96(99.0)	102(99.0)	97(100.0)
STILLBORN	MEAN±S.D.	0.1 ± 0.4	0.1 ± 0.4	0.0 ± 0.0
	N(%)	1(1.0)	1(1.0)	0(0.0)
CULLED	N	23	26	24
PUPS FOUND DEAD OR PRESUMED CANNIBALIZED				
DAY 1	N/N(%)	0/ 96(0.0)	0/102(0.0)	1/ 97(1.0)
DAYS 2- 4	N/N(%)	3/ 96(3.1)	1/102(1.0)	2/ 96(2.1)
DAYS 5- 7	N/N(%)	0/ 70(0.0)	0/ 75(0.0)	0/ 70(0.0)
DAYS 8-14	N/N(%)	0/ 70(0.0)	0/ 75(0.0)	0/ 70(0.0)
DAYS 15-21	N/N(%)	0/ 70(0.0)	0/ 75(0.0)	0/ 70(0.0)
VIABILITY INDEX c	%	96.9	99.0	96.9
	N/N	93/ 96	101/102	94/ 97
LACTATION INDEX d	%	100.0	100.0	100.0
	N/N	70/ 70	75/ 75	70/ 70

DAY(S) = DAY(S) POSTPARTUM

a. Dosage occurred on day 1 of study until day 0 of gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Number of live pups on day 4 (preculling) postpartum/number of liveborn pups on day 1 postpartum.
d. Number of live pups on day 21 (weaning) postpartum/number of live pups on day 4 (postculling) postpartum.

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TABLE 16 (PAGE 2): LITTER OBSERVATIONS (NATURALLY DELIVERED PUPS) - SUMMARY - F1 GENERATION LITTERS

MATERNAL DOSAGE GROUP		I	II	III
MATERNAL DOSAGE (MG/KG/DAY)a		0 (VEHICLE)	0.1b	1.6b
DELIVERED LITTERS WITH ONE OR MORE LIVEBORN PUPS	N	7	8	7
SURVIVING PUPS/LITTER c				
DAY 1 d	MEAN±S.D.	13.7 ± 1.4	12.8 ± 3.0	13.8 ± 1.7
DAY 4 PRECULLING	MEAN±S.D.	13.3 ± 1.0	12.6 ± 3.0	13.4 ± 1.8
DAY 4 POSTCULLING	MEAN±S.D.	10.0 ± 0.0	9.4 ± 0.9	10.0 ± 0.0
DAY 7	MEAN±S.D.	10.0 ± 0.0	9.4 ± 0.9	10.0 ± 0.0
DAY 14	MEAN±S.D.	10.0 ± 0.0	9.4 ± 0.9	10.0 ± 0.0
DAY 21	MEAN±S.D.	10.0 ± 0.0	9.4 ± 0.9	10.0 ± 0.0
PERCENT MALE PUPS PER NUMBER OF PUPS SEXED				
DAY 1 d	MEAN±S.D.	44.9 ± 17.9	46.6 ± 11.2	50.9 ± 9.7
DAY 4 PRECULLING	MEAN±S.D.	46.2 ± 17.9	47.3 ± 12.1	50.4 ± 10.9
DAY 4 POSTCULLING	MEAN±S.D.	48.6 ± 12.1	46.5 ± 5.2	48.6 ± 3.8
DAY 7	MEAN±S.D.	48.6 ± 12.1	46.5 ± 5.2	48.6 ± 3.8
DAY 14	MEAN±S.D.	48.6 ± 12.1	46.5 ± 5.2	48.6 ± 3.8
DAY 21	MEAN±S.D.	48.6 ± 12.1	46.5 ± 5.2	48.6 ± 3.8

DAY = DAY POSTPARTUM

a. Dosage occurred on day 1 of study until day 0 of gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Average number of live pups per litter, including litters with no surviving pups.
d. Includes pups born alive, found dead day 1 postpartum.

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TABLE 16 (PAGE 3): LITTER OBSERVATIONS (NATURALLY DELIVERED PUPS) - SUMMARY - F1 GENERATION LITTERS

MATERNAL DOSAGE GROUP			I	II	III
MATERNAL DOSAGE (MG/KG/DAY)a			0 (VEHICLE)	0.1b	1.6b
DELIVERED LITTERS WITH ONE OR MORE LIVEBORN PUPS	N		7	8	7
LIVE LITTER SIZE AT WEIGHING					
DAY 1		MEAN±S.D.	13.7 ± 1.4	12.8 ± 3.0	13.6 ± 1.7
DAY 4 PRECULLING		MEAN±S.D.	13.3 ± 1.0	12.6 ± 3.0	13.4 ± 1.8
DAY 4 POSTCULLING		MEAN±S.D.	10.0 ± 0.0	9.4 ± 0.9	10.0 ± 0.0
DAY 7		MEAN±S.D.	10.0 ± 0.0	9.4 ± 0.9	10.0 ± 0.0
DAY 14		MEAN±S.D.	10.0 ± 0.0	9.4 ± 0.9	10.0 ± 0.0
DAY 21		MEAN±S.D.	10.0 ± 0.0	9.4 ± 0.9	10.0 ± 0.0
PUP WEIGHT/LITTER (GRAMS)					
DAY 1		MEAN±S.D.	6.4 ± 0.4	6.5 ± 0.5	6.2 ± 0.6
DAY 4 PRECULLING		MEAN±S.D.	8.9 ± 0.9	8.5 ± 1.4	8.2 ± 0.8
DAY 4 POSTCULLING		MEAN±S.D.	9.0 ± 0.9	8.5 ± 1.4	8.3 ± 0.8
DAY 7		MEAN±S.D.	14.1 ± 1.3	13.2 ± 1.8	12.8 ± 1.3
DAY 14		MEAN±S.D.	29.8 ± 1.6	29.4 ± 2.4	26.6 ± 2.6
DAY 21		MEAN±S.D.	47.1 ± 3.6	47.5 ± 2.9	42.4 ± 3.9

DAY = DAY POSTPARTUM

a. Dosage occurred on day 1 of study until day 0 of presumed gestation.

b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

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TABLE 17 (PAGE 1): CLINICAL OBSERVATIONS FROM BIRTH TO DAY 21 POSTPARTUM - SUMMARY - F1 GENERATION PUPS

MATERNAL DOSAGE GROUP		I	II	III
MATERNAL DOSAGE (MG/KG/DAY)a		0 (VEHICLE)	0.1b	1.6b
LITTERS EXAMINED (N)		7	8	7
PERSISTENT CLINICAL OBSERVATIONS: c				
TIP OF TAIL, BLACK	N/N	0/ 0	15/ 1	0/ 0

N/N = TOTAL FREQUENCY (DAYS x PUPS)/LITTERS WITH OBSERVATIONS

a. Dosage occurred on day 1 of study until day 0 of gestation.

b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

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

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TABLE 18 (PAGE 1): NECROPSY OBSERVATIONS - SUMMARY - F1 GENERATION PUPS

MATERNAL DOSAGE GROUP		I	II	III
MATERNAL DOSAGE (MG/KG/DAY)a		0 (VEHICLE)	0.1b	1.6b
LITTERS EXAMINED (N)		7	8	7
TOTAL PUPS STILLBORN OR FOUND DEAD c	N	2	2	2
STILLBORN	N	1	1	0
FOUND DEAD	N	1	1	2
NO MILK IN STOMACH e	N(%)	0(0.0)	1(100.0)	2(100.0)
PUPS SACRIFICED AND NECROPSIED ON DAY 4 AND/OR 21 POSTPARTUM d				
LITTERS EXAMINED	N	7	8	7
PUPS EVALUATED	N	80	85	80
APPEARED NORMAL				
LITTER INCIDENCE	N(%)	7(100.0)	8(100.0)	7(100.0)
PUP INCIDENCE	N(%)	80(100.0)	85(100.0)	80(100.0)

a. Dosage occurred on day 1 of study until day 0 of gestation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Restricted to pups in which complete necropsies were performed. Complete necropsies were not performed on pups in which autolysis or cannibalization precluded evaluation.
d. Refer to the individual pup clinical observations table (Table 31) for external clinical observations confirmed at necropsy.
e. Analysis restricted to pups found dead and necropsied.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 19 (PAGE 1): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

DOSAGE GROUP I		VEHICLE CONTROL	0 (VEHICLE) MG/KG/DAY
RAT #		DESCRIPTION	
13726		NO ADVERSE FINDINGS	
13727		NO ADVERSE FINDINGS	
13728	DL(22)	CHEST: SWOLLEN (RIGHT SIDE, 2.0 CM X 1.5 CM; LEFT SIDE, 2.0 CM X 1.0 CM)a	
13729	DS(44- 45)	CHROMODACRYORRHEA	
	DS(44- 45)	EXOPHTHALMOS	
	DS(44- 45)	RIGHT EYE: HEMORRHAGIC AREA	
	DG(0- 4)	CHROMODACRYORRHEA	
	DG(0- 4)	EXOPHTHALMOS	
	DG(0- 4)	RIGHT EYE: HEMORRHAGIC AREA	
	DG(4)	EXCLUDED FROM STUDY	
13730	DG(4)	EXCLUDED FROM STUDY	
13731	DG(15)	RED PERINASAL SUBSTANCE a	
	DG(15)	FORE AND HINDPAWS: BLUE	
	DG(15)	GASPING	
	DG(15)	ACCIDENTAL DEATH	
13732	DG(4)	EXCLUDED FROM STUDY	
13733	DG(4)	EXCLUDED FROM STUDY	
13734		NO ADVERSE FINDINGS	
13735		NO ADVERSE FINDINGS	
13736	DG(14)	CHROMORHINORRHEA	
	DL(16- 18)	SOFT OR LIQUID FECES	
	DL(20- 22)	RIGHT EAR: TORN a	
13737		NO ADVERSE FINDINGS	

DS = DAY OF STUDY DG = DAY OF PRESUMED GESTATION
DL = DAY OF LACTATION
a. Observation confirmed at necropsy.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 19 (PAGE 2): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

DOSAGE GROUP II		LOW DOSAGE	0.1 MG/KG/DAY a
RAT #		DESCRIPTION	
13738	DS(45)	URINE-STAINED ABDOMINAL FUR	
	DG(0- 1)	URINE-STAINED ABDOMINAL FUR	
	DG(4)	EXCLUDED FROM STUDY	
13739		NO ADVERSE FINDINGS	
13740	DG(11- 12)	CHROMORHINORRHEA	
	DL(2- 11)	CHROMORHINORRHEA	
13741		NO ADVERSE FINDINGS	
13742	DG(4- 6)	LOCALIZED ALOPECIA: LIMBS	
	DG(6)	EXCLUDED FROM STUDY	
13743	DS(1- 2)	LOCALIZED ALOPECIA: HEAD	
	DS(3)	ALOPECIA NO LONGER APPARENT	
	DS(50)	EXCLUDED FROM STUDY	
13744	DL(16)	CHROMORHINORRHEA	
	DL(16)	RED DRIED PERIORAL SUBSTANCE	
13745	DG(16- 19)	EXOPHTHALMOS	
	DG(16- 19)	RIGHT EYE: HEMORRHAGIC AREA	
	DG(16- 20)	CHROMODACRYORRHEA	
	DG(20)	RIGHT EYE: REMOVED	
	DL(1- 22)	RIGHT EYE: MISSING b	
	DL(1- 7)	CHROMODACRYORRHEA	
	DL(1- 7)	AROUND RIGHT EYE: SWOLLEN	
	DL(8)	SWELLING RESOLVED	
13746	DL(18- 20)	CHROMODACRYORRHEA	
	DL(18- 22)	CHROMORHINORRHEA b	
13747	DG(3- 4)	LOCALIZED ALOPECIA: LIMBS	
	DG(4)	EXCLUDED FROM STUDY	
13748	DG(9- 13)	CHROMODACRYORRHEA	
	DG(10- 16)	CHROMORHINORRHEA	
	DL(4- 7)	CHROMORHINORRHEA	
13749	DG(4- 5)	CHROMODACRYORRHEA	

DS = DAY OF STUDY DG = DAY OF PRESUMED GESTATION
DL = DAY OF LACTATION

a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.
b. Observation confirmed at necropsy.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 19 (PAGE 3): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

DOSAGE GROUP III		HIGH DOSAGE	1.6 MG/KG/DAY a
RAT #		DESCRIPTION	
13750	DS(28- 32)	INCISORS: MISSING/BROKEN	
	DS(33)	INCISORS: GROWN IN	
	DS(28- 45)	INCISORS: MISALIGNED	
	DS(34- 45)	CHROMODACRYORRHEA	
	DG(0- 4)	CHROMODACRYORRHEA	
	DG(0- 4)	INCISORS: MISALIGNED	
	DG(4)	EXCLUDED FROM STUDY	
13751		NO ADVERSE FINDINGS	
13752	DL(16- 22)	RIGHT EYE: CORNEAL OPACITY b	
13753		NO ADVERSE FINDINGS	
13754		NO ADVERSE FINDINGS	
13755		NO ADVERSE FINDINGS	
13756	DG(9- 16)	LOCALIZED ALOPECIA: LIMBS	
	DG(17)	ALOPECIA NO LONGER APPARENT	
	DL(17)	CHROMODACRYORRHEA	
13757	DS(36- 40)	FOREPAW: RIGHT, ABRASION (0.2 CM X 0.3 CM)	
	DS(41)	ABRASION HEALED	
	DG(4- 6)	LOCALIZED ALOPECIA: LIMBS	
	DG(6)	EXCLUDED FROM STUDY	
13758		NO ADVERSE FINDINGS	
13759		NO ADVERSE FINDINGS	
13760	DG(6)	EXCLUDED FROM STUDY	
13761	DG(1- 3)	CHROMORHINORRHEA	
	DG(3)	EXCLUDED FROM STUDY	

DS = DAY OF STUDY DG = DAY OF PRESUMED GESTATION
DL = DAY OF LACTATION

a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
b. Observation confirmed at necropsy.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 20 (PAGE 1): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

DOSAGE GROUP DOSAGE (MG/KG/DAY)	RAT NUMBER	DAY OF NECROPSY	PREGNANCY STATUS	DOSAGES ADMINISTERED	OBSERVATIONS a
I					
0 (VEHICLE)	13726	DL 22	P	45	ALL TISSUES APPEARED NORMAL.
	13727	DL 22	P	43	ALL TISSUES APPEARED NORMAL.
	13728	DL 22	P	43	CERVICAL MAMMARY GLAND: LARGE. ALL OTHER TISSUES APPEARED NORMAL.
	13731	DG 15	P	44	ACCIDENTAL DEATH ON DAY 15 OF GESTATION. THORACIC CAVITY: RED SUBSTANCE. ALL OTHER TISSUES APPEARED NORMAL. UTERINE CONTENTS: 17 IMPLANTATION SITES (16 DEAD FETUSES AND ONE EARLY RESORPTION).b
	13734	DL 22	P	45	ALL TISSUES APPEARED NORMAL.
	13735	DL 22	P	43	ALL TISSUES APPEARED NORMAL.
	13736	DL 22	P	46	ALL TISSUES APPEARED NORMAL.
	13737	DL 22	P	46	ALL TISSUES APPEARED NORMAL.
II					
0.1c	13739	DL 22	P	44	ALL TISSUES APPEARED NORMAL.
	13740	DL 22	P	43	ALL TISSUES APPEARED NORMAL.
	13741	DL 22	P	45	ALL TISSUES APPEARED NORMAL.
	13744	DL 22	P	46	ALL TISSUES APPEARED NORMAL.
	13745	DL 22	P	43	ALL TISSUES APPEARED NORMAL.
	13746	DL 22	P	46	ALL TISSUES APPEARED NORMAL.
	13748	DL 22	P	43	ALL TISSUES APPEARED NORMAL.
	13749	DL 22	P	43	ALL TISSUES APPEARED NORMAL.

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

a. Refer to the individual clinical observations table (Table 19) for external observations confirmed at necropsy.
b. Viability of fetuses unable to be determined because of maternal death.
c. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 20 (PAGE 2): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

DOSAGE GROUP DOSAGE (MG/KG/DAY)	RAT NUMBER	DAY OF NECROPSY	PREGNANCY STATUS	DOSAGES ADMINISTERED	OBSERVATIONS a
III					
1.6b	13751	DL 22	P	44	ALL TISSUES APPEARED NORMAL.
	13752	DL 22	P	45	ALL TISSUES APPEARED NORMAL.
	13753	DL 22	P	44	ALL TISSUES APPEARED NORMAL.
	13754	DL 22	P	46	ALL TISSUES APPEARED NORMAL.
	13755	DG 25	NP	46	ALL TISSUES APPEARED NORMAL.
	13756	DL 22	P	45	ALL TISSUES APPEARED NORMAL.
	13758	DL 22	P	46	ALL TISSUES APPEARED NORMAL.
	13759	DL 22	P	43	ALL TISSUES APPEARED NORMAL.

P = PREGNANT NP = NOT PREGNANT
DG = DAY OF GESTATION DL = DAY OF LACTATION
a. Refer to the individual clinical observations table (Table 19) for external observations confirmed at necropsy.
b. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 21 (PAGE 1): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
RAT #	DOSAGE GROUP I				VEHICLE CONTROL				0 (VEHICLE) MG/KG/DAY							
13726	203.	198.	206.	210.	213.	210.	215.	216.	214.	212.	218.	221.	224.	223.	229.	227.
13727	242.	248.	249.	251.	246.	244.	251.	252.	245.	247.	252.	255.	252.	253.	262.	260.
13728	229.	231.	226.	235.	238.	242.	238.	244.	243.	250.	244.	244.	252.	260.	259.	259.
13729	225.	219.	225.	227.	229.	228.	235.	238.	237.	237.	243.	245.	246.	247.	247.	253.
13730	219.	214.	219.	224.	221.	220.	226.	228.	226.	225.	230.	232.	233.	230.	238.	242.
13731	229.	237.	239.	239.	236.	241.	243.	244.	238.	241.	245.	251.	257.	257.	258.	263.
13732	218.	216.	222.	225.	228.	226.	221.	232.	228.	230.	228.	228.	236.	237.	236.	236.
13733	228.	237.	236.	236.	233.	242.	246.	240.	244.	247.	250.	246.	247.	257.	257.	260.
13734	222.	218.	218.	227.	232.	233.	234.	230.	235.	239.	236.	233.	235.	244.	245.	248.
13735	227.	229.	227.	220.	228.	230.	232.	224.	226.	232.	234.	229.	234.	239.	241.	233.
13736	219.	220.	216.	224.	222.	218.	221.	228.	222.	223.	224.	231.	232.	236.	234.	235.
13737	239.	248.	250.	253.	258.	247.	247.	249.	247.	242.	239.	245.	252.	252.	248.	256.

DAY	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
13726	229.	226.	232.	235.	235.	234.	239.	241.	237.	237.	243.	246.	244.	244.	249.	251.
13727	258.	258.	254.	260.	262.	257.	253.	249.	253.	258.	259.	260.	253.	256.	263.	267.
13728	252.	254.	266.	268.	266.	261.	271.	270.	273.	272.	266.	268.	271.	272.	273.	275.
13729	258.	256.	253.	254.	259.	259.	262.	262.	263.	265.	267.	269.	268.	269.	276.	274.
13730	241.	233.	239.	245.	242.	241.	242.	248.	250.	246.	255.	256.	258.	256.	258.	263.
13731	270.	268.	262.	262.	269.	273.	270.	265.	258.	266.	272.	273.	268.	267.	272.	280.
13732	236.	244.	243.	246.	241.	241.	247.	248.	250.	246.	248.	258.	255.	256.	254.	248.
13733	258.	256.	265.	269.	263.	267.	263.	263.	263.	262.	263.	273.	273.	272.	270.	271.
13734	244.	247.	251.	255.	255.	251.	252.	252.	258.	259.	266.	268.	260.	261.	258.	265.
13735	239.	241.	241.	234.	240.	243.	240.	233.	242.	244.	244.	238.	244.	247.	248.	243.
13736	236.	234.	226.	232.	236.	234.	225.	232.	239.	237.	234.	236.	241.	238.	232.	240.
13737	256.	256.	256.	260.	268.	266.	261.	270.	268.	269.	269.	277.	280.	280.	273.	283.

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

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 21 (PAGE 2): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

DAY	33	34	35	36	37	38	39	40	41	42	43a
RAT #	DOSAGE GROUP I				VEHICLE CONTROL				0 (VEHICLE) MG/KG/DAY		
13726	248.	244.	248.	256.	255.	252.	257.	260.	258.	251.	251.
13727	260.	259.	268.	269.	267.	266.	262.	271.	280.	278.	274.
13728	276.	280.	278.	284.	290.	288.	289.	287.	288.	290.	289.
13729	277.	273.	279.	282.	284.	281.	284.	287.	290.	284.	287.
13730	261.	258.	267.	268.	263.	260.	267.	271.	272.	270.	272.
13731	280.	276.	276.	282.	291.	293.	284.	285.	289.	290.	288.
13732	255.	257.	260.	255.	255.	261.	262.	260.	261.	259.	270.
13733	271.	275.	271.	273.	280.	282.	276.	277.	284.	278.	294.
13734	269.	268.	268.	266.	272.	277.	274.	269.	271.	275.	278.
13735	251.	254.	250.	247.	250.	253.	255.	248.	256.	258.	254.
13736	242.	241.	234.	239.	243.	243.	238.	242.	248.	245.	241.
13737	285.	284.	285.	290.	292.	295.	292.	298.	298.	296.	296.

DAY = DAY OF STUDY
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. Last value recorded before cohabitation.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 21 (PAGE 3): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
RAT #	DOSAGE GROUP II				LOW DOSAGE				0.1 MG/KG/DAY a							
13738	208.	209.	208.	205.	214.	216.	216.	215.	213.	216.	219.	218.	221.	220.	225.	228.
13739	242.	240.	235.	239.	249.	253.	252.	251.	249.	256.	260.	259.	255.	266.	270.	266.
13740	233.	241.	235.	234.	236.	242.	240.	238.	238.	241.	244.	243.	248.	254.	254.	248.
13741	232.	228.	231.	240.	239.	239.	240.	247.	243.	240.	246.	252.	249.	245.	252.	257.
13742	218.	219.	219.	222.	229.	230.	224.	227.	236.	242.	242.	241.	246.	250.	254.	250.
13743	233.	235.	242.	235.	241.	249.	253.	248.	254.	258.	259.	255.	266.	274.	274.	268.
13744	225.	228.	226.	228.	234.	237.	241.	237.	239.	245.	247.	246.	248.	258.	256.	256.
13745	228.	233.	227.	226.	235.	241.	242.	237.	242.	244.	246.	244.	249.	254.	250.	249.
13746	221.	221.	219.	226.	229.	234.	232.	226.	234.	239.	242.	238.	236.	244.	247.	248.
13747	235.	231.	235.	242.	239.	236.	240.	245.	247.	242.	247.	251.	251.	248.	254.	255.
13748	224.	223.	220.	226.	228.	232.	227.	232.	234.	240.	241.	238.	239.	246.	253.	249.
13749	227.	219.	228.	237.	234.	229.	226.	236.	244.	242.	242.	237.	247.	250.	248.	247.

DAY	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
13738	229.	228.	225.	228.	236.	234.	233.	228.	233.	237.	237.	235.	232.	238.	243.	243.
13739	259.	268.	268.	266.	262.	272.	269.	268.	263.	271.	268.	272.	267.	273.	280.	275.
13740	254.	255.	257.	253.	255.	261.	260.	255.	258.	265.	263.	264.	264.	269.	271.	270.
13741	259.	256.	259.	265.	259.	258.	260.	266.	265.	261.	272.	272.	271.	269.	271.	278.
13742	247.	250.	252.	256.	253.	250.	255.	259.	258.	255.	255.	259.	264.	261.	262.	260.
13743	284.	275.	280.	278.	286.	290.	285.	280.	286.	290.	291.	283.	292.	295.	296.	288.
13744	261.	259.	263.	261.	263.	265.	264.	261.	267.	270.	273.	268.	276.	277.	280.	276.
13745	254.	255.	256.	251.	257.	263.	256.	255.	260.	264.	263.	261.	266.	270.	264.	264.
13746	246.	242.	247.	252.	252.	244.	243.	248.	251.	249.	243.	240.	245.	253.	253.	244.
13747	254.	250.	251.	257.	258.	253.	256.	258.	259.	256.	259.	264.	260.	256.	259.	263.
13748	255.	255.	252.	248.	250.	252.	246.	241.	244.	248.	244.	242.	247.	245.	247.	240.
13749	245.	254.	256.	257.	250.	248.	254.	259.	256.	256.	258.	260.	260.	261.	265.	270.

DAY = DAY OF STUDY
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.

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TABLE 21 (PAGE 4): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

DAY	33	34	35	36	37	38	39	40	41	42	43a
RAT #	DOSAGE GROUP II				LOW DOSAGE				0.1 MG/KG/DAYb		
13738	241.	240.	249.	252.	247.	251.	246.	251.	252.	251.	254.
13739	274.	286.	290.	283.	284.	291.	294.	288.	289.	302.	298.
13740	271.	279.	277.	273.	276.	281.	276.	276.	280.	282.	269.
13741	278.	276.	284.	281.	281.	281.	287.	291.	292.	287.	295.
13742	264.	268.	268.	265.	266.	267.	267.	265.	274.	274.	269.
13743	299.	302.	301.	296.	302.	308.	311.	306.	312.	316.	314.
13744	274.	283.	286.	284.	279.	280.	285.	293.	297.	290.	286.
13745	266.	270.	275.	269.	272.	275.	273.	266.	275.	271.	271.
13746	246.	252.	251.	249.	254.	251.	252.	259.	263.	255.	257.
13747	264.	260.	265.	272.	268.	268.	268.	272.	273.	269.	278.
13748	244.	247.	246.	242.	248.	252.	247.	242.	251.	252.	256.
13749	270.	266.	267.	269.	274.	272.	268.	273.	279.	276.	270.

DAY = DAY OF STUDY
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. Last value recorded before cohabitation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.

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TABLE 21 (PAGE 5): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
RAT #	DOSAGE GROUP III				HIGH DOSAGE				1.6 MG/KG/DAYa							
13750	213.	206.	214.	217.	215.	212.	218.	216.	214.	212.	217.	223.	218.	215.	221.	222.
13751	256.	260.	266.	263.	256.	259.	260.	261.	257.	259.	262.	268.	262.	274.	274.	271.
13752	225.	223.	227.	237.	231.	233.	239.	238.	237.	236.	244.	245.	245.	245.	252.	252.
13753	227.	233.	225.	239.	240.	237.	233.	237.	233.	238.	235.	247.	250.	244.	245.	250.
13754	219.	224.	217.	224.	227.	224.	222.	226.	227.	227.	228.	229.	232.	231.	230.	233.
13755	236.	235.	231.	238.	240.	239.	235.	240.	236.	241.	235.	238.	244.	240.	239.	225.
13756	218.	227.	228.	232.	230.	230.	236.	240.	238.	242.	239.	246.	248.	250.	250.	249.
13757	233.	241.	235.	235.	239.	248.	246.	247.	243.	246.	250.	254.	255.	252.	256.	260.
13758	219.	219.	218.	221.	226.	229.	223.	226.	223.	228.	227.	233.	239.	235.	238.	237.
13759	235.	238.	232.	232.	239.	240.	240.	231.	223.	233.	233.	236.	236.	236.	241.	240.
13760	212.	213.	214.	211.	220.	215.	215.	214.	215.	216.	215.	220.	224.	223.	226.	225.
13761	223.	227.	220.	226.	228.	228.	230.	231.	231.	231.	232.	236.	238.	241.	236.	241.

DAY	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
13750	221.	214.	222.	226.	223.	218.	223.	220.	216.	214.	221.	215.	221.	214.	220.	223.
13751	268.	277.	277.	278.	271.	274.	277.	274.	261.	267.	275.	277.	271.	276.	279.	283.
13752	250.	247.	252.	256.	253.	250.	252.	253.	252.	249.	255.	255.	256.	257.	262.	261.
13753	250.	246.	245.	248.	252.	254.	248.	251.	253.	254.	254.	257.	259.	262.	258.	255.
13754	237.	234.	228.	231.	235.	232.	232.	236.	235.	232.	233.	237.	234.	236.	232.	236.
13755	248.	244.	240.	242.	244.	244.	240.	240.	239.	241.	239.	240.	245.	240.	238.	239.
13756	254.	250.	252.	253.	247.	253.	254.	254.	251.	252.	257.	253.	253.	255.	251.	254.
13757	257.	260.	259.	260.	266.	265.	257.	256.	263.	267.	269.	265.	265.	273.	273.	274.
13758	239.	236.	238.	238.	241.	243.	232.	232.	234.	234.	228.	234.	241.	236.	233.	233.
13759	243.	239.	244.	241.	242.	245.	238.	239.	238.	237.	237.	241.	244.	239.	241.	244.
13760	229.	222.	225.	225.	232.	226.	226.	232.	231.	229.	230.	232.	231.	233.	234.	236.
13761	240.	238.	237.	242.	246.	239.	234.	240.	241.	241.	237.	243.	243.	242.	237.	243.

DAY = DAY OF STUDY
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 21 (PAGE 6): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

DAY	33	34	35	36	37	38	39	40	41	42	43a
RAT #	DOSAGE GROUP III				HIGH DOSAGE				1.6 MG/KG/DAYb		
13750	217.	219.	226.	223.	222.	219.	218.	224.	223.	223.	212.
13751	269.	279.	282.	286.	278.	288.	291.	289.	285.	284.	287.
13752	259.	257.	262.	265.	267.	265.	267.	267.	266.	262.	269.
13753	262.	264.	264.	259.	256.	261.	264.	265.	260.	263.	263.
13754	236.	235.	229.	232.	238.	233.	229.	233.	236.	234.	231.
13755	240.	239.	241.	246.	244.	246.	242.	244.	243.	242.	239.
13756	254.	255.	253.	253.	259.	260.	255.	254.	256.	262.	256.
13757	269.	266.	275.	277.	276.	272.	269.	280.	286.	282.	276.
13758	238.	235.	238.	238.	240.	238.	237.	239.	243.	240.	232.
13759	245.	243.	245.	244.	246.	246.	239.	244.	238.	242.	240.
13760	239.	239.	239.	237.	240.	236.	234.	236.	242.	242.	244.
13761	243.	243.	242.	244.	246.	243.	239.	246.	247.	247.	241.

DAY = DAY OF STUDY
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. Last value recored before cohabitation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 22 (PAGE 1): MATERNAL BODY WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

RAT #	DOSAGE GROUP I			VEHICLE CONTROL				0 (VEHICLE) MG/KG/DAY					
PREGNANCY STATUS	DAY 0	1	2	3	4	5	6	7	8	9	10	11	12
13726 P	259.	265.	270.	275.	282.	283.	282.	281.	278.	283.	293.	291.	301.
13727 P	281.	292.	297.	296.	303.	304.	320.	305.	316.	316.	325.	333.	340.
13728 P	295.	289.	293.	308.	309.	314.	325.	323.	320.	320.	329.	335.	352.
13729 a	281.	297.	302.	302.	303.								
13730 a	281.	281.	285.	288.	296.								
13731 P	288.	291.	302.	306.	309.	323.	322.	310.	322.	328.	330.	347.	342.
13732 a	278.	282.	282.	288.	294.								
13733 a	298.	309.	311.	310.	311.								
13734 P	279.	283.	292.	300.	302.	303.	305.	316.	313.	312.	320.	317.	328.
13735 P	259.	262.	270.	272.	274.	277.	281.	285.	284.	289.	286.	294.	303.
13736 P	260.	273.	275.	284.	284.	288.	288.	295.	279.	293.	296.	304.	310.
13737 P	316.	318.	317.	331.	336.	329.	335.	332.	329.	341.	334.	355.	349.

	DAY 13	14	15	16	17	18	19	20	21	22	23	24	25
13726 P	306.	308.	312.	315.	326.	337.	352.	360.	370.	372.			
13727 P	335.	348.	354.	348.	366.	379.	397.	413.	421.				
13728 P	342.	353.	364.	368.	384.	399.	427.	441.	464.				
13729 a													
13730 a													
13731 P	358.	357.	369.	ACCIDENTAL DEATH ON DAY 15 OF GESTATION									
13732 a													
13733 a													
13734 P	334.	332.	344.	347.	363.	367.	385.	399.	406.				
13735 P	298.	309.	314.	313.	324.	333.	346.	362.	373.	360.			
13736 P	314.	310.	318.	327.	340.	355.	371.	385.	409.				
13737 P	359.	359.	363.	370.	386.	400.	408.	426.	444.				

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)
DAY = DAY OF PRESUMED GESTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. Rat was not selected for continuation on study; values excluded from group averages.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 22 (PAGE 2): MATERNAL BODY WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

RAT #	DOSAGE GROUP II	LOW DOSAGE						0.1 MG/KG/DAY a				
PREGNANCY STATUS	DAY 0	1	2	3	4	5	6	7	8	9	10	11	12
13738 b	261.	265.	269.	272.	282.								
13739 P	294.	308.	315.	313.	309.	316.	314.	305.	319.	322.	330.	335.	335.
13740 P	282.	288.	297.	298.	298.	300.	313.	317.	310.	310.	316.	320.	325.
13741 P	310.	314.	319.	325.	333.	331.	323.	331.	326.	327.	341.	339.	343.
13742 b	282.	284.	291.	296.	295.	291.	300.						
13743 b													
13744 P	302.	311.	311.	318.	318.	320.	321.	326.	326.	332.	334.	351.	357.
13745 P	280.	281.	288.	294.	292.	294.	307.	308.	297.	304.	316.	315.	328.
13746 P	252.	268.	275.	279.	278.	282.	276.	292.	281.	287.	290.	301.	311.
13747 b	293.	295.	296.	295.	305.								
13748 P	254.	267.	273.	270.	277.	283.	289.	286.	284.	288.	290.	297.	308.
13749 P	275.	289.	300.	305.	304.	302.	318.	311.	312.	322.	328.	332.	338.

	DAY 13	14	15	16	17	18	19	20	21	22	23	24	25
13738 b													
13739 P	347.	348.	364.	367.	379.	401.	415.	436.	455.				
13740 P	322.	334.	341.	337.	347.	356.	368.	374.	385.				
13741 P	349.	352.	364.	364.	377.	397.	415.	407.	437.				
13742 b													
13743 b													
13744 P	358.	363.	366.	374.	385.	402.	410.	425.	448.				
13745 P	322.	339.	350.	336.	347.	358.	369.	384.	392.				
13746 P	318.	314.	308.	332.	346.	362.	379.	385.	405.				
13747 b													
13748 P	303.	312.	326.	324.	344.	355.	374.	387.	369.	387.			
13749 P	333.	346.	358.	354.	365.	384.	391.	397.	416.				

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)
DAY = DAY OF PRESUMED GESTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.
b. Rat was not selected for continuation on study; values excluded from group averages.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 22 (PAGE 3): MATERNAL BODY WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

RAT #	DOSAGE GROUP III	HIGH DOSAGE					1.6 MG/KG/DAY a					
PREGNANCY STATUS DAY	0	1	2	3	4	5	6	7	8	9	10	11	12
13750 b	232.	221.	229.	237.	241.								
13751 P	295.	302.	315.	314.	312.	309.	310.	305.	312.	321.	326.	342.	333.
13752 P	277.	287.	278.	279.	282.	278.	284.	289.	281.	289.	290.	296.	298.
13753 P	263.	274.	276.	278.	280.	287.	284.	270.	281.	289.	292.	308.	304.
13754 P	246.	254.	256.	259.	259.	263.	267.	264.	264.	275.	271.	281.	288.
13755 NP	252.	255.	258.	263.	264.	263.	266.	269.	265.	273.	266.	280.	282.
13756 P	261.	262.	271.	271.	276.	274.	274.	278.	282.	282.	298.	295.	306.
13757 b	284.	296.	302.	302.	305.	305.	321.						
13758 P	243.	254.	254.	256.	256.	263.	269.	265.	267.	275.	281.	283.	284.
13759 P	242.	248.	259.	258.	261.	265.	270.	269.	269.	278.	283.	287.	299.
13760 b	236.	243.	250.	250.	252.	258.	261.						
13761 b	252.	257.	255.	266.									

	DAY 13	14	15	16	17	18	19	20	21	22	23	24	25
13750 b													
13751 P	352.	349.	361.	370.	380.	398.	395.	436.	432.	437.			
13752 P	297.	304.	324.	326.	348.	359.	371.	384.	411.				
13753 P	318.	321.	334.	335.	345.	367.	382.	405.	413.				
13754 P	290.	288.	294.	302.	321.	336.	337.	355.	366.				
13755 NP	279.	275.	276.	274.	276.	282.	278.	284.	287.	278.	289.	290.	298.
13756 P	306.	308.	319.	322.	336.	351.	364.	380.	394.				
13757 b													
13758 P	294.	302.	301.	321.	330.	348.	364.	381.	394.				
13759 P	296.	310.	320.	324.	331.	356.	373.	389.	406.				
13760 b													
13761 b													

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)
DAY = DAY OF PRESUMED GESTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
b. Rat was not selected for continuation on study; values excluded from group averages.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 23 (PAGE 1): MATERNAL BODY WEIGHTS - LACTATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

RAT #	DOSAGE GROUP I			VEHICLE CONTROL			0 (VEHICLE) MG/KG/DAY						
	DAY 1	2	3	4	5	6	7	8	9	10	11	12	13
13726	270.	270.	278.	280.	282.	284.	293.	299.	298.	303.	310.	325.	322.
13727	309.	325.	332.	325.	331.	338.	327.	335.	339.	336.	346.	351.	351.
13728	324.	318.	329.	327.	333.	333.	337.	348.	348.	352.	358.	358.	368.
13731	ACCIDENTAL DEATH ON DAY 15 OF GESTATION												
13734	310.	313.	317.	320.	326.	323.	324.	332.	331.	341.	326.	360.	343.
13735	276.	265.	279.	275.	280.	286.	295.	293.	298.	308.	312.	309.	316.
13736	292.	299.	294.	289.	291.	290.	300.	306.	317.	316.	321.	327.	322.
13737	316.	328.	325.	321.	318.	319.	325.	334.	339.	346.	361.	363.	375.

	DAY 14	15	16	17	18	19	20	21	22
13726	323.	321.	325.	336.	332.	332.	337.	328.	312.
13727	352.	360.	360.	358.	359.	357.	356.	342.	327.
13728	344.	367.	362.	356.	375.	358.	352.	354.	353.
13731	ACCIDENTAL DEATH ON DAY 15 OF GESTATION								
13734	325.	337.	338.	343.	353.	350.	337.	327.	330.
13735	312.	328.	327.	319.	329.	341.	339.	328.	313.
13736	314.	325.	318.	303.	328.	332.	325.	333.	334.
13737	350.	360.	363.	357.	366.	352.	368.	362.	353.

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

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 23 (PAGE 2): MATERNAL BODY WEIGHTS - LACTATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

RAT #	DOSAGE GROUP II			LOW DOSAGE			0.1 MG/KG/DAY a						
	DAY 1	2	3	4	5	6	7	8	9	10	11	12	13
13739	316.	302.	317.	324.	325.	329.	323.	335.	337.	345.	350.	345.	351.
13740	310.	297.	303.	296.	307.	307.	313.	317.	324.	338.	337.	340.	348.
13741	320.	315.	333.	333.	323.	324.	317.	336.	342.	346.	343.	358.	356.
13744	327.	339.	340.	342.	336.	322.	343.	350.	358.	367.	364.	366.	351.
13745	313.	279.	253.	242.	282.	299.	312.	312.	325.	330.	338.	343.	354.
13746	284.	272.	293.	302.	298.	295.	307.	319.	325.	333.	348.	337.	344.
13748	281.	288.	296.	297.	301.	298.	308.	314.	320.	325.	319.	331.	306.
13749	338.	327.	330.	326.	330.	339.	331.	342.	339.	347.	350.	351.	328.

	DAY 14	15	16	17	18	19	20	21	22
13739	352.	356.	352.	347.	342.	355.	350.	362.	362.
13740	340.	334.	341.	343.	343.	338.	333.	335.	306.
13741	366.	359.	359.	366.	382.	364.	352.	340.	338.
13744	367.	375.	379.	378.	371.	378.	389.	386.	374.
13745	309.	357.	368.	363.	360.	365.	357.	362.	348.b
13746	324.	316.	331.	340.	339.	340.	327.	320.	316.
13748	336.	334.	342.	348.	346.	346.	342.	338.	331.
13749	359.	360.	352.	369.	374.	358.	364.	347.	333.

DAY = DAY OF LACTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.
b. Dead body weight.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 23 (PAGE 3): MATERNAL BODY WEIGHTS - LACTATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

RAT #	DOSAGE GROUP III			HIGH DOSAGE			1.6 MG/KG/DAY a						
	DAY 1	2	3	4	5	6	7	8	9	10	11	12	13
13751	333.	321.	323.	331.	333.	331.	341.	341.	342.	353.	355.	361.	389.
13752	278.	289.	298.	293.	292.	298.	312.	307.	315.	319.	331.	329.	338.
13753	299.	300.	290.	293.	300.	305.	300.	309.	320.	321.	325.	336.	336.
13754	264.	253.	272.	271.	281.	285.	297.	303.	319.	314.	325.	330.	315.
13755	NOT PREGNANT												
13756	311.	296.	292.	290.	292.	299.	298.	309.	305.	316.	321.	328.	342.
13758	296.	284.	283.	288.	291.	292.	289.	302.	309.	309.	322.	326.	325.
13759	274.	280.	286.	274.	291.	288.	294.	298.	302.	316.	325.	325.	334.

	DAY 14	15	16	17	18	19	20	21	22
13751	370.	371.	380.	372.	389.	370.	376.	367.	386.
13752	333.	333.	342.	340.	343.	334.	325.	319.	330.
13753	340.	333.	321.	333.	339.	343.	344.	342.	326.
13754	322.	324.	340.	338.	334.	304.	333.	332.	336.
13755	NOT PREGNANT								
13756	340.	328.	344.	295.	323.	341.	342.	356.	337.
13758	322.	317.	320.	323.	329.	330.	340.	308.	311.
13759	338.	345.	343.	342.	347.	342.	362.	350.	339.

DAY = DAY OF LACTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 24 (PAGE 1): FEED CONSUMPTION VALUES - PRECOHABITATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

DAYS	1- 8	8- 15	15- 22	22- 29	29- 36	36- 43a
RAT #	DOSAGE GROUP I		VEHICLE CONTROL			0 (VEHICLE) MG/KG/DAY
13726	140.	b	138.	131.	137.	137.
13727	141.	129.	128.	106.	130.	137.
13728	135.	149.	139.	143.	141.	159.
13729	131.	143.	141.	136.	142.	142.
13730	140.	135.	146.	147.	154.	155.
13731	144.	138.	144.	120.	130.	146.
13732	127.	114.	120.	117.	118.	124.
13733	144.	138.	b	b	b	141.
13734	134.	129.	147.	136.	129.	144.
13735	b	b	b	b	b	b
13736	122.	119.	114.	107.	108.	120.
13737	151.	126.	155.	143.	150.	163.
RAT #	DOSAGE GROUP II		LOW DOSAGE			0.1 MG/KG/DAY c
13738	116.	114.	124.	114.	128.	128.
13739	b	147.	140.	122.	144.	144.
13740	138.	135.	138.	126.	146.	141.
13741	137.	130.	139.	132.	142.	153.
13742	131.	150.	137.	137.	142.	146.
13743	b	164.	b	155.	b	163.
13744	139.	143.	146.	130.	143.	139.
13745	139.	144.	133.	126.	126.	135.
13746	128.	133.	121.	99.	116.	120.
13747	142.	153.	b	b	b	168.
13748	135.	150.	148.	b	b	b
13749	119.	131.	121.	124.	122.	126.

DAYS = DAYS OF STUDY
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. Last value recorded before cohabitation.
b. Spilled feed precluded the calculation of this value.
c. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 24 (PAGE 2): FEED CONSUMPTION VALUES - PRECOHABITATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

DAYS	1- 8	8- 15	15- 22	22- 29	29- 36	36- 43a
RAT #	DOSAGE GROUP III			HIGH DOSAGE		1.6 MG/KG/DAY b
13750	114.	110.	111.	98.	100.	89.
13751	148.	134.	135.	111.	124.	133.
13752	134.	126.	124.	114.	117.	123.
13753	131.	128.	123.	122.	131.	171.
13754	123.	119.	121.	108.	125.	116.
13755	121.	113.	115.	105.	113.	114.
13756	129.	128.	121.	105.	107.	115.
13757	131.	133.	133.	124.	135.	134.
13758	124.	130.	133.	105.	108.	117.
13759	149.	141.	c	134.	c	137.
13760	109.	113.	108.	99.	111.	112.
13761	122.	122.	123.	107.	111.	110.

DAYS = DAYS OF STUDY
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. Last value recorded before cohabitation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Spilled feed precluded the calculation of this value.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 25 (PAGE 1): MATERNAL FEED CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

RAT #	DOSAGE GROUP I			VEHICLE CONTROL			0 (VEHICLE) MG/KG/DAY						
PREGNANCY STATUS	DAYS 0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7	7 - 8	8 - 9	9 - 10	10 - 11	11 - 12	12 - 13
13726 P	25.	24.	28.	22.	23.	22.	41.	19.	22.	23.	27.	19.	26.
13727 P	26.	24.	21.	27.	25.	25.	24.	21.	24.	25.	29.	20.	31.
13728 P	18.	41.	14.	28.	28.	27.	23.	24.	25.	28.	30.	29.	31.
13729 a	b	24.	25.	18.									
13730 a	24.	25.	28.	25.									
13731 P	16.	28.	26.	27.	25.	27.	13.	29.	26.	27.	30.	29.	25.
13732 a	25.	22.	24.	20.									
13733 a	28.	27.	25.	21.									
13734 P	23.	27.	27.	22.	27.	28.	30.	27.	28.	24.	35.	22.	32.
13735 P	24.	25.	28.	23.	29.	24.	b	24.	22.	20.	23.	22.	28.
13736 P	28.	23.	23.	23.	25.	24.	24.	16.	20.	27.	19.	25.	26.
13737 P	24.	25.	26.	29.	24.	27.	28.	21.	25.	24.	24.	26.	29.

	DAYS 13 - 14	14 - 15	15 - 16	16 - 17	17 - 18	18 - 19	19 - 20	20 - 21	21 - 22	22 - 23	23 - 24	24 - 25
13726 P	22.	33.	22.	23.	23.	24.	20.	b	14.			
13727 P	18.	22.	19.	29.	27.	30.	26.	23.				
13728 P	20.	25.	26.	29.	29.	34.	29.	24.				
13729 a												
13730 a												
13731 P	27.	29.	ACCIDENTAL DEATH ON DAY 15 OF GESTATION									
13732 a												
13733 a												
13734 P	27.	27.	25.	27.	31.	31.	21.	26.				
13735 P	20.	32.	25.	29.	25.	24.	24.	29.	10.			
13736 P	24.	20.	25.	26.	23.	26.	20.	25.				
13737 P	24.	29.	24.	32.	26.	22.	25.	25.				

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)
DAYS = DAYS OF PRESUMED GESTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. Rat was not selected for continuation on study; values excluded from group averages.
b. Spilled feed precluded the calculation of this value.

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TABLE 25 (PAGE 2): MATERNAL FEED CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

RAT #	DOSAGE GROUP II	LOW DOSAGE	0.1 MG/KG/DAY a									
PREGNANCY STATUS DAYS	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7	7 - 8	8 - 9	9 - 10	10 - 11	11 - 12	12 - 13
13738 b	24.	21.	22.	21.									
13739 P	22.	28.	26.	23.	20.	25.	19.	25.	24.	27.	22.	32.	20.
13740 P	24.	24.	27.	25.	26.	26.	23.		25.	25.	25.	24.	28.
13741 P	26.	27.	30.	26.	24.	24.	27.	20.	21.	23.	30.	18.	26.
13742 b	24.	24.	28.	27.	27.	24.							
13743 b													
13744 P	25.	23.	22.	22.	26.	24.	27.	26.	21.	32.	23.	28.	29.
13745 P	19.	23.	27.	23.	25.	23.	24.	21.	27.	26.	25.	26.	30.
13746 P	24.	22.	15.	16.	20.	22.	23.	20.	19.	25.	19.	30.	31.
13747 b	29.	24.	28.	23.									
13748 P	25.	23.	28.	39.	29.	23.	22.	21.	24.	20.	24.	25.	30.
13749 P	27.	22.	29.	26.	26.	24.	14.	22.	31.	28.	29.	25.	33.

DAYS	13 - 14	14 - 15	15 - 16	16 - 17	17 - 18	18 - 19	19 - 20	20 - 21	21 - 22	22 - 23	23 - 24	24 - 25
13738 b												
13739 P	24.	34.	23.	27.	28.	27.	27.	39.				
13740 P	23.	25.	24.	26.	28.	26.	27.	20.				
13741 P	23.	26.	26.	27.	28.	28.	18.	28.				
13742 b												
13743 b												
13744 P	27.	22.	25.	29.	27.	22.	29.	27.				
13745 P	25.	30.	19.	24.	26.	27.	34.	25.				
13746 P	27.	17.	28.	34.	35.	30.	25.	28.				
13747 b												
13748 P	16.	34.	26.	32.	31.	30.	30.	10.	14.			
13749 P	22.	33.	21.	33.	33.	24.	30.	29.				

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

a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.

b. Rat was not selected for continuation on study; values excluded from group averages.

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TABLE 25 (PAGE 3): MATERNAL FEED CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

RAT #	DOSAGE GROUP III HIGH DOSAGE 1.6 MG/KG/DAY a											
PREGNANCY STATUS / DAYS	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7	7 - 8	8 - 9	9 - 10	10 - 11	11 - 12	12 - 13
13750 b	8.	18.	21.	12.									
13751 P	20.	29.	22.	23.	16.	21.	18.	20.	26.	23.	23.	28.	23.
13752 P	28.	15.	16.	16.	16.	17.	23.	17.	20.	15.	25.	15.	21.
13753 P	23.	21.	23.	23.	18.	18.	16.	19.	23.	23.	22.	27.	19.
13754 P	22.	22.	18.	20.	20.	20.	24.	20.	20.	24.	19.	25.	22.
13755 NP	22.	21.	18.	22.	22.	20.	29.	25.	23.	26.	22.	25.	19.
13756 P	17.	20.	18.	16.	16.	16.	26.	18.	20.	23.	25.	18.	20.
13757 b	26.	22.	25.	26.	26.	26.							
13758 P	23.	22.	18.	21.	22.	22.	45.	28.	22.	30.	17.	16.	25.
13759 P	20.	25.	22.	24.	25.	23.	28.	23.	23.	27.	24.	28.	30.
13760 b	15.	18.	19.	20.	19.	17.							
13761 b	20.	19.	20.										

DAYS	13 - 14	14 - 15	15 - 16	16 - 17	17 - 18	18 - 19	19 - 20	20 - 21	21 - 22	22 - 23	23 - 24	24 - 25
13750 b												
13751 P	25.	29.	33.	25.	25.	23.	35.	24.	23.			
13752 P	19.	32.	25.	25.	26.	22.	22.	30.				
13753 P	24.	32.	23.	29.	24.	27.	26.					
13754 P	22.	23.	24.	27.	29.	14.	23.	27.				
13755 NP	21.	21.	22.	25.	25.	15.	38.	27.	17.	20.	20.	22.
13756 P	20.	25.	24.	24.	24.	21.	21.	28.				
13757 b												
13758 P	27.	30.	28.	26.	24.	23.	23.	33.				
13759 P	24.	34.	28.	28.	30.	28.	26.	32.				
13760 b												
13761 b												

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

a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
b. Rat was not selected for continuation on study; values excluded from group averages.

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TABLE 26 (PAGE 1): MATERNAL FEED CONSUMPTION VALUES - LACTATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

	DAYS 1 - 4	4 - 7	7 - 10	10 - 14a
RAT #	DOSAGE GROUP I		VEHICLE CONTROL	0 (VEHICLE) MG/KG/DAY
13726	85.	144.	171.	281.
13727	106.	128.	152.	252.
13728	91.	136.	173.	282.
13731	ACCIDENTAL DEATH ON DAY 15 OF GESTATION			
13734	93.	136.	170.	268.
13735	119.	c	161.	280.
13736	71.	110.	150.	c
13737	92.	204.	165.	271.
RAT #	DOSAGE GROUP II		LOW DOSAGE	0.1 MG/KG/DAY b
13739	49.	108.	146.	223.
13740	74.	130.	149.	233.
13741	99.	127.	169.	268.
13744	97.	109.	175.	265.
13745	20.	111.	166.	250.
13746	121.	206.	219.	c
13748	206.	c	159.	262.
13749	57.	93.	133.	218.

DAY = DAY OF LACTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. It is presumed that the pups begin to consume the maternal feed after day 14 of lactation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.
c. Spilled feed precluded the calculation of this value.

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TABLE 26 (PAGE 2): MATERNAL FEED CONSUMPTION VALUES - LACTATION - INDIVIDUAL DATA - Fo GENERATION FEMALE RATS

	DAYS 1 - 4	4 - 7	7 - 10	10 - 14a
RAT #	DOSAGE GROUP III		HIGH DOSAGE	1.6 MG/KG/DAY b
13751	65.	110.	157.	234.
13752	72.	119.	140.	232.
13753	69.	115.	161.	244.
13754	70.	151.	181.	240.
13755	NOT PREGNANT			
13756	52.	99.	121.	228.
13758	72.	115.	150.	223.
13759	87.	133.	161.	264.

DAYS = DAYS OF LACTATION
ALL WEIGHTS WERE RECORDED IN GRAMS (G).
a. It is presumed that the pups begin to consume the maternal feed after day 14 of lactation.
b. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

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

RAT/ 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 1 M	1 F	4a M	4a F	4b M	4b F	7 M	7 F	14 M	14 F	21 M	21 F	TOTAL IMPLAN-TATIONS N
MATERNAL DOSAGE GROUP I		VEHICLE CONTROL							0 (VEHICLE) MG/KG/DAY								
13726	23	13	0	13	4	9	4	9	4	6	4	6	4	6	4	6	14
13727	23	14	0	14	7	7	7	7	5	5	5	5	5	5	5	5	16
13728	23	15	1	16	7	8	7	6	5	5	5	5	5	5	5	5	16
13731	ACCIDENTAL DEATH ON DAY 15 OF GESTATION																
13734	23	13	0	13	7	6	7	6	5	5	5	5	5	5	5	5	15
13735	23	12	0	12	3	9	3	9	3	7	3	7	3	7	3	7	14
13736	c	13	0	13	10	3	10	3	7	3	7	3	7	3	7	3	15
13737	c	16	0	16	5	11	5	10	5	5	5	5	5	5	5	5	16
MATERNAL DOSAGE GROUP II		LOW DOSAGE							0.1 MG/KG/DAY d								
13739	23	16	0	16	9	7	9	7	5	5	5	5	5	5	5	5	16
13740	23	9	0	9	4	5	4	5	4	5	4	5	4	5	4	5	16
13741	23	16	0	16	7	9	7	9	5	5	5	5	5	5	5	5	16
13744	c	14	0	14	4	10	4	10	4	6	4	6	4	6	4	6	15
13745	c	12	0	12	7	5	7	4	4	4	4	4	4	4	4	4	13
13746	23	13	1	14	8	5	8	5	5	5	5	5	5	5	5	5	17
13748	23	14	0	14	6	8	6	8	5	5	5	5	5	5	5	5	15
13749	23	8	0	8	3	5	3	5	3	5	3	5	3	5	3	5	11

M = MALE F = FEMALE

a. Number of live pups preculling.
b. Number of live pups postculling.
c. Delivery observations were not recorded, values excluded from group averages.
d. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

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

MATERNAL DOSAGE GROUP III HIGH DOSAGE 1.6 MG/KG/DAY a

RAT/ 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 1 M	1 F	4b M	4b F	4c M	4c F	7 M	7 F	14 M	14 F	21 M	21 F	TOTAL IMPLAN-TATIONS N
13751	23	13(1)	0	13	7	5	7	5	5	5	5	5	5	5	5	5	17
13752	22	15	0	15	6	9	5	9	5	5	5	5	5	5	5	5	17
13753	22	14	0	14	7	7	7	7	5	5	5	5	5	5	5	5	16
13754	d	11	0	11	4	7	4	7	4	6	4	6	4	6	4	6	11
13755	NOT PREGNANT																
13756	22	13	0	13	7	6	6	6	5	5	5	5	5	5	5	5	14
13758	22	15	0	15	9	6	9	6	5	5	5	5	5	5	5	5	17
13759	22	16	0	16	10	6	10	6	5	5	5	5	5	5	5	5	16

M = MALE F = FEMALE

( ) = NUMBER OF PUPS DYING PRIOR TO WEIGHING ON DAY 1 POSTPARTUM.

a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.

b. Number of live pups preculling.

c. Number of live pups postculling.

d. Delivery observations were not recorded, values excluded from group averages.

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TABLE 28 (PAGE 1): PUP BODY WEIGHT LITTER AVERAGES FROM BIRTH TO DAY 21 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION LITTERS

RAT/ LITTER NUMBER	DAY 1			DAY 4			DAY 7			DAY 14			DAY 21		
	M	F	T	M	F	T	M	F	T	M	F	T	M	F	T
MATERNAL DOSAGE GROUP I	VEHICLE CONTROL									0 (VEHICLE) MG/KG/DAY					
13726	7.0	6.3	6.5	9.8	9.2	9.4	15.4	14.7	15.0	31.2	30.4	30.8	50.7	48.3	49.3
13727	6.2	6.0	6.1	9.4	9.0	9.2	15.2	14.1	14.7	30.3	28.7	29.5	48.6	48.0	48.3
13728	7.0	6.3	6.6	10.2	9.6	9.9	15.8	14.9	15.3	33.3	31.7	32.5	55.0	51.8	53.4
13731	ACCIDENTAL DEATH ON DAY 15 OF GESTATION														
13734	6.3	5.7	6.0	9.0	8.3	8.7	15.3	13.9	14.6	29.6	28.2	28.9	44.3	41.1	42.7
13735	6.4	5.8	6.0	9.0	8.4	8.5	14.0	12.2	12.8	29.7	27.2	28.0	46.5	43.2	44.2
13736	7.3	6.8	7.2	9.6	9.1	9.4	14.9	14.3	14.7	30.8	29.0	30.3	46.4	45.6	46.2
13737	6.5	6.1	6.2	7.4	6.9	7.0	11.9	11.5	11.7	28.7	27.9	28.3	45.6	45.1	45.4
MATERNAL DOSAGE GROUP II	LOW DOSAGE									0.1 MG/KG/DAY a					
13739	6.4	6.2	6.3	7.8	7.5	7.7	11.6	11.6	11.6	25.9	26.2	26.0	42.8	42.2	42.5
13740	7.3	6.6	6.9	10.6	9.6	10.0	15.6	13.8	14.6	32.4	29.9	31.0	51.8	47.2	49.3
13741	6.4	6.0	6.2	9.4	9.2	9.3	16.0	15.3	15.7	32.6	31.6	32.1	49.9	47.7	48.8
13744	6.8	6.4	6.5	7.2	6.9	7.0	11.5	11.1	11.3	31.6	31.0	31.2	46.0	44.0	44.8
13745	5.7	5.1	5.4	6.5	6.3	6.4	11.3	10.8	11.0	28.8	27.8	28.3	50.2	48.6	49.4
13746	6.9	6.5	6.7	9.0	8.3	8.8	14.2	13.5	13.8	26.9	25.3	26.1	47.3	46.6	47.0
13748	7.0	6.5	6.7	8.7	8.4	8.5	13.1	13.0	13.0	30.0	28.5	29.2	48.2	45.2	46.7
13749	7.3	6.9	7.1	11.0	10.4	10.6	15.7	14.7	15.0	32.6	30.9	31.5	54.1	49.9	51.5

M = MALE F = FEMALE T = TOTAL (SUM OF PUP WEIGHTS/NUMBER OF LIVE PUPS) DAY = DAY POSTPARTUM
ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.

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TABLE 28 (PAGE 2): PUP BODY WEIGHT LITTER AVERAGES FROM BIRTH TO DAY 21 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION LITTERS

RAT/ LITTER NUMBER	DAY 1			DAY 4			DAY 7			DAY 14			DAY 21		
	M	F	T	M	F	T	M	F	T	M	F	T	M	F	T
MATERNAL DOSAGE GROUP III				HIGH DOSAGE						1.6 MG/KG/DAY a					
13751	7.3	6.6	7.0	10.0	8.9	9.5	15.0	13.4	14.2	30.9	28.0	29.4	45.3	48.5	46.9
13752	6.1	5.9	6.0	8.7	8.0	8.3	13.5	12.3	12.9	26.7	25.8	26.2	42.4	40.0	41.2
13753	6.5	6.4	6.5	8.6	8.7	8.7	13.1	13.6	13.3	28.6	28.7	28.6	45.4	45.2	45.3
13754	7.1	6.8	6.9	8.6	8.6	8.6	14.2	13.9	14.0	29.3	28.9	29.1	47.9	46.0	46.8
13755	NOT PREGNANT														
13756	6.1	5.7	5.9	7.9	7.3	7.6	10.8	10.3	10.5	23.7	20.8	22.3	38.5	35.3	36.9
13758	5.5	5.6	5.6	7.1	7.2	7.1	11.6	11.8	11.7	24.3	24.9	24.6	38.9	39.0	39.0
13759	6.0	5.6	5.8	8.0	7.5	7.8	12.9	12.4	12.7	26.4	25.3	25.8	42.0	40.2	41.1

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. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 29 (PAGE 1): PUP BODY WEIGHTS FROM BIRTH TO DAY 21 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	20
RAT/ LITTER #	MATERNAL DOSAGE GROUP I					VEHICLE CONTROL				0 (VEHICLE) MG/KG/DAY						POSTPARTUM DAY 1				
13726	7.6	6.9	6.6	7.0	6.2	6.1	6.4	6.3	6.0	5.8	6.4	7.2	6.1							
13727	6.3	6.4	6.1	6.1	6.4	6.3	6.2	5.8	6.1	5.9	6.1	5.7	6.2	6.0						
13728	7.1	6.9	6.9	7.2	7.4	6.4	7.2	6.3	4.5	7.1	6.4	6.1	6.8	6.4	7.0	FS				
13731	ACCIDENTAL DEATH ON DAY 15 OF GESTATION																			
13734	6.4	6.3	5.5	6.8	6.2	6.4	6.8	6.0	5.7	5.6	6.0	5.3	5.5							
13735	6.3	7.0	5.9	6.3	6.2	6.0	5.6	6.0	5.6	5.7	5.0	5.9								
13736	7.7	7.6	6.6	7.6	7.6	6.9	7.7	7.4	7.2	7.1	7.0	6.9	6.4							
13737	6.8	6.3	6.2	6.8	6.3	6.4	5.7	6.0	6.1	6.1	6.7	6.1	6.0	5.9	5.8	5.9				
	MATERNAL DOSAGE GROUP II					LOW DOSAGE				0.1 MG/KG/DAY a						POSTPARTUM DAY 1				
13739	6.3	6.8	5.7	5.9	6.7	6.2	6.8	6.3	6.5	6.1	6.2	6.4	6.3	6.4	6.1	6.0				
13740	7.2	7.8	6.8	7.5	6.8	6.6	6.6	6.9	6.2											
13741	6.1	6.1	6.7	6.7	6.3	6.5	6.2	5.6	6.2	6.2	5.7	6.3	6.0	5.7	6.4	6.3				
13744	7.0	7.1	6.8	6.5	6.0	6.2	6.8	6.4	6.3	6.0	6.2	6.8	6.5	6.6						
13745	5.8	5.8	5.8	5.7	5.8	5.7	5.1	4.0	5.3	5.4	5.4	5.5								
13746	6.6	6.8	7.2	7.4	6.9	6.8	7.5	5.9	MS	6.6	6.0	6.2	6.7	6.9						
13748	7.3	7.2	7.6	6.6	6.8	6.6	6.6	7.0	6.9	6.6	6.2	5.8	6.0	6.6						
13749	7.3	7.5	7.1	6.6	6.9	6.8	7.0	7.3												

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.
FIRST LETTER -- M-MALE, F-FEMALE
SECOND LETTER -- A-ALIVE, S-STILLBORN, D-DIED, C-CULLED, M-MISSING (PRESUMED CANNIBALIZED),
NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 29 (PAGE 2): PUP BODY WEIGHTS FROM BIRTH TO DAY 21 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	20
RAT/ LITTER #	MATERNAL DOSAGE GROUP III					HIGH DOSAGE				1.6 MG/KG/DAY a								POSTPARTUM DAY 1		
13751	7.0	7.9	7.2	7.0	7.6	7.4	7.2	6.3	6.6	6.4	6.6	7.0	FD 1							
13752	4.1	6.5	6.2	6.8	6.4	6.6	6.0	6.0	5.2	5.9	6.0	6.1	6.4	5.5	5.8					
13753	6.9	6.8	7.0	6.2	6.8	5.5	6.5	6.8	6.6	6.3	6.2	6.2	7.1	6.0						
13754	7.0	7.4	7.0	7.1	6.8	6.6	7.0	7.1	6.7	6.6	7.1									
13755	NOT PREGNANT																			
13756	6.1	6.4	5.8	5.9	6.0	6.2	6.2	5.7	6.3	5.7	5.4	5.5	5.7							
13758	5.4	5.7	5.4	5.6	5.5	5.6	5.5	5.3	MA	5.5	5.4	5.3	6.0	5.7	6.0					
13759	5.7	6.1	6.2	6.2	6.2	4.9	6.5	5.9	6.1	6.1	5.2	5.9	4.6	5.8	5.9	6.0				

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.
FIRST LETTER -- M-MALE, F-FEMALE
SECOND LETTER -- A-ALIVE, S-STILLBORN, D-DIED, C-CULLED, M-MISSING (PRESUMED CANNIBALIZED),
NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 29 (PAGE 3): PUP BODY WEIGHTS FROM BIRTH TO DAY 21 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	20
RAT/ LITTER #	MATERNAL DOSAGE GROUP I					VEHICLE CONTROL				0 (VEHICLE) MG/KG/DAY					POSTPARTUM DAY 4 (PRECULLING)					
13726	9.7	9.2	10.5	9.8	8.9	9.9	9.2	9.2	9.0	9.5	9.2	9.4	9.0							
13727	9.5	9.4	9.1	9.4	9.2	9.7	9.4	8.5	9.4	8.8	9.2	9.1	9.2	8.9						
13728	10.3	10.6	9.9	10.0	10.4	9.9	10.4	10.3	9.8	9.3	9.0	9.0	10.0	FD 3	FM 2	FS				
13731	ACCIDENTAL DEATH ON DAY 15 OF GESTATION																			
13734	9.0	9.2	9.5	8.8	9.6	9.3	7.8	8.9	7.8	8.8	8.6	7.1	8.4							
13735	9.4	9.0	8.5	8.7	8.8	7.9	8.3	8.7	8.7	8.5	7.2	8.4								
13736	9.1	8.8	9.6	9.8	10.1	8.8	10.0	9.1	10.2	10.1	9.6	8.4	9.3							
13737	7.6	7.6	7.2	6.9	7.7	7.1	6.9	6.9	7.5	7.1	6.8	7.0	5.7	6.7	7.0	FM 4				
	MATERNAL DOSAGE GROUP II					LOW DOSAGE				0.1 MG/KG/DAY a					POSTPARTUM DAY 4 (PRECULLING)					
13739	8.1	8.4	8.5	7.9	7.7	7.2	7.8	7.5	7.4	7.9	7.7	7.3	7.9	7.0	7.4	7.3				
13740	10.7	10.8	10.2	10.9	9.5	9.4	9.7	9.5	9.8											
13741	9.7	9.1	9.9	8.8	9.0	9.2	10.2	8.6	9.3	9.8	9.8	8.3	9.8	9.5	8.2	9.4				
13744	6.1	7.5	7.5	7.5	7.7	7.5	6.0	7.0	6.7	6.8	7.4	6.7	5.9	7.0						
13745	6.6	5.8	6.5	6.8	6.6	6.8	6.6	6.3	6.2	6.4	6.3	FD 2								
13746	9.3	9.0	8.6	9.2	9.6	8.8	9.7	8.2	MS	8.4	9.0	9.1	7.4	7.6						
13748	9.3	9.7	8.8	7.8	8.5	7.9	8.3	8.1	7.9	9.0	8.9	9.3	7.1	8.6						
13749	10.9	11.2	10.8	10.6	10.8	10.2	10.2	10.4												

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.
FIRST LETTER -- M-MALE, F-FEMALE
SECOND LETTER -- A-ALIVE, S-STILLBORN, D-DIED, C-CULLED, M-MISSING (PRESUMED CANNIBALIZED),
NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 29 (PAGE 4): PUP BODY WEIGHTS FROM BIRTH TO DAY 21 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	20
RAT/ LITTER #	MATERNAL DOSAGE GROUP III					HIGH DOSAGE				1.6 MG/KG/DAY					POSTPARTUM DAY 4 (PRECULLING)					
13751	10.1	10.1	10.0	9.6	10.0	10.5	9.8	9.0	9.2	8.1	9.8	8.2	FD 1							
13752	9.2	7.6	8.5	8.9	9.1	MD 4	7.1	8.1	8.1	8.6	8.1	7.0	8.3	8.8	8.3					
13753	7.7	8.8	9.2	9.4	8.8	8.4	8.3	8.2	9.2	8.9	8.3	8.4	8.4	9.6						
13754	8.4	8.9	8.5	8.8	9.6	8.1	9.2	8.7	8.8	7.7	8.0									
13755	NOT PREGNANT																			
13756	8.2	7.7	7.8	8.0	8.0	7.8	MM 3	6.6	6.9	7.3	7.0	7.4	8.5							
13758	7.1	6.6	7.1	7.7	7.1	7.4	7.3	6.9	6.5	7.5	6.9	7.2	6.7	7.7	6.9					
13759	8.0	8.9	8.3	6.6	8.3	7.4	8.2	8.8	8.0	8.0	5.9	8.0	8.2	7.3	7.6	8.1				

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.
FIRST LETTER -- M-MALE, F-FEMALE
SECOND LETTER -- A-ALIVE, S-STILLBORN, D-DIED, C-CULLED, M-MISSING (PRESUMED CANNIBALIZED),
NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 29 (PAGE 5): PUP BODY WEIGHTS FROM BIRTH TO DAY 21 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	20
RAT/ LITTER #	MATERNAL DOSAGE GROUP I					VEHICLE CONTROL				0 (VEHICLE) MG/KG/DAY							POSTPARTUM DAY 4 (POSTCULLING)			
13726	9.7	9.2	10.5	9.8	FC 4	9.9	9.2	9.2	FC 4	9.5	9.2	FC 4	9.0							
13727	9.5	MC 4	9.1	9.4	9.2	9.7	MC 4	FC 4	9.4	8.8	9.2	9.1	FC 4	8.9						
13728	10.3	10.6	9.9	MC 4	MC 4	9.9	10.4	10.3	FC 4	9.3	9.0	9.0	10.0	FD 3	FM 2	FS				
13731	ACCIDENTAL DEATH ON DAY 15 OF GESTATION																			
13734	9.0	9.2	MC 4	8.8	9.6	9.3	MC 4	8.9	FC 4	8.8	8.6	7.1	8.4							
13735	9.4	9.0	8.5	8.7	FC 4	7.9	8.3	8.7	8.7	8.5	7.2	FC 4								
13736	MC 4	MC 4	9.6	MC 4	10.1	8.8	10.0	9.1	10.2	10.1	9.6	8.4	9.3							
13737	7.6	7.6	7.2	6.9	7.7	7.1	6.9	FC 4	7.5	7.1	FC 4	7.0	FC 4	FC 4	FC 4	FM 4				
	MATERNAL DOSAGE GROUP II					LOW DOSAGE				0.1 MG/KG/DAY a							POSTPARTUM DAY 4 (POSTCULLING)			
13739	MC 4	MC 4	MC 4	7.9	MC 4	7.2	7.8	7.5	7.4	7.9	7.7	7.3	FC 4	7.0	7.4	FC 4				
13740	10.7	10.8	10.2	10.9	9.5	9.4	9.7	9.5	9.8											
13741	MC 4	9.1	9.9	8.8	MC 4	9.2	10.2	8.6	9.3	FC 4	FC 4	8.3	9.8	FC 4	FC 4	9.4				
13744	6.1	7.5	7.5	7.5	7.7	7.5	6.0	7.0	FC 4	6.8	7.4	FC 4	FC 4	FC 4						
13745	MC 4	MC 4	6.5	MC 4	6.6	6.8	6.6	6.3	6.2	6.4	6.3	FD 2								
13746	MC 4	MC 4	8.6	9.2	9.6	8.8	MC 4	8.2	MS	8.4	9.0	9.1	7.4	7.6						
13748	9.3	9.7	8.8	7.8	8.5	MC 4	FC 4	8.1	FC 4	9.0	FC 4	9.3	7.1	8.6						
13749	10.9	11.2	10.8	10.6	10.8	10.2	10.2	10.4												

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.
FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE
SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, C-CULLED, M-MISSING (PRESUMED CANNIBALIZED), X-OTHER
NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 29 (PAGE 6): PUP BODY WEIGHTS FROM BIRTH TO DAY 21 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	20
RAT/ LITTER #	MATERNAL DOSAGE GROUP III HIGH DOSAGE 1.6 MG/KG/DAY POSTPARTUM DAY 4 (POSTCULLING)																			
13751	MC 4	10.1	MC 4	9.6	10.0	10.5	9.8	9.0	9.2	8.1	9.8	8.2	FD 1							
13752	9.2	7.6	8.5	8.9	9.1	MD 4	FC 4	FC 4	8.1	FC 4	FC 4	7.0	8.3	8.8	8.3					
13753	7.7	8.8	MC 4	9.4	MC 4	8.4	8.3	FC 4	9.2	8.9	8.3	FC 4	8.4	9.6						
13754	8.4	8.9	8.5	8.8	9.6	8.1	9.2	8.7	8.8	7.7	FC 4									
13755	NOT PREGNANT																			
13756	8.2	MC 4	7.8	8.0	8.0	7.8	MM 3	6.6	6.9	7.3	7.0	7.4	FC 4							
13758	MC 4	MC 4	7.1	MC 4	7.1	7.4	7.3	MC 4	6.5	7.5	6.9	7.2	FC 4	7.7	6.9					
13759	MC 4	8.9	8.3	MC 4	MC 4	MC 4	8.2	8.8	8.0	MC 4	FC 4	8.0	8.2	7.3	7.6	8.1				

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.
FIRST LETTER -- M-MALE, F-FEMALE, U-SEX UNDETERMINABLE
SECOND LETTER -- A-ALIVE, S-STILLBORN, U-UNCERTAIN, D-DIED, C-CULLED, M-MISSING (PRESUMED CANNIBALIZED), X-OTHER
NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 29 (PAGE 7): PUP BODY WEIGHTS FROM BIRTH TO DAY 21 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	20
RAT/ LITTER #	MATERNAL DOSAGE GROUP I					VEHICLE CONTROL				0 (VEHICLE) MG/KG/DAY							POSTPARTUM DAY 7			
13726	15.3	15.1	16.6	14.4	FC 4	14.7	15.1	14.3	FC 4	14.5	15.0	FC 4	14.6							
13727	15.6	MC 4	14.7	15.4	14.9	15.5	MC 4	FC 4	14.6	14.7	13.7	13.4	FC 4	14.3						
13728	15.1	15.6	15.9	MC 4	MC 4	16.0	16.2	15.6	FC 4	14.8	15.6	14.2	14.4	FD 3	FM 2	FS				
13731	ACCIDENTAL DEATH ON DAY 15 OF GESTATION																			
13734	15.6	15.6	MC 4	14.5	15.1	15.6	MC 4	12.6	FC 4	14.4	14.3	13.6	14.7							
13735	14.2	13.2	14.5	11.7	FC 4	10.7	13.9	11.2	12.0	13.3	12.8	FC 4								
13736	MC 4	MC 4	15.6	MC 4	15.9	14.6	13.3	15.1	15.9	13.8	14.8	14.5	13.5							
13737	12.9	13.0	11.1	10.6	12.0	12.6	11.7	FC 4	11.3	10.5	FC 4	11.4	FC 4	FC 4	FC 4	FM 4				
	MATERNAL DOSAGE GROUP II							0.1 MG/KG/DAY a						POSTPARTUM DAY 7						
13739	MC 4	MC 4	MC 4	11.4	MC 4	12.3	12.2	11.4	10.8	10.9	12.4	10.8	FC 4	12.5	11.3	FC 4				
13740	16.1	14.7	15.2	16.2	14.4	13.6	13.1	13.8	13.9											
13741	MC 4	15.4	15.9	16.9	MC 4	16.4	15.5	14.8	15.9	FC 4	FC 4	14.4	14.8	FC 4	FC 4	16.6				
13744	12.0	11.9	10.3	11.7	11.1	11.6	12.2	11.2	FC 4	10.6	10.0	FC 4	FC 4	FC 4						
13745	MC 4	MC 4	11.2	MC 4	11.8	11.0	11.2	10.8	11.1	10.6	10.7	FD 2								
13746	MC 4	MC 4	14.1	14.3	14.2	15.3	MC 4	13.2	MS	11.9	12.4	14.4	14.9	13.8						
13748	12.7	14.0	12.8	10.9	15.1	MC 4	FC 4	13.1	FC 4	13.6	FC 4	10.2	14.5	13.5						
13749	15.5	15.4	16.1	14.2	14.4	15.0	14.4	15.3												

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.
FIRST LETTER -- M-MALE, F-FEMALE
SECOND LETTER -- A-ALIVE, S-STILLBORN, D-DIED, C-CULLED, M-MISSING (PRESUMED CANNIBALIZED), X-OTHER
NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 29 (PAGE 8): PUP BODY WEIGHTS FROM BIRTH TO DAY 21 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	20
RAT/ LITTER #	MATERNAL DOSAGE GROUP III				HIGH DOSAGE					1.6 MG/KG/DAY a							POSTPARTUM DAY 7			
13751	MC 4	15.7	MC 4	15.2	15.2	14.2	14.8	13.4	13.3	13.7	12.2	14.4	FD 1							
13752	14.0	14.0	12.1	14.2	13.3	MD 4	FC 4	FC 4	10.4	FC 4	FC 4	12.9	13.1	12.8	12.4					
13753	13.1	13.2	MC 4	14.1	MC 4	13.2	11.8	FC 4	14.4	12.5	13.9	FC 4	12.9	14.2						
13754	13.5	14.4	14.7	14.0	14.4	14.1	13.7	12.3	15.0	13.8	FC 4									
13755	NOT PREGNANT																			
13756	13.0	MC 4	12.3	8.8	11.6	8.4	MM 3	10.8	8.7	11.0	11.0	9.8	FC 4							
13758	MC 4	MC 4	11.5	MC 4	11.5	11.8	11.4	MC 4	12.0	12.6	11.6	12.1	FC 4	11.3	11.2					
13759	MC 4	12.5	12.4	MC 4	MC 4	MC 4	12.6	13.2	14.0	MC 4	FC 4	12.9	11.5	12.7	12.2	12.7				

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.
FIRST LETTER -- M-MALE, F-FEMALE
SECOND LETTER -- A-ALIVE, S-STILLBORN, D-DIED, C-CULLED, M-MISSING (PRESUMED CANNIBALIZED),
NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 29 (PAGE 9): PUP BODY WEIGHTS FROM BIRTH TO DAY 21 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	20
RAT/ LITTER #	MATERNAL DOSAGE GROUP I					VEHICLE CONTROL				0 (VEHICLE) MG/KG/DAY						POSTPARTUM DAY 14				
13726	31.2	29.8	31.1	32.9	FC 4	30.4	30.4	29.5	FC 4	30.6	31.1	FC 4	30.6							
13727	29.8	MC 4	30.5	29.0	31.7	30.5	MC 4	FC 4	28.9	27.5	29.3	28.6	FC 4	29.0						
13728	32.8	33.6	33.0	MC 4	MC 4	33.9	33.0	32.8	FC 4	30.8	30.0	32.9	31.8	FD 3	FM 2	FS				
13731	ACCIDENTAL DEATH ON DAY 15 OF GESTATION																			
13734	30.7	30.3	MC 4	29.8	28.1	29.2	MC 4	28.6	FC 4	31.3	28.3	24.1	28.9							
13735	30.8	30.0	28.4	28.3	FC 4	27.7	24.5	30.1	27.7	26.3	26.1	FC 4								
13736	MC 4	MC 4	32.2	MC 4	32.1	29.1	29.8	30.2	31.6	31.0	29.1	28.4	29.6							
13737	30.1	29.7	26.3	28.2	29.0	27.9	27.5	FC 4	27.7	30.0	FC 4	26.4	FC 4	FC 4	FC 4	FM 4				
	MATERNAL DOSAGE GROUP II					LOW DOSAGE				0.1 MG/KG/DAY a						POSTPARTUM DAY 14				
13739	MC 4	MC 4	MC 4	25.0	MC 4	26.9	25.4	26.9	25.5	25.9	27.0	27.0	FC 4	24.9	26.0	FC 4				
13740	31.7	31.3	33.5	33.3	29.8	30.8	30.2	28.8	29.7											
13741	MC 4	32.9	33.4	33.8	MC 4	31.2	31.6	31.4	33.9	FC 4	FC 4	30.3	33.0	FC 4	FC 4	29.6				
13744	31.9	31.3	28.7	34.5	32.3	27.5	31.5	33.2	FC 4	28.9	32.6	FC 4	FC 4	FC 4						
13745	MC 4	MC 4	28.7	MC 4	29.2	28.4	28.7	28.5	28.1	26.5	28.2	FD 2								
13746	MC 4	MC 4	27.4	26.5	26.6	27.5	MC 4	26.6	MS	24.6	26.9	24.6	26.5	24.1						
13748	30.7	26.9	32.4	29.6	30.3	MC 4	FC 4	30.3	FC 4	29.4	FC 4	29.9	28.1	24.7						
13749	33.1	32.5	32.2	29.8	30.0	31.9	32.8	29.9												

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.
FIRST LETTER -- M-MALE, F-FEMALE
SECOND LETTER -- A-ALIVE, S-STILLBORN, D-DIED, C-CULLED, M-MISSING (PRESUMED CANNIBALIZED),
NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 29 (PAGE 10): PUP BODY WEIGHTS FROM BIRTH TO DAY 21 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	20
RAT/ LITTER #	MATERNAL DOSAGE GROUP III					HIGH DOSAGE					1.6 MG/KG/DAY a								POSTPARTUM DAY 14	
13751	MC 4	32.0	MC 4	30.9	31.2	30.6	29.6	28.4	27.6	30.0	26.3	27.8	FD 1							
13752	28.6	26.4	27.4	25.7	25.3	MD 4	FC 4	FC 4	26.2	FC 4	FC 4	27.0	26.2	23.0	26.5					
13753	29.8	29.7	MC 4	29.0	MC 4	27.8	26.7	FC 4	29.4	27.8	29.0	FC 4	29.6	27.6						
13754	29.9	30.2	28.2	28.8	29.9	30.2	29.0	28.7	27.2	28.6	FC 4									
13755	NOT PREGNANT																			
13756	18.5	MC 4	24.7	27.3	28.5	19.6	MM 3	19.5	26.2	21.4	17.7	19.3	FC 4							
13758	MC 4	MC 4	26.0	MC 4	25.6	23.8	22.3	MC 4	24.0	26.2	23.7	26.6	FC 4	24.9	23.3					
13759	MC 4	26.5	27.9	MC 4	MC 4	MC 4	26.5	25.7	25.4	MC 4	FC 4	23.4	25.1	25.2	26.9	25.9				

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.
FIRST LETTER -- M-MALE, F-FEMALE
SECOND LETTER -- A-ALIVE, S-STILLBORN, D-DIED, C-CULLED, M-MISSING (PRESUMED CANNIBALIZED),
NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 29 (PAGE 11): PUP BODY WEIGHTS FROM BIRTH TO DAY 21 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	20
RAT/ LITTER #	MATERNAL DOSAGE GROUP I					VEHICLE CONTROL				0 (VEHICLE) MG/KG/DAY						POSTPARTUM DAY 21				
13726	49.7	49.6	52.8	50.6	FC 4	48.7	48.0	48.1	FC 4	47.5	48.4	FC 4	49.3							
13727	48.2	MC 4	48.4	48.9	52.3	45.1	MC 4	FC 4	47.7	48.2	47.9	47.6	FC 4	48.4						
13728	54.4	55.6	54.1	MC 4	MC 4	55.0	55.9	52.2	FC 4	52.4	53.4	50.5	50.4	FD 3	FM 2	FS				
13731	ACCIDENTAL DEATH ON DAY 15 OF GESTATION																			
13734	45.8	46.3	MC 4	41.8	42.4	45.4	MC 4	42.1	FC 4	41.0	43.3	40.4	38.6							
13735	48.2	45.3	46.1	44.3	FC 4	42.9	38.3	41.1	43.9	48.7	43.6	FC 4								
13736	MC 4	MC 4	47.8	MC 4	48.3	45.9	45.6	48.7	45.2	43.4	45.7	45.1	46.0							
13737	46.7	48.5	44.4	41.2	47.4	44.9	42.4	FC 4	45.5	49.0	FC 4	43.6	FC 4	FC 4	FC 4	FM 4				
	MATERNAL DOSAGE GROUP II					LOW DOSAGE				0.1 MG/KG/DAY a						POSTPARTUM DAY 21				
13739	MC 4	MC 4	MC 4	43.6	MC 4	46.1	40.5	42.2	41.5	39.2	41.8	44.1	FC 4	44.0	41.8	FC 4				
13740	48.6	53.7	54.2	50.9	47.5	44.8	49.7	47.6	46.4											
13741	MC 4	51.4	49.0	49.2	MC 4	51.0	49.0	46.7	49.5	FC 4	FC 4	51.9	45.1	FC 4	FC 4	45.5				
13744	45.0	46.6	45.9	46.4	41.9	42.6	44.2	47.1	FC 4	46.1	41.8	FC 4	FC 4	FC 4						
13745	MC 4	MC 4	49.7	MC 4	52.2	49.9	49.0	48.3	47.9	49.2	48.8	FD 2								
13746	MC 4	MC 4	50.9	47.7	43.3	47.6	MC 4	47.1	MS	42.4	46.4	50.4	50.4	43.3						
13748	48.5	47.6	44.8	49.7	50.4	MC 4	FC 4	40.8	FC 4	45.1	FC 4	47.2	46.7	46.2						
13749	53.8	55.4	53.2	47.3	51.0	52.5	50.9	47.7												

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.
FIRST LETTER -- M-MALE, F-FEMALE
SECOND LETTER -- A-ALIVE, S-STILLBORN, D-DIED, C-CULLED, M-MISSING (PRESUMED CANNIBALIZED),
NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 29 (PAGE 12): PUP BODY WEIGHTS FROM BIRTH TO DAY 21 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	20
RAT/ LITTER #	MATERNAL DOSAGE GROUP III					HIGH DOSAGE					1.6 MG/KG/DAY a								POSTPARTUM DAY 21	
13751	MC 4	46.7	MC 4	48.4	43.4	44.0	44.1	51.6	48.3	46.3	50.9	45.4	FD 1							
13752	41.3	46.4	42.5	40.5	41.5	MD 4	FC 4	FC 4	40.4	FC 4	FC 4	35.4	40.4	40.8	42.9					
13753	46.5	45.3	MC 4	45.6	MC 4	47.8	41.9	FC 4	47.5	46.5	43.4	FC 4	43.4	45.2						
13754	46.8	50.4	46.4	48.1	46.8	44.2	44.9	47.5	46.1	46.7	FC 4									
13755	NOT PREGNANT																			
13756	39.7	MC 4	42.4	33.8	33.4	43.0	MM 3	33.9	41.6	30.7	34.1	36.4	FC 4							
13758	MC 4	MC 4	39.6	MC 4	38.7	39.0	38.4	MC 4	39.0	36.9	39.0	40.7	FC 4	41.3	37.3					
13759	MC 4	41.9	44.1	MC 4	MC 4	MC 4	39.8	40.8	43.2	MC 4	FC 4	41.8	39.3	36.7	41.2	42.2				

ALL WEIGHTS WERE RECORDED IN GRAMS (G). MEAN LITTER WEIGHTS INCLUDE ONLY WEIGHTS OF LIVE PUPS.
FIRST LETTER -- M-MALE, F-FEMALE
SECOND LETTER -- A-ALIVE, S-STILLBORN, D-DIED, C-CULLED, M-MISSING (PRESUMED CANNIBALIZED),
NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 30 (PAGE 1): PUP VITAL STATUS AND SEX FROM BIRTH TO DAY 21 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	20	21	22	23
RAT/ LITTER #	MATERNAL DOSAGE GROUP I									VEHICLE CONTROL										0 (VEHICLE) MG/KG/DAY			
13726	M	A	M	A	M	A	M	A	FC 4	F	A	F	A	F	A	FC 4	F	A	F	A	FC 4	F	A
13727	M	A	MC 4	M	A	M	A	M	A	M	A	MC 4	FC 4	F	A	F	A	F	A	F	A	FC 4	F	A
13728	M	A	M	A	M	A	MC 4	MC 4	M	A	M	A	F	A	FC 4	F	A	F	A	F	A	FD 3	FM 2	F	S
13731	ACCIDENTAL DEATH ON DAY 15 OF GESTATION																						
13734	M	A	M	A	MC 4	M	A	M	A	M	A	MC 4	F	A	FC 4	F	A	F	A	F	A	F	A
13735	M	A	M	A	M	A	F	A	FC 4	F	A	F	A	F	A	F	A	F	A	FC 4			
13736	MC 4	MC 4	M	A	MC 4	M	A	M	A	M	A	M	A	M	A	M	A	F	A	F	A	F	A
13737	M	A	M	A	M	A	M	A	M	A	F	A	F	A	FC 4	F	A	F	A	FC 4	F	A	FC 4	FC 4	FC 4	FM 4
	MATERNAL DOSAGE GROUP II									LOW DOSAGE										0.1 MG/KG/DAY a			
13739	MC 4	MC 4	MC 4	M	A	MC 4	M	A	M	A	M	A	M	A	F	A	F	A	F	A	FC 4	F	A	F	A	FC 4
13740	M	A	M	A	M	A	M	A	F	A	F	A	F	A	F	A										
13741	MC 4	M	A	M	A	M	A	MC 4	M	A	M	A	F	A	F	A	FC 4	FC 4	F	A	F	A	FC 4	FC 4	F	A
13744	M	A	M	A	M	A	M	A	F	A	F	A	F	A	FC 4	F	A	F	A	FC 4	FC 4	FC 4				
13745	MC 4	MC 4	M	A	MC 4	M	A	M	A	M	A	F	A	F	A	F	A	F	A	FD 2						
13746	MC 4	MC 4	M	A	M	A	M	A	M	A	MC 4	M	A	M	S	F	A	F	A	F	A	F	A	F	A	
13748	M	A	M	A	M	A	M	A	M	A	MC 4	FC 4	F	A	FC 4	F	A	FC 4	F	A	F	A	F	A		
13749	M	A	M	A	M	A	F	A	F	A	F	A	F	A	F	A										

FIRST LETTER -- M-MALE, F-FEMALE
SECOND LETTER -- A-ALIVE, S-STILLBORN, D-DIED, C-CULLED, M-MISSING (PRESUMED CANNIBALIZED),
NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 30 (PAGE 2): PUP VITAL STATUS AND SEX FROM BIRTH TO DAY 21 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	20	21	22	23
RAT/ LITTER #	MATERNAL DOSAGE GROUP III HIGH DOSAGE 1.6 MG/KG/DAY a																						
13751	MC 4	M	A	MC 4	M	A	M	A	M	A	M	A	F	A	F	A	F	A	F	A	FD 1		
13752	M	A	M	A	M	A	M	A	M	A	MD 4	FC 4	FC 4	F	A	FC 4	FC 4	F	A	F	A	F	A
13753	M	A	M	A	MC 4	M	A	MC 4	M	A	M	A	FC 4	F	A	F	A	F	A	FC 4	F	A	F A
13754	M	A	M	A	M	A	M	A	F	A	F	A	F	A	F	A	F	A	FC 4				
13755	NOT PREGNANT																						
13756	M	A	MC 4	M	A	M	A	M	A	M	A	MM 3	F	A	F	A	F	A	F	A	FC 4		
13758	MC 4	MC 4	M	A	MC 4	M	A	M	A	M	A	MC 4	M	A	F	A	F	A	F	A	FC 4	F	A F A
13759	MC 4	M	A	M	A	MC 4	MC 4	MC 4	M	A	M	A	M	A	MC 4	FC 4	F	A	F	A	F	A	F A

FIRST LETTER -- M-MALE, F-FEMALE
SECOND LETTER -- A-ALIVE, S-STILLBORN, D-DIED, C-CULLED, M-MISSING (PRESUMED CANNIBALIZED),
NUMBER FOLLOWING "SECOND LETTER" INDICATES THE DAY POSTPARTUM THE EVENT OCCURRED.
a. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 31 (PAGE 1): CLINICAL OBSERVATIONS FROM BIRTH TO DAY 21 POSTPARTUM - INDIVIDUAL DATA - F1 GENERATION PUPS

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	LITTER NUMBER	DAY(S) POSTPARTUM	OBSERVATION a
I 0 (VEHICLE)	-	-	-
II 0.1b	13746	7-21	1/10 PUPS: TIP OF TAIL, BLACK. c
III 1.6b	-	-	-

a. Tabulation restricted to adverse observations; all other pups appeared normal.
b. As a result of an error in calculation, which resulted in an error in test article preparation, Group II rats were dosed with 0.125 mg/kg/day and Group III rats were dosed with 2 mg/kg/day on days 1 through 4 of study.
c. Observation confirmed at necropsy.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 32 (PAGE 1): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION PUPS

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	LITTER NUMBER	DAY(S) POSTPARTUM	OBSERVATIONS a
I 0 (VEHICLE)	13726	4, 21	ALL PUPS APPEARED NORMAL.
	13727	4, 21	ALL PUPS APPEARED NORMAL.
	13728	1	1 PUP: STILLBORN. ALL TISSUES APPEARED NORMAL.
		3	1 PUP: FOUND DEAD. ALL TISSUES APPEARED NORMAL.
		4, 21	ALL PUPS APPEARED NORMAL.
	13734	4, 21	ALL PUPS APPEARED NORMAL.
	13735	4, 21	ALL PUPS APPEARED NORMAL.
	13736	4, 21	ALL PUPS APPEARED NORMAL.
	13737	4, 21	ALL PUPS APPEARED NORMAL.

a. Complete necropsies were not performed on pups in which autolysis or cannibalization precluded evaluation. Refer to the individual pup clinical observations table (Table 31) for external observations confirmed at necropsy.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 32 (PAGE 2): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION PUPS

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	LITTER NUMBER	DAY(S) POSTPARTUM	OBSERVATIONS a
II 0.1b	13739	4, 21	ALL PUPS APPEARED NORMAL.
	13740	21	ALL PUPS APPEARED NORMAL.
	13741	4, 21	ALL PUPS APPEARED NORMAL.
	13744	4, 21	ALL PUPS APPEARED NORMAL.
	13745	2	1 PUP: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL.
		4, 21	ALL PUPS APPEARED NORMAL.
	13746	1	1 PUP: STILLBORN. ALL TISSUES APPEARED NORMAL.
		4, 21	ALL PUPS APPEARED NORMAL.
	13748	4, 21	ALL PUPS APPEARED NORMAL.
	13749	21	ALL PUPS APPEARED NORMAL.

a. Complete necropsies were not performed on pups in which autolysis or cannibalization precluded evaluation. Refer to the individual pup clinical observations table (Table 31) for external observations confirmed at necropsy.
b. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 0.125 mg/kg/day on days 1 through 4 of study.

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: T-6295.14)

TABLE 32 (PAGE 3): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - F1 GENERATION PUPS

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)	LITTER NUMBER	DAY(S) POSTPARTUM	OBSERVATIONS a
III 1.6b	13751	1	1 PUP: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL.
		4, 21	ALL PUPS APPEARED NORMAL.
	13752	4	1 PUP: FOUND DEAD. NO MILK IN STOMACH. ALL OTHER TISSUES APPEARED NORMAL. ALL OTHER PUPS APPEARED NORMAL.
		21	ALL PUPS APPEARED NORMAL.
	13753	4, 21	ALL PUPS APPEARED NORMAL.
	13754	4, 21	ALL PUPS APPEARED NORMAL.
	13756	4, 21	ALL PUPS APPEARED NORMAL.
	13758	4, 21	ALL PUPS APPEARED NORMAL.
	13759	4, 21	ALL PUPS APPEARED NORMAL.

a. Complete necropsies were not performed on pups in which autolysis or cannibalization precluded evaluation. Refer to the individual pup clinical observations table (Table 31) for external observations confirmed at necropsy.
b. As a result of an error in calculation, which resulted in an error in test article preparation, rats were dosed with 2 mg/kg/day on days 1 through 4 of study.

APPENDIX C

PROTOCOL AND AMENDMENT

PRIMEDICA

Argus Research Laboratories, Inc.
905 Sheehy Drive, Building A
Horsham, PA 19044
Telephone: (215) 443-8710
Telefax: (215) 443-8587

PROTOCOL 418-015

SPONSOR'S STUDY NUMBER: T-6295.14

STUDY TITLE: Oral (Gavage) Pharmacokinetic Recovery Study of PFOS in Rats

PURPOSE: The purpose of this study is to evaluate the pharmacokinetics of PFOS in Fo generation and F1 generation rats during gestation and lactation following cessation of PFOS treatment of Crl:CD®BR VAF/Plus® female rats at confirmed mating.

TESTING FACILITY: Argus Research Laboratories, Inc.
905 Sheehy Drive, Building A
Horsham, Pennsylvania 19044-1297
Telephone: (215) 443-8710
Telefax: (215) 443-8587

STUDY DIRECTOR: Raymond G. York, Ph.D., DABT
Associate Director of Research

SPONSOR: 3M Corporate Toxicology
3M Center, Building 220-2E-02
St. Paul, Minnesota 55144-1000

STUDY MONITOR: Marvin T. Case, D.V.M., Ph.D.
Telephone: (651) 733-5180
Telefax: (651) 733-1773

ALTERNATE STUDY MONITOR: Andrew M. Seacat, Ph.D.
Telephone: (651) 575-3161
Telefax: (651) 733-1773

REGULATORY CITATIONS:

U.S. Food and Drug Administration (1994). International Conference on Harmonisation; Guideline on detection of toxicity to reproduction for medicinal products. *Federal Register*, September 22, 1994, Vol. 59, No. 183.

U.S. Food and Drug Administration. Good Laboratory Practice Regulations; Final Rule. 21 CFR Part 58.

Japanese Ministry of Health and Welfare (1997). *Good Laboratory Practice Standard for Safety Studies on Drugs*, MHW Ordinance Number 21, March 26, 1997.

European Economic Community (1989). *Council decision on 28 July 1989 on the acceptance by the European Economic Community of an OECD decision/recommendation on compliance with principles of good laboratory practice*. Official Journal of the European Communities: Legislation. 32 (No. L 315; 28 October): 1-17.

REGULATORY COMPLIANCE:

This study will be conducted in compliance with the Good Laboratory Practice (GLP) regulations cited above.

All changes or revisions of this protocol shall be documented, signed by the Study Director and the Sponsor, dated and maintained with the protocol.

The Quality Assurance Unit (QAU) will audit the protocol, the raw data and the report, and will inspect critical phases of the study in accordance with the Standard Operating Procedures of Argus Research Laboratories, Inc.

The final report will include a 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 significant 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.

SCHEMATIC OF STUDY DESIGN AND STUDY SCHEDULE:

See ATTACHMENT 1 to the protocol.

TEST ARTICLE AND VEHICLE:

Identification:

Test Article:

Name:	PFOS (Synonym: FC-95).
Physical Description:	Light-colored powder.
Lot/Batch Number:	217.
Specific Gravity:	~0.6.
Purity:	98.9%.
Expiration Date:	May 2000.

Information on the identity, composition, strength and purity of the test article is on file with the Sponsor.

Vehicle:

0.5% Tween® 80 in Reverse Osmosis Membrane Processed Deionized Water (R.O. Deionized Water). Supplier and lot identification of Tween® 80 to be documented in the raw data.

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.

Safety Precautions:

Gloves, mask, appropriate eye protection and a uniform/lab coat are to be worn during formulation preparation and administration. The Material Safety Data Sheet (MSDS) is attached to the protocol (ATTACHMENT 2).

Storage:

Bulk Test Article:	Room temperature.
Vehicle Components:	Room temperature.
Prepared Vehicle:	Room temperature.
Prepared Formulations:	Room temperature.

All test article shipments to the Testing Facility should be addressed to the attention of Julian Gulbinski, Manager of Formulations, at the previously cited 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.

FORMULATION:

Frequency of Preparation:

Formulations (suspensions) will be prepared daily at the Testing Facility. Data verifying the stability of the test article in the vehicle for 48 hours under the conditions of administration are on file with the Sponsor.

Detailed preparation procedures are attached to this protocol (ATTACHMENT 3).

Adjustment for Purity:

The test article will be considered 100% pure for the purpose of dosage calculations.

Testing Facility Reserve Samples:

The Sponsor will reserve a sample (1 g) of each lot of the bulk test article used during the course of this study. The Testing Facility will reserve a sample (5 mL) of each lot of the vehicle components used during the course of this study. Samples will be stored under the previously cited conditions.

ANALYSES:

Samples additional to those described below may be taken if deemed necessary during the course of the study.

Bulk Test Article Sampling:

No analyses of the bulk test article will be conducted during the course of this study. Information on the stability of the bulk test article is on file with the Sponsor.

Analyses of Prepared Formulations:

Homogeneity and stability of prepared formulations is on file with the Sponsor. However, records will be maintained to document how the test article formulations were prepared.

Concentration of Test Article Formulations:

Concentration of the prepared formulations will be verified during the course of this study. Duplicate samples (2 mL each) will be taken from the first and last preparation on the day prepared. One sample of each set will be shipped for analysis; the remaining samples will be retained at the Testing Facility as backup samples. Backup samples will be stored frozen (-70°C or below) and discarded at the Testing Facility upon request of the Sponsor.

Shipping Instructions:

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

Kris J. Hansen, Ph.D.
3M Environmental Technology and Safety Services
935 Bush Avenue
Building 2-3E-09
St. Paul, Minnesota 55133-3331
Telephone: (612) 778-6018
Telefax: (612) 778-6176

The recipient will be notified in advance of sample shipment.

DISPOSITION:

Prepared formulations will be discarded at the Testing Facility. All remaining bulk test article will be returned to the Study Monitor at the previously cited address upon completion of all work with the test article.

TEST SYSTEM:

Species/Strain and Reason for Selection:

The Crl:CD®BR VAF/Plus® (Sprague-Dawley) rat was selected as the Test System because: 1) this strain of rat was used in the reproductive and developmental toxicity studies; 2) historical data and experience exist at the Testing Facility[1-3]; and 3) the test article is pharmacologically active in the species and strain.

Number:

Initial population acclimated:	36 virgin female rats.
Population selected for study:	24 mated female rats (8 per dosage group).

Body Weight and Age:

Female rats will be ordered to have body weights of 200 g to 225 g each at receipt, at which time they will be expected to be at least 60 days of age. Actual body weights will be recorded the day after receipt and will be documented in the raw data. The weight range will be included in the final report.

Sex:

Female rats will be given the test article. Male rats of the same source and strain will be used only as breeders and are not considered part of the Test System.

Source:

Charles River Laboratories, Inc.

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

Identification:

Fo Generation:

Rats are permanently identified using Monel® self-piercing ear tags (Gey Band and Tag Co., Inc., No. MSPT 20101). Male rats are given unique permanent identification numbers upon assignment to the Testing Facility's breeder male rat population. Female rats are assigned temporary numbers at receipt and given unique permanent identification numbers when assigned to the study.

F1 Generation:

Pups will not be individually identified during lactation; all parameters will be evaluated in terms of the litter.

ANIMAL HUSBANDRY:

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

Housing:

Fo Generation Rats/F1 Generation Litters:

Fo generation rats will be individually housed in stainless steel, wire-bottomed cages, except during the cohabitation and postpartum periods. During cohabitation, each pair of rats will be housed in the male rat's cage. Beginning no later than day 20 of presumed gestation, Fo generation female rats will be individually housed in nesting boxes, except during collection intervals for urine and fecal samples. During these collection intervals, the female rats will be housed individually in metabolism cages. Each dam and delivered litter will be housed in a common nesting box during the postpartum period.

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. Analyses for possible contamination are conducted annually and documented in the raw data.

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 (Airo Clean® room). Room temperature will be maintained at 64°F (18°C) to 79°F (26°C) and monitored constantly. Room humidity will also be monitored constantly and maintained at 30% to 70%.

Light:

An automatically controlled 12-hour light:12-hour dark fluorescent light cycle will be maintained. Each dark period will begin at 1900 hours EST.

Diet:

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

Water:

Water will be available *ad libitum* from individual bottles attached to the cages 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.

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.

RANDOMIZATION AND COHABITATION:

Upon arrival, male and female rats will be assigned to individual housing on the basis of computer-generated random units. After acclimation, 36 virgin female rats will be selected for study on the basis of physical appearance and body weights recorded during acclimation. The female rats will be assigned to dosage groups (12 female rats per dosage group) based on computer-generated (weight-ordered) randomization procedures and treated with either the vehicle or the test article for 42 days prior to cohabitation.

Within each dosage group, consecutive order will be used to assign female rats to cohabitation with breeder male rats, one male rat per female rat. The cohabitation period will consist of a maximum of five days. Female rats with spermatozoa observed in a smear of the vaginal contents and/or a copulatory plug observed *in situ* will be considered to be at day 0 of presumed gestation and assigned to individual housing.

Eight mated female rats (those with confirmed evidence of mating) will be assigned to each dosage group. Any remaining female rats with or without confirmed evidence of mating that were assigned to either of the treated groups or the control group prior to cohabitation will be sacrificed and discarded without further evaluation at the discretion of the Study Director and the Study Monitor.

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).

On day 4 postpartum, litters will be culled to five male pups and five female pups per litter, where possible. Pups not selected for continued evaluation will be sacrificed via decapitation; the lungs (saved in Bouin's solution) and the liver (saved in neutral buffered 10% formalin) will be collected from the first ten culled pups from each dosage group (irrespective of litter) determined to be at day 4 postpartum and preserved for possible future histopathological evaluation. Remaining culled pups will be sacrificed via decapitation and discarded without necropsy evaluation.

ADMINISTRATION:

Route and Reason for Choice:

The oral (gavage) route was selected for use because: 1) this was the route of administration in the developmental and reproductive toxicology studies; and 2) it is one of the possible routes of human exposure.

Method and Frequency:

Fo Generation Female Rats:

Female rats will be given the test article once daily beginning 42 days prior to cohabitation until day 0 of presumed gestation (confirmed evidence of mating, such as observation of spermatozoa in a smear of the vaginal contents or a copulatory plug *in situ*). Female rats will not be given the test article or the vehicle on day 0 of presumed gestation. Dosages will be adjusted daily for body weight changes and given at approximately the same time each day.

F1 Generation Pups:

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

Rationale for Dosage Selection:

Dosages were selected on the basis of a previous study conducted with the test article (Argus Research Laboratories, Inc., Protocol 418-008).

Dosage Levels, Concentrations and Volumes:

Dosage Group	Number of Female Rats	Dosage (mg/kg/day)	Concentration (mg/mL)	Dosage Volume (mL/kg)	Argus Batch Number
I	8	0 (Vehicle)	0	5	B-418-015-A(Day.Month.Year)
II	8	0.1	0.02	5	B-418-015-B(Day.Month.Year)
III	8	1.6	0.32	5	B-418-015-C(Day.Month.Year)

The test article will be considered 100% pure for the purpose of dosage calculations.

TESTS, ANALYSES AND MEASUREMENTS - Fo GENERATION:

Viability:

All Periods: At least twice daily.

Clinical Observations and/or General Appearance:

Acclimation Period: At least once.

Dosage Period:	Twice daily. Prior to administration and once approximately one hour postdosage.
All Other Periods:	Once daily.
Maternal Behavior:	Days 1, 4, 7, 10, 14 and 21 postpartum. Observed abnormal behavior will be recorded daily.

Clinical observations may be recorded more frequently than cited above, if deemed appropriate by the Study Director and/or Study Monitor.

Body Weights:

Acclimation Period:	At least once.
Dosage Period:	Daily.
All Other Periods:	Daily.
Sacrifice:	Terminal weight.

Feed Consumption Values (recorded and tabulated):

Acclimation Period:	At least once.
Dosage Period:	Weekly to cohabitation.
All Other Periods:	Daily during presumed gestation and days 1, 4, 7, 10 and 14 postpartum. Feed consumption will not be tabulated after day 14 postpartum, when it is expected that pups will begin to consume maternal feed.

Feed consumption values may be recorded more frequently if it is necessary to replenish the feed. These intervals will not be tabulated.

Mating Performance:

Mating will be evaluated daily during the cohabitation period and confirmed by observation of spermatozoa in a smear of the vaginal contents and/or a copulatory plug observed *in situ*.

Natural Delivery:

Female rats will be evaluated for:

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

Litter Size (defined as all pups delivered).

Live Litter Size (live born pups only).

Pup Viability at Birth.

Pharmacokinetic Sample Collection:

Urine and Fecal Samples:

Female rats will be housed individually in metabolism cages for collection of urine and fecal samples for the following intervals: one day prior to initiation of cohabitation to the following morning and days 6 to 7, 14 to 15 and 20 to 21 of presumed gestation, as well as days 21 to 22 postpartum. Following each 24-hour collection interval, samples will be collected into centrifuge tubes, placed on dry ice and stored frozen (-70°C or below) until shipment for analysis.

In the event that a dam begins to deliver before completion of urine and fecal sample collection on day 20 to day 21 of presumed gestation, the dam will be removed from the metabolism cage and placed in a nesting box with sufficient bedding.

Blood Samples:

Blood samples will be collected from each of the maternal rats following removal from metabolism caging (prior to administration) on each of the following days: on the day cohabitation is initiated (prior to cohabitation), and on days 7, 15 and 21 of presumed gestation, as well as on days 14 and 22 postpartum. The time of blood collection will be recorded in the raw data.

On all days of collection except day 22 postpartum, blood samples (approximately 1 mL each) will be collected from the orbital sinus. If necessary, whole blood may be collected from an alternate site; if so, the alternate site will be documented in the raw data. On day 22 postpartum, blood samples (approximately 4 mL each) will be collected via the inferior vena cava. Blood will be collected and transferred into serum separator tubes. The samples will be spun in a refrigerated centrifuge. The serum will be transferred into polypropylene tubes labeled with the study number, animal identification, date of collection, study day and collection timepoint. All samples will be immediately frozen on dry ice and maintained frozen (-70°C or below) until shipment to the Sponsor for analysis.

Shipping Instructions:

All samples will be maintained frozen (-70°C or below) until shipment for analysis. Samples will be shipped on frozen on dry ice via overnight mail. A packing list will be included with the samples and sent to Kris J. Hansen, Ph.D., at the previously cited address. Both the recipient and the Study Monitor will be notified in advance of sample shipment.

METHOD OF SACRIFICE - Fo GENERATION RATS:

Rats will be sacrificed by carbon dioxide asphyxiation.

NECROPSY - Fo GENERATION RATS:

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 rat 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.

Rats Not Selected for Continued Evaluation:

Any remaining female rats with or without confirmed evidence of mating that were assigned to either of the treated groups or the control group prior to cohabitation will be sacrificed and discarded without further evaluation at the discretion of the Study Director and the Study Monitor.

Rats Not Delivering a Litter:

Rats that do not deliver a litter will be sacrificed on day 25 of presumed gestation and examined for gross lesions. Uteri will be stained with 10% ammonium sulfide to confirm the absence of implantation sites[5].

Scheduled Sacrifice:

On day 22 postpartum, following the final collection interval for urine and fecal samples and blood sample collection, female rats will be sacrificed, and a gross necropsy of the thoracic, abdominal and pelvic viscera will be performed. The number and distribution of implantation sites will be recorded. A liver section (right lateral lobe) from each dam will be collected, frozen and stored (-70°C or below) until shipment to the Sponsor for analysis.

Dams with No Surviving Pups:

Dams with no surviving pups will be sacrificed after the last pup is found dead, missing or presumed cannibalized.

Prior to sacrifice, a blood sample (approximately 4 mL) will be collected from the maternal rat via the inferior vena cava and transferred into serum separator tubes. The sample will be spun in a refrigerated centrifuge. The serum will be transferred into a polypropylene tube labeled with the study number, animal identification, date of collection, study day and collection timepoint. The sample will be immediately frozen on dry ice and maintained frozen (-70°C or below) until shipment to the Sponsor for analysis.

A gross necropsy of the thoracic, abdominal and pelvic viscera will be performed. A liver section (right lateral lobe) from each dam will be collected, frozen and stored (-70°C or below) until shipment to the Sponsor for analysis. Postpartum data for these dams will be excluded from summary tables.

Rats Found Dead or Moribund:

Rats that die or are sacrificed because of moribund condition, abortion or premature delivery will be examined for the cause of death or moribund condition on the day the observation is made. The rats will be examined for gross lesions. A liver section (right lateral lobe) from each dam will be collected, frozen and stored (-70°C or below) until shipment to the Sponsor for analysis. Pregnancy status and uterine contents of female rats will be recorded. Aborted fetuses and/or delivered pups will be examined to the extent possible. Uteri of apparently nonpregnant rats will be stained with 10% ammonium sulfide to confirm the absence of implantation sites[5].

Shipping Instructions:

All samples will be maintained frozen (-70°C or below) until shipment for analysis. Samples will be shipped frozen on dry ice via overnight mail. A packing list will be included with the samples and sent to Kris J. Hansen, Ph.D., at the previously cited address. Both the recipient and the Study Monitor will be notified in advance of sample shipment.

TESTS, ANALYSES AND MEASUREMENTS - F1 GENERATION:

Viability:

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

Clinical Observations and/or General Appearance:

Postpartum Period:	Once daily.

Clinical observations may be recorded more frequently than cited above, if deemed appropriate by the Study Director and/or the Study Monitor.

Body Weights:

Postpartum Period:	Days 1 (birth), 4, 7, 14 and 21 postpartum.
Sacrifice:	Terminal weight.

METHOD OF SACRIFICE - F1 GENERATION RATS:

As previously cited for Fo generation rats.

NECROPSY - F1 GENERATION RATS:

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 rat 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.

Caps and labeled tubes will be weighed (combined weight, to the nearest .001 gram) before and after retention of pooled pup samples. These weights will be documented in the raw data, and copies of these weights will be included with the packing list prior to shipment.

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. All lungs will be preserved in Bouin's solution for possible future evaluation.

Pups Found Dead or Moribund on Days 2 to 21 Postpartum:

Pups found dead or sacrificed because of moribundity will be examined for gross lesions and for the cause of death or the moribund condition. Pups with gross lesions found on days 2 to 4 postpartum will be preserved in Bouin's solution for possible future evaluation; gross lesions of pups found on days 5 to 21 postpartum will be preserved in neutral buffered 10% formalin.

For all pups found dead on days 2 to 4 postpartum, all lungs will be preserved in Bouin's solution for possible future evaluation. For all pups found dead on days 5 to 21 postpartum, all lungs will be preserved in neutral buffered 10% formalin for possible future evaluation.

Pups Not Selected for Continued Observation - Day 4 Postpartum:

All pups culled on day 4 postpartum will be sacrificed via decapitation. All lungs and livers will be collected from the first ten pups culled (irrespective of litter) from each dosage group; the lungs will be individually retained in Bouin's solution, and the livers will be individually retained in neutral buffered 10% formalin for possible future evaluation. Remaining culled pups will be sacrificed and discarded without evaluation.

Scheduled Sacrifice:

On day 21 postpartum, blood samples will be collected from all remaining pups on study.

Blood samples will be collected via the inferior vena cava from each pup, pooled (per litter) and transferred into serum separator tubes. The samples will be spun in a refrigerated centrifuge. The serum will be transferred into polypropylene tubes labeled with the study number, animal identification, date of collection, study day and collection timepoint. All samples will be immediately frozen on dry ice and maintained frozen (-70°C or below) until shipment to the Sponsor for analysis.

The pups will be examined for gross lesions. The liver from each pup will be collected, pooled (per litter), frozen and stored (-70°C or below) until shipment to the Sponsor for analysis.

Shipping Instructions:

All samples will be maintained frozen (-70°C or below) until shipment for analysis. Samples will be shipped frozen on dry ice via overnight mail. A packing list will be included with the samples and sent to Kris J. Hansen, Ph.D., at the previously cited address. Both the recipient and the Study Monitor will be notified in advance of sample shipment.

STATISTICAL EVALUATION:

Averages and percentages will be calculated. Litter values will be used where appropriate. Additional procedures and/or analyses may be performed, if deemed appropriate.

DATA ACQUISITION, VERIFICATION AND STORAGE:

Data will be hand- and/or computer-recorded. Records will be reviewed by the Study Director and/or appropriate management personnel within 21 days after generation. All original records will be stored in the archives of the Testing Facility. All original data will be bound and indexed. A copy of all raw data will be supplied to the Sponsor upon request. Preserved tissues will be stored at the Testing Facility at no charge for one year after mailing of the draft final report, after which time the Sponsor will be contacted to determine the disposition of these materials.

RECORDS TO BE MAINTAINED:

Protocol and Amendments.
Test Article, Vehicle and/or Reagent Receipt, Preparation and Use.
Animal Acquisition.
Randomization Schedules.
Mating History.
Treatment (if prescribed by Staff Veterinarian).
General Comments.
Clinical Observations and/or General Appearance.
Tissue and Sample Collection, Processing and Shipment.
Cap and Labeled Tube Weights.
Body Weights.
Feed Consumption Values.
Natural Delivery Observations.
Litter Observations.
Gross Necropsy Observations.
Organ Weights (if required).
Photographs (if required).
Study Maintenance (room and environmental records).
Feed, Water and Bedding Analyses.
Packing and/or Shipment Lists.

KEY PERSONNEL:

Executive Director of Research: Mildred S. Christian, Ph.D., Fellow, ATS
Director of Research: Alan M. Hoberman, Ph.D., DABT
Associate Director of Research and Study Director: Raymond G. York, Ph.D., DABT
Director of Laboratory Operations: John F. Barnett, B.S.
Director of Study Management: Valerie A. Sharper, M.S.
Manager of Animal Operations and Chairperson, Institutional Animal Care and Use Committee: Dena C. Lebo, V.M.D.
Director of Operations and Compliance: Barbara J. Patterson, B.A.
Consultant, Veterinary Pathology: W. Ray Brown, D.V.M., Ph.D., ACVP

FINAL REPORT:

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.

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 Sponsor's signature below documents the fact that information concerning the necessity for conducting this study and the fact that this is not an unnecessarily duplicative study may be obtained from the Sponsor. No alternative (*in vitro*) procedures were available for meeting the stated purposes of the study.

REFERENCES:

1. Christian, M.S. and Voytek, P.E. (1982). *In Vivo Reproductive and Mutagenicity Tests*. Environmental Protection Agency, Washington, D.C. National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161.

2. Christian, M.S. (1984). Reproductive toxicity and teratology evaluations of naltrexone (Proceedings of Naltrexone Symposium, New York Academy of Sciences, November 7, 1983), J. Clin. Psychiat. 45(9):7-10.

3. Lang, P.L. (1988). *Embryo and Fetal Developmental Toxicity (Teratology) Control Data in the Charles River Crl:CD®BR Rat*. Charles River Laboratories, Inc., Wilmington, MA 01887-0630. (Data base provided by Argus Research Laboratories, Inc.)

4. Institute of Laboratory Animal Resources (1996). *Guide for the Care and Use of Laboratory Animals*. National Academy Press, Washington, D.C.

5. Salewski, E. (1964). Färbemethode zum makroskopischen Nachweis von Implantationsstellen am Uterus der Ratte. Arch. Pathol. Exp. Pharmakol. 247:367.

PROTOCOL APPROVAL:

FOR THE TESTING FACILITY

Alan M. Hoberman, Ph.D., DABT
Director of Research

16-NOV-98
Date

Raymond G. York, Ph.D., DABT
Associate Director of Research
Study Director

16-NOV-98
Date

Dena C. Lebo, V.M.D.
Chairperson, Institutional Animal Care and Use Committee

16 Nov 98
Date

FOR THE SPONSOR

Marvin T. Case, D.V.M., Ph.D.
Study Monitor

17 Nov 98
Date

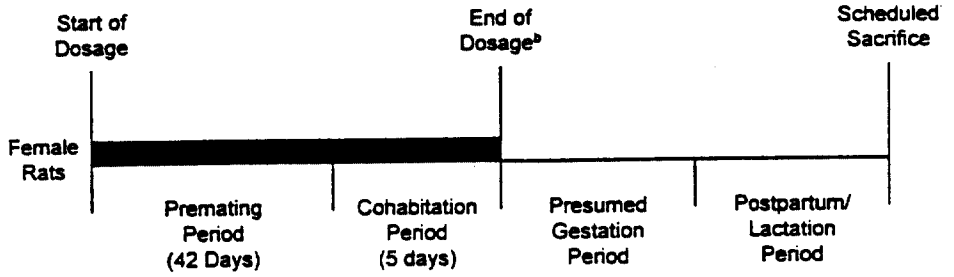
ATTACHMENT 1

SCHEMATIC OF STUDY DESIGN AND STUDY SCHEDULE

ATTACHMENT 1

STUDY SCHEMATIC

PHARMACOKINETIC RECOVERY STUDY[a]



■ Dosage Period.

a. For additional details see "Tests, Analyses and Measurements" section of the protocol.

b. Fo generation female rats will receive test article or vehicle until mating is confirmed (day 0 of presumed gestation).

SCHEDULE[a]

17 NOV 98	Animals Arrive - Acclimation Begins.
23 NOV 98	Dosage Period - Female Rats [42 days prior to cohabitation until confirmed mating (day 0 of presumed gestation)].
04 JAN 99 PM - 09 JAN 99 AM	Cohabitation Period.
05 JAN 99	First Possible Day 0 of Presumed Gestation.
09 JAN 99	Last Possible Day 0 of Presumed Gestation.
26 JAN 99	First Possible Delivery (Day 21 of presumed gestation).
03 FEB 99	Last Possible Delivery (Day 25 of presumed gestation).
29 JAN 99	First Possible Day 4 Postpartum Culling.
06 FEB 99	Last Possible Day 4 Postpartum Culling.
30 JAN 99	First Possible Day 25 of Presumed Gestation Female Sacrifice.
03 FEB 99	Last Possible Day 25 of Presumed Gestation Female Sacrifice.
15 FEB 99 - 23 FEB 99	Scheduled Sacrifice - F1 Generation Pups (Day 21 postpartum).
16 FEB 99 - 24 FEB 99	Scheduled Sacrifice - Fo Generation Dams (Day 22 postpartum).
29 JUN 99	Draft Final Report.

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a. The study initiation date is the day the Study Director signs the protocol.

ATTACHMENT 2

MATERIAL SAFETY DATA SHEET

MATERIAL SAFETY
DATA SHEET

3M
3M Center
St. Paul, Minnesota
55144-1000
1-800-364-3577 or (612) 737-6501 (24 hours)

DIVISION: 3M CHEMICALS
TRADE NAME:
FC-95 FLUORAD Brand Fluorochemical Surfactant
ID NUMBER/U.P.C.:
98-0207-0103-7 00-51135-09054-1 98-0207-0104-5 00-51135-09055-8
98-0211-0888-5 00-51135-09362-7 98-0211-3916-1 00-51135-02311-2
ZF-0002-1044-1 - - -
ISSUED: January 29, 1998
SUPERSEDES: November 05, 1997
DOCUMENT: 10-3796-9

1. INGREDIENT

INGREDIENT	C.A.S. NO.	PERCENT
POTASSIUM PERFLUOROALKYL SULFONATE.....	2795-39-3	82 - 86
POTASSIUM PERFLUOROALKYL SULFONATE.....	3871-99-6	3 - 8
POTASSIUM PERFLUOROALKYL SULFONATE.....	29420-49-3	3 - 7
POTASSIUM PERFLUOROALKYL SULFONATE.....	60270-55-5	2 - 6
POTASSIUM PERFLUOROALKYL SULFONATE.....	3872-25-1	1 - 3

2. PHYSICAL DATA

BOILING POINT:..... N/A
VAPOR PRESSURE:..... N/A
VAPOR DENSITY:..... N/A
EVAPORATION RATE:..... N/A
SOLUBILITY IN WATER:..... slight
SPECIFIC GRAVITY:..... ca. 0.6 Water=1
(Bulk)
PERCENT VOLATILE:..... 0 %
pH:..... 7 - 8
(0.1% Aqueous)
VISCOSITY:..... N/D
MELTING POINT:..... N/D

APPEARANCE AND ODOR:
Light colored, free flowing powder.

Abbreviations: N/D - Not Determined N/A - Not Applicable CA - Approximately

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT:..... None
FLAMMABLE LIMITS - LEL:..... N/A
FLAMMABLE LIMITS - UEL:..... N/A
AUTOIGNITION TEMPERATURE:..... N/A

EXTINGUISHING MEDIA:
Water, Carbon dioxide, Dry chemical, Foam

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

UNUSUAL FIRE AND EXPLOSION HAZARDS:
See Hazardous Decomposition section for products of combustion.

4. REACTIVITY DATA

STABILITY: Stable

INCOMPATIBILITY - MATERIALS/CONDITIONS TO AVOID:
Not applicable.

HAZARDOUS POLYMERIZATION: Hazardous polymerization will not occur.

HAZARDOUS DECOMPOSITION PRODUCTS:
Carbon Monoxide and Carbon Dioxide, Oxides of Sulfur, Hydrogen Fluoride, Toxic Vapors, Gases or Particulates.

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
Observe precautions from other sections. Vacuum, use wet sweeping compound or water to avoid dusting. CAUTION! A vacuum cleaner could be an ignition source. Clean up residue with water. Place in an approved metal container. Seal the container.

RECOMMENDED DISPOSAL:
Do not release to waterways or sewer. Do not use in products or processes that could result in aquatic concentrations greater than 1/10 of the lowest EC50 or LC50 concentration. Incinerate in an industrial or commercial facility in the presence of a combustible material. Combustion products will include HF. Disposal alternative: Dispose of waste product in a facility permitted to

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5. ENVIRONMENTAL INFORMATION (continued)

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accept chemical waste.

ENVIRONMENTAL DATA:
96-Hr. Aquatic Fish LC50, Fathead Minnow(Pimephales promelas)=38 mg/l, Bluegill Sunfish(Lepomis macrochirus)=68 mg/l, Rainbow Trout(Salmo gairdneri)=11 mg/l; 48-Hr. EC50, Daphnia Magna = 50 mg/l; COD=.004 g/g; BOD20 = Nil.

REGULATORY INFORMATION:
Volatile Organic Compounds: N/A.
VOC Less H2O & Exempt Solvents: N/A.

Since regulations vary, consult applicable regulations or authorities before disposal. U.S. EPA Hazardous Waste Number = None (Not U.S. EPA Hazardous).

This product complies with the chemical registration requirements of TSCA, EINECS, CDSL, AICS, MITI and Korea.

EPCRA HAZARD CLASS:
FIRE HAZARD: No PRESSURE: No REACTIVITY: No ACUTE: Yes CHRONIC: Yes

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6. SUGGESTED FIRST AID

EYE CONTACT:
Immediately flush eyes with large amounts of water for at least 15 minutes. Get immediate medical attention.

SKIN CONTACT:
Immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation persists, call a physician. Wash contaminated clothing before reuse.

INHALATION:
If signs/symptoms occur, remove person to fresh air. If signs/symptoms continue, call a physician.

IF SWALLOWED:
Drink two glasses of water. Call a physician.

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7. PRECAUTIONARY INFORMATION

EYE PROTECTION:
Avoid eye contact. Wear vented goggles.

Abbreviations: N/D - Not Determined N/A - Not Applicable CA - Approximately

7. PRECAUTIONARY INFORMATION (continued)

SKIN PROTECTION:
Avoid skin contact. Wear appropriate gloves when handling this material. A pair of gloves made from the following material(s) are recommended: butyl rubber. Use one or more of the following personal protection items as necessary to prevent skin contact: head covering, coveralls. Protective garments (other than gloves) should be made of either of the following materials: polyethylene/polyvinylidene chloride (Saranex).

RECOMMENDED VENTILATION:
Use with appropriate local exhaust ventilation. Use in a well-ventilated area. Provide sufficient ventilation to maintain emissions below recommended exposure limits. If exhaust ventilation is not adequate, use appropriate respiratory protection.

RESPIRATORY PROTECTION:
Avoid breathing of dust. Select one of the following NIOSH approved respirators based on airborne concentration of contaminants and in accordance with OSHA regulations: half-mask dust and mist respirator, half-mask supplied air respirator, full-face dust and mist respirator, full-face supplied air respirator.

PREVENTION OF ACCIDENTAL INGESTION:
Do not eat, drink or smoke when using this product. Wash exposed areas thoroughly with soap and water. Wash hands after handling and before eating.

RECOMMENDED STORAGE:
Keep container dry. Keep container closed when not in use.

FIRE AND EXPLOSION AVOIDANCE:
Nonflammable.

OTHER PRECAUTIONARY INFORMATION:
No smoking: Smoking while using this product can result in contamination of the tobacco and/or smoke and lead to the formation of the hazardous decomposition products mentioned in section 4 of this MSDS.

HMIS HAZARD RATINGS: HEALTH: 2 FLAMMABILITY: 0 REACTIVITY: 0
PERSONAL PROTECTION: X (See precautions, section 7.)

EXPOSURE LIMITS

INGREDIENT	VALUE	UNIT	TYPE	AUTH	SKIN*
POTASSIUM PERFLUOROALKYL SULFONATE...	0.1	MG/M3	TWA	3M	Y
POTASSIUM PERFLUOROALKYL SULFONATE...	0.1	MG/M3	TWA	3M	Y
POTASSIUM PERFLUOROALKYL SULFONATE...	0.1	MG/M3	TWA	3M	Y
POTASSIUM PERFLUOROALKYL SULFONATE...	0.1	MG/M3	TWA	3M	Y

Abbreviations: N/D - Not Determined N/A - Not Applicable CA - Approximately

EXPOSURE LIMITS (continued)

INGREDIENT	VALUE	UNIT	TYPE	AUTH	SKIN*
POTASSIUM PERFLUOROALKYL SULFONATE...	0.1	MG/M3	TWA	3M	Y

* SKIN NOTATION: Listed substances indicated with 'Y' under SKIN refer to the potential contribution to the overall exposure by the cutaneous route including mucous membrane and eye, either by airborne or, more particularly, by direct contact with the substance. Vehicles can alter skin absorption.

SOURCE OF EXPOSURE LIMIT DATA:
- 3M: 3M Recommended Exposure Guidelines

8. HEALTH HAZARD DATA

EYE CONTACT:
Mild Eye Irritation: signs/symptoms can include redness, swelling, pain, and tearing.

SKIN CONTACT:
Mild Skin Irritation (after prolonged or repeated contact): signs/symptoms can include redness, swelling, and itching.

May be absorbed through the skin and persist in the body for an extended time.

INHALATION:
May be harmful if inhaled.

May be absorbed by inhalation and persist in the body for an extended time.

Single overexposure, above recommended guidelines, may cause:

Irritation (upper respiratory): signs/symptoms can include soreness of the nose and throat, coughing and sneezing.

IF SWALLOWED:
Ingestion is not a likely route of exposure to this product.

Illness may result from a single swallowing of a moderate quantity of this material.

May be harmful if swallowed.

MUTAGENICITY:
Mutagenicity assays indicate the product is not mutagenic.

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8. HEALTH HAZARD DATA (continued)

REPRODUCTIVE/DEVELOPMENTAL TOXINS:
Not teratogenic in the rat at oral doses below maternally toxic levels.

OTHER HEALTH HAZARD INFORMATION:
This product is not known to contain any substances regulated under California Proposition 65.

A Product Toxicity Summary Sheet is available.

SECTION CHANGE DATES

HEADING	SECTION CHANGED SINCE November 05, 1997 ISSUE

Abbreviations: N/D - Not Determined N/A - Not Applicable CA - Approximately

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ATTACHMENT 3

TEST ARTICLE AND VEHICLE PREPARATION PROCEDURE

ATTACHMENT 3

TEST ARTICLE AND VEHICLE PREPARATION PROCEDURE

Test Article: PFOS
Vehicle: 0.5% Tween® 80 in R.O. Deionized Water

A. Purpose: The purpose of this procedure is to provide a method for the preparation of dosage suspensions of PFOS and the vehicle for oral administration to rats on Argus Study 418-015.

B. General Information:

1. All suspension containers will be labeled and color coded. Each label will specify the protocol number, test article identification, Argus batch number, concentration, dosage level, preparation date, expiration date and storage conditions.

2a. Suspensions will be prepared:
_X_ Daily ___ Weekly ___ For___ days of use

2b. Vehicle will be prepared:
___ Daily _X_ Weekly ___ For___ days of use

3. Suspensions will be prepared at a final dosage volume of 5 mL/kg.

4. Safety:
_X_ Gloves, lab coat, goggles or safety glasses and faceshield
_X_ Dust-Mist Respirator
___ Half-Face Respirator
___ Full-Face Respirator/Positive Pressure Hood
___ Tyvek Suit/Apron

5. Dosage suspensions adjusted for Free base and % Purity.
___ Yes _X_ No (Calculations based on 100%)
___ Free Base ___ Purity

6. Sampling requirements: Cited in protocol.

7. Storage: Cited in protocol.

ATTACHMENT 3

TEST ARTICLE AND VEHICLE PREPARATION PROCEDURE

NOTE: Test article will be prepared as a serial dilution from the high dosage to the low dosage. Once the final volumes are achieved, stir bars are to be added to the containers; mixing should occur during sampling and/or administration.

C. Preparation of Vehicle

1. Add the required amount of R.O. deionized water to an appropriately labeled container. Heat the water to 50°C ± 5°C, add the required amount of Tween® 80 and mix until uniform (See TEST ARTICLE CALCULATIONS).

D. Test Article Suspension Preparation:

1. To prepare the 0.32 mg/mL, Group III suspension, add the required amount of test article (See TEST ARTICLE CALCULATIONS) into an appropriately sized, labeled container. QS ad to the required amount with vehicle and heat the mixture to 80°C ±5°C for approximately 30 minutes or until the TA/S dissolves.

2. Once the test article has dissolved; spin while the suspension cools. (Be sure there is a visible vortex, this will achieve the desired emulsion. This may be prepared the day before use.)

3. To prepare the 0.02 mg/mL, Group II suspension, remove the required amount of stock suspension (Group III) (See TEST ARTICLE CALCULATIONS), QS ad with the vehicle and mix.

4. To prepare the 0 mg/mL, Group I suspension, add required amount of vehicle to an appropriately sized, labeled container (See TEST ARTICLE CALCULATIONS) and mix.

Written by: _____

Approved by: _____ Date: 16-NOV-98

Clarification: ✓ No ___ Yes (See attached clarification form.)

Initials/Date : _____ 3/3/99

PRIMEDICA

Argus Research Laboratories, Inc.
905 Sheehy Drive, Building A
Horsham, PA 19044
Telephone: (215) 443-8710
Telefax: (215) 443-8587

PROTOCOL 418-015

Oral (Gavage) Pharmacokinetc Recovery Study of PFOS in Rats

SPONSOR'S STUDY NUMBER: T-6295.14

Amendment 1 – 07 January 1999

1. Analyses of Prepared Formulations, Concentration of Test Article Formulations (Page 4 of the protocol):

[Effective date: 06 January 1999] Duplicate samples (2 mL each) will be taken from the first and last preparation rather than, the first and last preparation on the day prepared.

Reason for Change:

The preparation occurs the day before it is used for dosage administration and, according the to protocol, day 0 of gestation is the last day of dosage administration. Since day 0 of gestation is the day that the rats are confirmed pregnant, the sample cannot be taken of the last day of preparation.

07-JAN-99
Alan M. Hoberman, Ph.D., DABT Date
Director of Research

07-JAN-99
Raymond G. York, Ph.D., DABT Date
Associate Director of Research and
Study Director

07Jan99
Dena C. Lebo, V.M.D. Date
Chairperson, Institutional Animal Care and
Use Committee

7 Jan 99
Marvin T. Case, D.V.M., Ph.D. Date
Study Monitor

APPENDIX D

DEVIATIONS FROM THE PROTOCOL AND THE STANDARD OPERATING PROCEDURES OF THE TESTING FACILITY

DEVIATIONS FROM THE PROTOCOL AND STANDARD OPERATING PROCEDURES OF THE TESTING FACILITY

1. All rats were administered the test article or vehicle on premating day 43, 4 January 1999. The rats should have been placed into cohabitation on premating day 42 after dosage administration. This deviation did not adversely affect the outcome or interpretation of the study because no data were lost.

2. From 23 November 1998 to 26 November 1998 (days 1 to 4 of the premating period), the following Fo generation female rats received the incorrectly calculated amount of test article in vehicle, resulting in the rats receiving 25% more of the test article than required.

Dosage Group	Dosage (mg/kg/day)	Rat Numbers
II	0.1	13738 – 13749
III	1.6	13750 - 13761

These deviations did not adversely affect the outcome or interpretation of the study because the dosages were only for the first four days out of a total of 43 days of test article administration prior to mating.

All deviations are documented in the raw data.

23-Dec-99

Raymond G. York, Ph.D., DABT Date
Associate Director of Research
and Study Director

APPENDIX E

TEMPERATURE AND RELATIVE HUMIDITY REPORTS

ARGUS

Temperature and Relative Humidity Report
Location: Room 15

Protocol Number: 418-015

Range of Dates: 17-Nov-1998 14:00 to 27-Nov-1998 08:55

	Temperature		Relative Humidity	
Target Range:	64°F to 79°F		30% to 70%	
Species: rat				
Total Number of Days:	11		11	
Total Number of Hours:	234.72		234.72	
Total Number of Data Points:	235		235	
Mean (± SD):	67.0	(± 0.9)	44.6	(± 4.8)
Maximum:	68.9		53.4	
Median:	67.2		45.6	
Minimum:	63.4		30.3	
Number of Points in Range (%):	232	(98.7)	235	(100.0)
Number of Points High (%):	0	(0.0)	0	(0.0)
Number of Points Low (%):	3	(1.3)	0	(0.0)

Report Generated: 28-Apr-1999 at 12:33

COMMENTS: _____

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REVIEWED BY: _____ **DATE:** 5/19/99

001143

ARGUS

Temperature and Relative Humidity Report
Location: Room 04

Protocol Number: 418-015

Range of Dates: 27-Nov-1998 08:55 to 30-Nov-1998 09:15

	Temperature		Relative Humidity	
Target Range:	64°F to 79°F		30% to 70%	
Species: rat				
Total Number of Days:	4		4	
Total Number of Hours:	71.99		71.99	
Total Number of Data Points:	75		75	
Mean (± SD):	72.4	(± 0.9)	45.1	(± 4.8)
Maximum:	74.3		68.7	
Median:	72.3		44.1	
Minimum:	69.6		40.0	
Number of Points in Range (%):	75	(100.0)	75	(100.0)
Number of Points High (%):	0	(0.0)	0	(0.0)
Number of Points Low (%):	0	(0.0)	0	(0.0)

Report Generated: 28-Apr-1999 at 12:35

COMMENTS: _____

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REVIEWED BY: _____ **DATE:** 5/15/99

001144

ARGUS

Temperature and Relative Humidity Report
Location: Room 27

Protocol Number: 418-015

Range of Dates: 30-Nov-1998 09:15 to 09-Dec-1998 14:30

	Temperature		Relative Humidity	
Target Range:	64°F to 79°F		30% to 70%	
Species: rat				
Total Number of Days:	10		10	
Total Number of Hours:	221.0		221.0	
Total Number of Data Points:	222		222	
Mean (± SD):	71.3	(± 0.5)	59.3	(± 6.7)
Maximum:	72.4		68.8	
Median:	71.3		61.2	
Minimum:	70.0		37.0	
Number of Points in Range (%):	222	(100.0)	222	(100.0)
Number of Points High (%):	0	(0.0)	0	(0.0)
Number of Points Low (%):	0	(0.0)	0	(0.0)

Report Generated: 28-Apr-1999 at 12:37

COMMENTS: _____

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REVIEWED BY: _____ **DATE:** 5/15/99

001145

ARGUS

Temperature and Relative Humidity Report
Location: Room 28-29

Protocol Number: 418-015

Range of Dates: 09-Dec-1998 14:30 to 15-Dec-1998 15:44

	Temperature		Relative Humidity	
Target Range:	64°F to 79°F		30% to 70%	
Species: rat				
Total Number of Days:	7		7	
Total Number of Hours:	145.01		145.01	
Total Number of Data Points:	146		146	
Mean (± SD):	70.7	(± 1.1)	49.0	(± 3.5)
Maximum:	76.5		59.4	
Median:	70.4		48.8	
Minimum:	69.1		39.6	
Number of Points in Range (%):	146	(100.0)	146	(100.0)
Number of Points High (%):	0	(0.0)	0	(0.0)
Number of Points Low (%):	0	(0.0)	0	(0.0)

Report Generated: 28-Apr-1999 at 12:39

COMMENTS: _____

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REVIEWED BY: AKA **DATE:** 5/15/99

001146

ARGUS

Temperature and Relative Humidity Report
Location: Room 27

Protocol Number: 418-015

Range of Dates: 15-Dec-1998 15:44 to 21-Dec-1998 13:45

	Temperature		Relative Humidity	
Target Range:	64°F to 79°F		30% to 70%	
Species: rat				
Total Number of Days:	7		7	
Total Number of Hours:	141.77		141.77	
Total Number of Data Points:	143		143	
Mean (± SD):	70.6	(± 0.8)	59.9	(± 2.6)
Maximum:	72.5		64.8	
Median:	70.5		60.1	
Minimum:	69.0		49.1	
Number of Points in Range (%):	143	(100.0)	143	(100.0)
Number of Points High (%):	0	(0.0)	0	(0.0)
Number of Points Low (%):	0	(0.0)	0	(0.0)

Report Generated: 28-Apr-1999 at 12:41

COMMENTS: _____

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REVIEWED BY: _____ **DATE:** 5/19/99

001147

ARGUS

Temperature and Relative Humidity Report
Location: Room 28-29

Protocol Number: 418-015

Range of Dates: 21-Dec-1998 13:45 to 20-Feb-1999 15:00

	Temperature		Relative Humidity	
Target Range:	64°F to 79°F		30% to 70%	
Species: rat				
Total Number of Days:	62		62	
Total Number of Hours:	1464.99		1464.99	
Total Number of Data Points:	1466		1466	
Mean (± SD):	69.0	(± 1.1)	49.0	(± 10.6)
Maximum:	71.9		81.6	
Median:	69.0		48.7	
Minimum:	66.9		10.0	
Number of Points in Range (%):	1466	(100.0)	1407	(96.0)
Number of Points High (%):	0	(0.0)	49	(3.3)
Number of Points Low (%):	0	(0.0)	10	(0.7)

Report Generated: 28-Apr-1999 at 12:46

COMMENTS: _____

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REVIEWED BY: _____ **DATE:** 5/5/99

ARGUS

Temperature Deviations Report
Location: Room 15

Protocol Number: 418-015

Range of Dates: 17-Nov-1998 14:00 to 27-Nov-1998 08:55

Temperature Target Range: 64°F to 79°F
Species: rat

Date	Time	Temp.	Date	Time	Temp.
25-Nov-1998	03:00	63.8 L			
25-Nov-1998	06:00	63.7 L			
25-Nov-1998	07:00	63.4 L			

H = Value out of range - High L = Value out of range - Low
Temp. = Temperature °F

Report Generated: 28-Apr-1999 at 12:34

✓ 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: 30 APR 99

ARGUS

Relative Humidity Deviations Report
Location: Room 28-29

Protocol Number: 418-015

Range of Dates: 21-Dec-1998 13:45 to 20-Feb-1999 15:00

Humidity Target Range: 30% to 70%
Species: rat

Date	Time	R.H.	Date	Time	R.H.
21-Dec-1998	18:00	77.2 H	21-Jan-1999	18:00	76.4 H
29-Dec-1998	12:00	70.3 H	22-Jan-1999	03:00	70.9 H
04-Jan-1999	13:00	29.4 L	22-Jan-1999	05:00	71.7 H
05-Jan-1999	22:00	26.3 L	22-Jan-1999	07:00	70.4 H
05-Jan-1999	23:00	26.8 L	22-Jan-1999	09:00	70.4 H
06-Jan-1999	00:00	19.3 L	22-Jan-1999	21:00	70.5 H
06-Jan-1999	01:00	20.7 L	23-Jan-1999	06:00	71.4 H
06-Jan-1999	02:00	17.0 L	23-Jan-1999	09:00	72.3 H
06-Jan-1999	03:00	14.7 L	23-Jan-1999	13:00	73.9 H
06-Jan-1999	04:00	15.7 L	23-Jan-1999	18:00	78.2 H
06-Jan-1999	05:00	10.0 L	23-Jan-1999	19:00	75.1 H
06-Jan-1999	06:00	10.2 L	23-Jan-1999	23:00	77.9 H
18-Jan-1999	11:00	75.4 H	24-Jan-1999	00:00	73.1 H
18-Jan-1999	15:00	72.4 H	24-Jan-1999	03:00	80.7 H
18-Jan-1999	18:00	72.0 H	24-Jan-1999	04:00	72.4 H
18-Jan-1999	20:00	73.4 H	24-Jan-1999	05:00	72.2 H
18-Jan-1999	21:00	75.4 H	24-Jan-1999	06:00	73.4 H

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

Report Generated: 28-Apr-1999 at 12:53

__✓__ 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: [signature] Date: 30-APR-99

ARGUS

Relative Humidity Deviations Report
Location: Room 28-29

Protocol Number: 418-015

Range of Dates: 21-Dec-1998 13:45 to 20-Feb-1999 15:00

Humidity Target Range: 30% to 70%
Species: rat

Date	Time	R.H.
24-Jan-1999	07:00	70.1 H
24-Jan-1999	09:00	70.3 H
24-Jan-1999	10:00	75.5 H
24-Jan-1999	11:00	75.6 H
24-Jan-1999	12:00	75.8 H
24-Jan-1999	13:00	78.2 H
24-Jan-1999	14:00	81.6 H
24-Jan-1999	15:00	75.5 H
24-Jan-1999	16:00	80.3 H
24-Jan-1999	17:00	78.7 H
24-Jan-1999	18:00	75.9 H
26-Jan-1999	11:00	70.9 H
26-Jan-1999	15:00	74.5 H
26-Jan-1999	16:00	75.7 H
26-Jan-1999	17:00	76.1 H
26-Jan-1999	18:00	73.6 H
26-Jan-1999	20:00	70.6 H
02-Feb-1999	19:00	77.7 H
02-Feb-1999	20:00	77.7 H
02-Feb-1999	21:00	70.7 H
02-Feb-1999	23:00	77.7 H
03-Feb-1999	01:00	76.7 H
03-Feb-1999	03:00	75.4 H
03-Feb-1999	07:00	75.2 H
06-Feb-1999	12:00	72.9 H

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

Report Generated: 28-Apr-1999 at 12:54

✓ 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: 30-APR-99

APPENDIX F

STATEMENT OF THE STUDY DIRECTOR

PRIMEDICA

Argus Research Laboratories, Inc.
905 Sheehy Drive, Building A
Horsham, PA 19044
Telephone: (215) 443-8710
Telefax: (215) 443-8587

PROTOCOL 418-015: ORAL (GAVAGE) PHARMACOKINETIC RECOVERY STUDY OF PFOS IN RATS
SPONSOR'S STUDY NUMBER: T-6295.14

STATEMENT OF THE STUDY DIRECTOR

This final report accurately reflects the raw data obtained during the performance of the study. No deviations from the U.S. Food and Drug Administration (FDA) Good Laboratory Practice Regulations; Final Rule[a], the Japanese Ministry of Health and Welfare (MHW) *Good Laboratory Practice Standard for Safety Studies on Drugs*[b] and the European Economic Community (EEC) *Council decision on 28 July 1989 on the acceptance by the European Economic Community of an OECD decision/recommendation on compliance with principles of good laboratory practice*[c] occurred that affected the quality or integrity of the study.

Raymond G. York, Ph.D., DABT Date
Associate Director of Research
and Study Director

---

a. U.S. Food and Drug Administration. Good Laboratory Practice Regulations; Final Rule. 21 CFR Part 58.

b. Japanese Ministry of Health and Welfare (1988). *Good Laboratory Practice Standard for Safety Studies on Drugs*, MHW Ordinance Number 21, March 26, 1997.

c. European Economic Community (1989). *Council decision on 28 July 1989 on the acceptance by the European Economic Community of an OECD decision/recommendation on compliance with principles of good laboratory practice*. Official Journal of the European Communities: Legislation. 32(No. L 315; 28 October): 1-17.

APPENDIX G

QUALITY ASSURANCE UNIT FINAL REPORT STATEMENT

PRIMEDICA

Argus Research Laboratories, Inc.
905 Sheehy Drive, Building A
Horsham, PA 19044
Telephone: (215) 443-8710
Telefax: (215) 443-8587

QUALITY ASSURANCE UNIT FINAL REPORT STATEMENT

Study Director: Raymond G. York, Ph.D., DABT

Executive Director of Research: Mildred S. Christian, Ph.D., Fellow, ATS

Protocol 418-015: Oral (Gavage) Pharmacokinetic Recovery Study of PFOS in Rats
Sponsor's Study Number: T-6295.14

The draft protocol for this study was audited for adherence to U.S. Food and Drug Administration (FDA) Good Laboratory Practice Regulations, Japanese Ministry of Health and Welfare (MHW); Good Laboratory Practice Standard for Safety Studies on Drugs, and European Economic Community (1989) council decision on 28 July 1989 on the acceptance by the European Economic Community of an OECD decision/recommendation on compliance with principles of good laboratory practice on 18 OCT 98.

Critical phases of this study were inspected 10 times; study information and raw data were audited twice (see tables 1 and 2 for dates and phases/data).

The draft final report and the raw data for this study were compared and audited for accuracy, for adherence to protocol requirements, and for adherence to U.S. Food and Drug Administration (FDA) Good Laboratory Practice Regulations, Japanese Ministry of Health and Welfare (MHW); Good Laboratory Practice Standard for Safety Studies on Drugs, and European Economic Community (1989) council decision on 28 July 1989 on the acceptance by the European Economic Community of an OECD decision/recommendation on compliance with principles of good laboratory practice between 10 MAY 99 and 15 JUN 99, and for revisions requested by the Sponsor on 20 JUL 99, 22 JUL 99, and for finalization on 23 JUL 99.

This study was conducted according to U.S. Food and Drug Administration (FDA) Good Laboratory Practice Regulations, Japanese Ministry of Health and Welfare (MHW); Good Laboratory Practice Standard for Safety Studies on Drugs. And European Economic Community (1989) council decision on 28 July 1989 on the acceptance by the European Economic Community of an OECD decision/recommendation on compliance with principles of good laboratory practice.

Nancy J. Gongliewski 23Jul99

Nancy J. Gongliewski Date
Quality Assurance Manager

Nancy J. Gongliewski 23Jul99

for Lisa A. Zaborowski, B.S. Date
Senior Quality Assurance Associate
and Principal Auditor

TABLE 1

CRITICAL PHASES INSPECTED

Test Article Administration - Gavage

Date of inspection: 23 NOV 98

Date results reported to the Study Director and Management: 25 NOV 98

Test Article Preparation

Date of inspection: 01 DEC 98

Date results reported to the Study Director and Management: 02 DEC 98

Urine/Fecal Collection

Date of inspection: 04 JAN 99

Date results reported to the Study Director and Management: 04 JAN 99

Blood Collection

Dates of inspection: 04 JAN 99, 17 FEB 99

Dates results reported to the Study Director and Management: 04 JAN 99, 17 FEB 99

Cohabitation

Date of inspection: 05 JAN 99

Date results reported to the Study Director and Management: 07 JAN 99

Natural Delivery/Litter Watch

Date of inspection: 27 JAN 99

Date results reported to the Study Director and Management: 02 FEB 99

Culling, Pup Scrifice: Day 4

Date of inspection: 01 FEB 99

Date results reported to the Study Director and Management: 03 FEB 99

Necropsy, Fo Dams, F_1 Pups

Dates of inspection: 17 FEB 99, 17 FEB 99

Dates results reported to the Study Director and Management: 22 FEB 99, 22 FEB 99

TABLE 2

RAW DATA AUDIT(S)

The following study information and raw data were audited from 07 APR 99 to 13 APR 99:

Protocol.
Protocol amendment.
List of personnel and computer operator codes.
Error codes and codes for clinical sign observations.
Animal receipt, randomization, physical examination and acclimation.
In-life transaction record.
Feed consumption.
Cohabitation.
Natural delivery observations.
Litter observations.
Pup body weights and status.
Pup Randomization.
Necropsy.
Organ weights.
Tissue packing lists.
Male breeder colony records.
General comments.
Study maintenance records.
Temperature and relative humidity reports.
Feed, water and bedding analyses.
Edit requests.
Deviations.
Data review page.
Blood collection data and packing lists.
Key for testing facility computer backup record abbreviations.
Urine/Fecal collection data and packing lists.

The results of this audit were reported to the Study Director and Management on 15 APR 99.

The following study information and raw data were audited on 20 APR 99:

Vehicle receipt, preparation and use.
Test article receipt, preparation and use.
Test article packing lists.
Deviations.

The results of this audit were reported to the Study Director and Management on 23 APR 99.