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3M
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FINAL REPORT

Study Title:

4-Week Capsule Toxicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295) in Cynomolgus Monkeys

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Study Completion Date:

To be determined

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Laboratory Project Identification:

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Sponsor Project Identification:

3M Study No. T-6295.6

COMPLIANCE STATEMENT

4-Week Capsule Toxicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295) in Cynomolgus Monkeys

All aspects of this study were in accordance with the Environmental Protection Agency Good Laboratory Practice Standards, 40 CFR 792.

Peter J. Thomford, PhD
Study Director
Covance Laboratories Inc.

Date

Andrew M. Seacat, PhD
Study Monitor
3M

Date

QUALITY ASSURANCE STATEMENT

This report, with the exception of Appendices 6, 7, 8, and 9, has been reviewed by the Quality Assurance Unit of Covance Laboratories Inc., in accordance with the Environmental Protection Agency (EPA) Good Laboratory Practice Standards, 40 CFR 792. The data in Appendices 6, 7, 8, and 9 were generated by and are the responsibility of the Sponsor and the Sponsor's designees. The following inspections were conducted and findings reported to the study director and study director management. Written status reports of inspections and findings are issued to Covance management according to standard operating procedures.

Inspection Dates			Date Reported to Study Director and
From	To	Phase	Study Director Management
04/21/98	04/21/98	Protocol Review	04/21/98
05/20/98	05/20/98	Protocol Amendment Review	05/20/98
05/20/98	05/20/98	Protocol Amendment Review	05/20/98
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08/14/98	08/14/98	Protocol Amendment Review	08/14/98
08/10/98	08/18/98	Report Review	08/18/98

Representative
Quality Assurance Unit

Date

STUDY IDENTIFICATION

4-Week Capsule Toxicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295) in Cynomolgus Monkeys

Test Material	Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295)
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Study Timetable	
Study Initiation Date	April 17, 1998
In-Life (Experimental) Start Date	April 23, 1998
In-Life Termination Date	May 22, 1998
Experimental Termination Date	To be determined

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ABSTRACT

The purpose of this study was to provide data for determining an estimated maximum-tolerated dose and lower dose levels to be used in a chronic toxicity study and to assess the effect of the test material, Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295), on critical enzyme levels, hormones, and other selected biochemical parameters.

Male and female cynomolgus monkeys were assigned to three groups (two animals/sex in Group 1, three animals/sex in Group 2, and one animal/sex in Group 3). Animals in Groups 2 and 3 received gelatin capsules containing 0.02 and 2.0 PFOS/kg of body weight/day (mg/kg/day), respectively, triturated with lactose (1:999 and 1:9, w:w, respectively). Animals in Group 1 received gelatin capsules containing lactose only. The total material dose level for each group was 20.0 mg/kg/day.

Food was provided once or twice daily. Water was provided *ad libitum*. The animals were observed twice daily (a.m. and p.m.) for mortality and moribundity. At least once daily, animals were examined for abnormalities and signs of toxicity, and food consumption was assessed qualitatively. In addition, animals were observed approximately 30, 60, and 90 minutes postdose for signs of poor health or abnormal behavior. Body weight data were collected twice weekly beginning 2 weeks before initiation of treatment, on Day -1, on the first day of treatment, and twice weekly thereafter. Rectal body temperatures were recorded twice weekly beginning 2 weeks before initiation of treatment. Blood samples for hormone analyses [estradiol, estrone, estriol, thyroid stimulating hormone, triiodothyronine (T3), and thyroxin (T4)] were collected before initiation of treatment and predose on Day 29. Serum was harvested, and the samples were sent to Ani Lytics Inc., for analyses. Blood samples for serum PFOS concentration analyses were collected before initiation of treatment and predose on Days 2, 3 (approximately 24 hours after the first and second dose, respectively), 7, 14, and 29. Serum was harvested, and samples were sent to the Sponsor for analyses. Blood samples were collected for hematology and clinical chemistry tests before initiation of treatment and on Day 29. In addition, blood for clinical chemistry tests was collected predose on Days 2, 7, and 14. Additional blood was collected at the time of exsanguination, and samples were shipped to the Sponsor for possible future analysis. On Day 30, the animals were anesthetized, weighed, exsanguinated, and necropsied. At necropsy, macroscopic observations were recorded, and selected tissues were collected

and preserved. In addition, a sample of liver was collected from each animal for palmitoyl CoA oxidase activity analyses. Representative samples of liver, testes, and pancreas were collected from each animal and sent to Pathology Associates International for proliferation cell nuclear antigen evaluation. A sample of liver was collected from each animal and sent to the Sponsor for PFOS concentration analyses. Microscopic examinations were done on the adrenals, eye, femoral bone marrow, lung, liver, kidney, pancreas, spleen, testes, and thymus from each animal.

All animals survived to the scheduled sacrifice. There were no test material-related effects on clinical observations, body weights, food consumption, rectal body temperatures, clinical pathology, or macroscopic or microscopic findings.

There were no apparent test material-related effects on estrone, estriol, thyroid stimulating hormone, or thyroxin. There were no apparent test material-related effects on estradiol or triiodothyronine at 0.02 mg/kg/day. Given the low number of animals in this study, it is not possible to determine conclusively whether there was a test material-related effect on estradiol or triiodothyronine. Estradiol levels for the male and female given 2.0 mg/kg/day were numerically lower than those of the control animals on Day 29 and their respective prestudy values. Triiodothyronine levels for the male and female given 2.0 mg/kg/day were numerically lower than those of the control animals on Day 29; however, their prestudy values were also considerably lower than the control values. Triiodothyronine levels for animals given 0 or 0.02 mg/kg/day were numerically higher on Day 29 compared with their prestudy levels while triiodothyronine levels for animals given 2.0 mg/kg/day were numerically lower compared with their prestudy levels.

In cynomolgus monkeys treated with 0, 0.02, or 2.0 mg PFOS/kg/day orally for at least 4 weeks, there were no apparent test material-related effects on clinical observations, body weights, food consumption, rectal body temperatures, or clinical or anatomical pathology findings. The one male and one female treated with 2.0 mg PFOS/kg/day appeared to have lower levels of estradiol on Day 29. Data from liver and serum PFOS analyses and cell proliferation evaluations will be provided by the Sponsor and Pathology Associates International, respectively.

PURPOSE

The purpose of this study was to provide data for determining an estimated maximum-tolerated dose and lower dose levels to be used in a chronic toxicity study and to assess the effect of the test material, Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295), on critical enzyme levels, hormones, and other selected biochemical parameters.

REGULATORY COMPLIANCE

All aspects of this study were done in accordance with the Environmental Protection Agency Good Laboratory Practice Standards, 40 CFR 792.

TEST MATERIAL AND VEHICLE

Test Material

The test material, Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295), Lot No. 217, is a white to off-white powder. It was received at Covance on September 4, 1997. The test material was stored at room temperature.

Information on synthesis methods, stability, purity, composition, or other characteristics that define the test material is on file with the Sponsor.

Vehicle

The vehicle was lactose (Spectrum, New Brunswick, New Jersey), Lot No. NN0192 (expiration date February 13, 1999). It was received at Covance on March 30, 1998. The vehicle was stored at room temperature.

Information on synthesis methods, purity, composition, or other characteristics that define the vehicle is on file with the manufacturer.

Reserve (Archive) Samples
A reserve sample (10 g each) of each lot of the test material, vehicle, and each test material/lactose trituration was taken before initiation of treatment and stored at room temperature. These samples will be transferred to the Sponsor after completion of the in-life phase.

Disposition
Remaining test material will be retained at Covance for use in possible future studies.

TEST SYSTEM

Test Animal
Young adult to adult cynomolgus monkeys were obtained from Covance Research Products Inc. (Alice, Texas), on March 10, 1998. The animals weighed 2.0 to 2.5 kg at initiation of treatment.

Identification
Each animal was assigned a permanent number upon arrival and identified with collar tag before initiation of treatment. All data for an animal are recorded under this number.

Acclimation
Seven males and seven females were received on March 10, 1998, transferred from the Covance in-house stock colony on March 16, 1998, and acclimated in Animal Room 2015 for 38 days before initiation of treatment. In general, animals in this shipment appeared healthy. During acclimation, the animals were examined for abnormalities indicative of health problems. In addition, three tuberculosis tests, a physical examination, and a fecal flotation for parasites were done on each animal.

The physical examination done after the animals were received revealed no major abnormalities. Results of the tuberculosis tests were negative for all animals; the results are recorded in the data. The results of the fecal flotation tests indicated the animals were negative for parasite ova. One male and one female were eliminated from study consideration based on clinical pathology findings or abnormal fecal observations during

acclimation. There were six males and six females in the randomization for assignment to groups (two animals/sex in Group 1, three animals/sex in Group 2, and one animal/sex in Group 3). Animals not selected for the study were transferred to the Covance stock colony.

Housing and Maintenance

Animal Room 2015 was used for this study. Environmental controls for the animal room were set to maintain 18 to 29EC, a relative humidity of 30 to 70%, and a 12-hour light/12-hour dark cycle. Variations from these conditions are documented in the data and are considered to have had no effect on the outcome of the study.

The animals were housed individually in stainless steel cages.

Certified primate diet (#8726C, Harlan Teklad) was provided once or twice daily. The lot numbers are recorded in the data. The diet is routinely analyzed by the manufacturer for nutritional components and environmental contaminants. Results of specified nutrient and contaminant analyses are on file with Covance-Madison. Fruits or additional supplements were provided, but did not require analysis.

Water was provided *ad libitum*. Samples of the water are analyzed for specified microorganisms and environmental contaminants. The results are on file with Covance-Madison.

There were no known contaminants in the diet or water at levels that would have interfered with this study.

Justification

PFOS is a known hepatic peroxisome proliferator (PP) in the rat. When exposed to PP, nonhuman primates (such as the cynomolgus monkey) respond similarly to humans (i.e., low to no hepatic response) and therefore are an appropriate human surrogate species.

PROCEDURES

This study was conducted in accordance with the Protocol dated April 17, 1998, and Protocol Amendment Nos. 1 through 3. The protocol, protocol amendments, and protocol deviations are in Appendix 1.

Group Designations and Dose Levels

Selection of animals for the study was based on clinical observations, clinical pathology, and other data as appropriate. Animals were assigned to treatment groups using a computerized blocking procedure designed to achieve body weight balance with respect to treatment group.

Group	Dose Level (mg/kg/day)	Total Material Dose Level (mg/kg/day)	Number of Animals Males	Females
1 (control)	0[a]	20.0[a]	2	2
2 (low dose)	0.02	20.0[b]	3	3
3 (high dose)	2.0	20.0[c]	1	1

a The control group (Group 1) received an equivalent amount of lactose in gelatin capsules as the total material administered to Group 3.
b The low-dose group received the test material triturated with lactose (1:999, w:w).
c The high-dose group received the test material triturated with lactose (1:9, w:w).

Dose Preparation

Gelatin capsules (Torpac, Inc., Fairfield, New Jersey), Size No. 2, Lot No. 122630 (expiration date June 26, 2002), were used for dose administration. The test material triturated with lactose and lactose only (control group) were dispensed into capsules twice weekly and stored at room temperature.

Vehicle. Lactose was used as the vehicle in the dose preparations. Dose levels were based on the vehicle as supplied for Group 1.

For Group 1 dose preparations, the specified amount of lactose was weighed and transferred into the gelatin capsule. The top and bottom halves of each capsule were joined, and the capsule was placed into the appropriate container labeled with study number, group number, animal number, and dose level.

Test Material. For Group 2 and 3 dose preparations, the test material was dissolved in acetone and triturated with lactose (1:999 and 1:9, w:w, respectively) once before initiation of treatment. Acetone (Spectrum, Gardena, California), Lot No. LH0253 (expiration date June 2000) was used to dilute the test material with lactose. Trituration with lactose was necessary to facilitate capsule preparation.

For Group 3 dose preparations, the specified amount of test material was weighed, placed into a labeled mixing container, and the appropriate volume of acetone was added to the container. The preparation was stirred manually until the test material was dissolved. The specified amount of lactose was weighed, placed into the mixing container, and thoroughly mixed using a spatula. This preparation was exposed to air until the acetone was evaporated and stirred periodically. Samples of the finished preparation for dose analyses were taken directly from the container. The triturated test material was transferred to a container and stored at room temperature and protected from light and moisture.

For Group 2 preparations, the required amount of the Group 3 preparation was measured and placed into a labeled mixing container. The specified amount of lactose was weighed, placed into the mixing container, and thoroughly mixed using a spatula for approximately 5 minutes. Samples of the finished preparation for dose analyses were taken directly from the container. The triturated test material was transferred to a container and stored at room temperature and protected from light and moisture.

The specified amount of triturated test material was weighed and transferred into the gelatin capsule. The top and bottom halves of each capsule were joined, and the capsule was placed into the appropriate container labeled with study number, group number, animal number, and dose level.

Dose Analyses

Samples (1 g each) were collected from the top, middle, and bottom of the test material/lactose preparations for the low- and high-dose groups and stored at room temperature. The samples were shipped under ambient conditions to the Sponsor for analysis.

Homogeneity samples collected from the middle of the preparations were used for the prestudy stability analysis. One set of samples (1 g each) were taken from the low- and high-dose test material/lactose preparations at the end of the in-life phase and shipped to the Sponsor for analysis.

Results of the homogeneity, stability, and dose confirmation analyses provided by the Sponsor are in Appendix 7.

Method of Administration

Gelatin capsules were used for test material preparation administration to compare with data from previous toxicology studies using the oral route, which is the most likely route of exposure.

The dose preparations were administered orally in gelatin capsules once daily (7 days/week) for 29 days (see Protocol Deviations for exceptions). The dosing tubes were flushed with 5 mL of reverse osmosis water. Individual doses were calculated based on the most recently recorded body weights, with the exception of body weight collection days when the previous body weight was used. Animals were dosed at approximately the same time each day.

Clinical Observations

The animals were observed twice daily (a.m. and p.m.) for mortality and moribundity. Each animal was observed daily, and food consumption was assessed qualitatively; abnormal findings were recorded. Animals were observed approximately 30, 60, and 90 minutes postdose for signs of poor health or abnormal behavior. Effects were recorded as they were observed. Animals were observed once weekly; abnormal findings or an indication of normal was recorded.

Body Weights
Individual body weight data were recorded twice weekly beginning 2 weeks before initiation of treatment (Monday and Thursday), on the first day of treatment, and twice weekly thereafter. An additional body weight was recorded on Day -1 for the Day 1 dose calculations.

Rectal Body Temperatures
Rectal body temperatures were taken at approximately 11:00 twice weekly beginning 2 weeks before initiation of treatment [Monday and Thursday (see Protocol Deviations for exceptions)]. Animals were not anesthetized for the procedure.

Blood Hormone Determination
Approximately 5 mL of whole blood were collected from a femoral vein of each animal before initiation of treatment (Day -7) and predose on Day 29. Blood was collected between 07:00 and 09:00. Animals were fasted overnight before collections. All samples were collected without anticoagulant, maintained at room temperature, and allowed to clot. Samples were centrifuged within 1 hour after collection, and serum samples were harvested. Serum was divided into two approximately equal aliquots (blood collected on Day 29 only) and stored in a freezer set to maintain -60 to -80°C until packed on dry ice and shipped to Ani Lytics Inc., for analyses. The samples were analyzed for estradiol, estrone, estriol, thyroid stimulating hormone, triiodothyronine (T3), and thyroxin (T4). Results of these analyses were provided by Ani Lytics Inc., and are in Appendix 6.

Serum PFOS Level Determination
Approximately 5 (Day -7 only) or 2 mL of whole blood were collected from a femoral vein of each animal before initiation of treatment (Day -7) and predose on Days 2, 3 (approximately 24 hours after the first and second dose, respectively), 7, 14, and 29. Animals were fasted overnight before collections. All samples were collected without anticoagulant, maintained at room temperature, and allowed to clot. Samples were centrifuged within 1 hour after collection, and serum was harvested and stored in a freezer set to maintain -60 to -80°C until packed on dry ice and shipped to the Sponsor for analyses. The samples were analyzed for PFOS. Results of analyses provided by the Sponsor are in Appendix 8.

Clinical Pathology

Blood samples were collected from each animal on Days -7 and 29 for hematology and clinical chemistry tests. In addition, blood for clinical chemistry tests was collected from each animal predose on Days 2, 7, and 14. Animals were fasted overnight; water was provided *ad libitum*. Blood was collected from the femoral vein. The following were evaluated:

Hematology

- red blood cell (erythrocyte) count
- hemoglobin
- hematocrit
- mean corpuscular volume
- mean corpuscular hemoglobin
- mean corpuscular hemoglobin concentration
- platelet count
- white blood cell (leukocyte) count
- differential blood cell count
  - segmented neutrophil count
  - lymphocyte count
  - monocyte count
  - eosinophil count
  - basophil count
- blood cell morphology
- reticulocyte count

Clinical Chemistry

- glucose
- urea nitrogen
- creatinine
- total protein
- albumin
- globulin
- total bilirubin
- cholesterol
- triglycerides
- aspartate aminotransferase
- alanine aminotransferase
- alkaline phosphatase
- gamma glutamyl transferase
- sorbitol dehydrogenase
- creatine kinase
- calcium
- inorganic phosphorus
- sodium
- potassium
- chloride
- serum bile acids
- amylase
- lipase
- pancreatic-specific amylase

Additional Blood Collection

Whole blood (approximately 20 mL) was collected from the vena cava of each animal at the time of exsanguination (See Protocol Deviations for exceptions). The anticoagulant was potassium EDTA. Samples were transferred into containers (approximately 5 mL each) and stored in a freezer set to maintain -60 to -80° C until packed on dry ice and shipped to the Sponsor possible future analysis.

Necropsy
On Day 30, animals that were fasted overnight were anesthetized with ketamine and xylazine, weighed, bled for required tests, exsanguinated, and necropsied. Animals were necropsied in random order.

The necropsy included a macroscopic examination of the external surface of the body; all orifices; the cranial cavity; the brain and spinal cord; the nasal cavity and paranasal sinuses; cervical tissues and organs; and the thoracic, abdominal, and pelvic cavities and viscera.

Palmitoyl CoA Oxidase Determinations
A sample of the right lateral lobe of liver was collected from each animal at scheduled sacrifice. The sample was flash-frozen in liquid nitrogen and stored in a freezer set to maintain -60 to -80°C until analyzed for palmitoyl CoA oxidase activity.

Cell Proliferation Evaluation
Representative samples of the liver, testes, and pancreas were collected and preserved in zinc formalin. After fixation, samples for proliferation cell nuclear antigen (PCNA) evaluation were embedded in paraffin and shipped to Pathology Associates International for PCNA evaluation. Results of the evaluation provided by Pathology Associates International are in Appendix 9.

Liver PFOS Determination
A sample of liver was collected from each animal at sacrifice, weighed, flash-frozen in liquid nitrogen, and stored in a freezer set to maintain -60 to -80°C until packed on dry ice and shipped with plasma samples to the Sponsor for PFOS analysis. Results of these analyses provided by the Sponsor are in Appendix 8.

Tissue Preservation
The following tissues (when present) or representative samples were collected and preserved in 10% neutral-buffered formalin, unless otherwise specified, for possible future microscopic examination:

adrenal (2)
aorta
brain
cecum
cervix
colon
duodenum
epididymis (2)
esophagus
eyes [preserved in Davidson=s fixative (2)]
femur with bone marrow (articular surface of the distal end)
gallbladder
heart
ileum
jejunum
kidney (2)
liver
lung
lymph node (mesenteric)
mammary gland
muscle (thigh)
ovary (2)
pancreas
pituitary
prostate
rectum
salivary gland [mandibular (2)]
sciatic nerve
seminal vesicle (2)
skin
spinal cord (cervical, thoracic, and lumbar)
spleen
sternum with bone marrow
stomach
testis (2)
thymus
thyroid (2) with parathyroid
trachea
urinary bladder
uterus
vagina

Histopathology

The adrenals, eye, femoral bone marrow, lung, liver, kidney, pancreas, spleen, testes, and thymus were embedded in paraffin, sectioned, stained with hematoxylin and eosin, and examined microscopically from each animal (see Protocol Deviations for exceptions).

Bone marrow smears from the sternum of each animal at the scheduled sacrifice were prepared, stained with Wright's stain, and retained for possible examination.

Statistical Analyses

Only data collected on or after the first day of treatment were analyzed statistically. Statistical analyses were not done on data collected for Group 3 due to the small number of animals.

One-way analysis of variance [ANOVA (Winer, 1971a)] was used to analyze initial body weights, rectal body temperature, palmitoyl CoA oxidase activities, and continuous clinical pathology values.

Levene's test (Levene, 1960) was done to test for variance homogeneity. In the case of heterogeneity of variance at $p \leq 0.05$, transformations were used to stabilize the variance.

ANOVA was done on the homogeneous or transformed data. If the ANOVA was significant, Dunnett's t-test (Dunnett, 1964) was used for control versus treated group comparisons.

One-way analysis of covariance [ANCOVA (Winer, 1971b)] was used to analyze body weights, with initial body weights as the covariate. Although Levene's test for variance homogeneity was done (see above), no transformations were used because covariance adjustment removed extraneous heterogeneity. If the ANCOVA was significant, least squares means t-test was used for control versus treated group comparisons.

For each sex, Group 2 was compared with Group 1 (Control). Group comparisons were evaluated at the 5.0% two-tailed probability level.

RECORD RETENTION

All raw data, documentation, records, protocol, and specimens generated as a result of this study will be archived in the storage facilities of Covance-Madison for a period of 1 year. One year after the submission of the final report, the Sponsor will determine the final disposition of the materials. All raw data stored on magnetic media and an original copy of the final report will be retained by Covance-Madison.

Within 1 year after submission of the final report, all of the aforementioned materials (as appropriate) from the Sponsor's designees (3M E.T. & S, Ani Lytics Inc., and Pathology Associates International) will be sent to the Sponsor (Andrew Seacat, PhD, 3M).

RESULTS

Dose Analyses

Results of analyses provided by the Sponsor are in Appendix 7.

Results of the dose analyses will be provided by the Sponsor.

Clinical Observations

Clinical observations are summarized in Tables 1 through 5; individual data are in Appendix 2.

All animals survived to the scheduled sacrifice. There were no test material-related clinical observations.

Body Weights

Body weight data are summarized in Table 6; individual data are in Appendix 3.

There were no apparent test material-related effects on body weights.

Food Consumption

Food consumption data are summarized in Table 1 (Summary of Clinical Observations - A.M./Weekly); individual data are included in the individual clinical observations in Appendix 2.

There were no test material-related effects on food consumption.

Rectal Body Temperatures

Rectal body temperature data are summarized in Tables 7; individual data are in Appendix 2.

There were no test material-related effects on rectal body temperatures.

Blood Hormone Analyses
Summary and individual hormone analyses data are in Appendix 6. Estradiol and triiodothyronine analyses data are illustrated in Figures 1 through 4 (Appendix 6).

There were no apparent test material-related effects on estrone, estriol, thyroid stimulating hormone, or thyroxin. There were no apparent test material-related effects on estradiol or triiodothyronine at 0.02 mg/kg/day. Given the low number of animals in this study, it is not possible to determine conclusively whether there was a test material-related effect on estradiol or triiodothyronine. Estradiol levels for the male and female given 2.0 mg/kg/day were numerically lower than those of the control animals on Day 29 and their respective prestudy values. Triiodothyronine levels for the male and female given 2.0 mg/kg/day were numerically lower than those of the control animals on Day 29; however, their prestudy values were also considerably lower than the control values. Triiodothyronine levels for animals given 0 or 0.02 mg/kg/day were numerically higher on Day 29 compared with their prestudy levels while triiodothyronine levels for animals given 2.0 mg/kg/day were numerically lower compared with their prestudy levels.

Serum PFOS Level Determination
Results of serum PFOS level determination provided by the Sponsor are in Appendix 8.

Results of the serum PFOS level determination will be provided by the Sponsor.

Clinical Pathology
Hematology and clinical chemistry data are summarized in Tables 8 through 15; individual data are in Appendix 4. The Pathology Report contains a discussion of the data.

Administration of PFOS had no effects on clinical pathology test results.

Cell Proliferation Evaluation
Results of cell proliferation evaluation provided by Pathology Associates International are in Appendix 9.

Results of the cell proliferation evaluation will be provided by Pathology Associates International.

Liver PFOS Determination

Results of liver PFOS level determination provided by the Sponsor are in Appendix 8.

Results of the liver PFOS level determination will be provided by the Sponsor.

Anatomical Pathology

Incidences of macroscopic and microscopic observations are summarized in Tables 16 and 17. Individual data are in Appendix 5. The Pathology Report contains a discussion of the data.

There were no test material-related macroscopic or microscopic changes in the organs and tissues examined.

CONCLUSIONS

In cynomolgus monkeys treated with 0, 0.02, or 2.0 mg PFOS/kg/day orally for at least 4 weeks, there were no apparent test material-related effects on clinical observations, body weights, food consumption, rectal body temperatures, or clinical or anatomical pathology findings. The one male and one female treated with 2.0 mg PFOS/kg/day appeared to have lower levels of estradiol on Day 29. Data from liver and serum PFOS analyses and cell proliferation evaluations will be provided by the Sponsor and Pathology Associates International, respectively.

SIGNATURES

Patricia K. McKee Pesik, BS, LAT
Study Coordinator
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Date

Peter J. Thomford, PhD
Study Director
Covance Laboratories Inc.

Date

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PATHOLOGY REPORT

SUMMARY

The purpose of this study was to provide data for determining an estimated maximum-tolerated dose and lower dose levels to be used in a chronic toxicity study and to assess the effect of the test material, Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295), on critical enzyme levels, hormones, and other selected biochemical parameters.

Administration of PFOS had no effects on clinical pathology test results and caused no test material-related macroscopic or microscopic changes in the organs and tissues examined.

METHODS

Three groups of male and female cynomolgus monkeys were administered the test material orally via capsule at a dose level of 0 (control group; received the vehicle, lactose), 0.02, or 2.0 mg/kg of body weight/day (mg/kg/day) for 29 days. The control group had two animals/sex, the low-dose group had three animals/sex, and the high-dose group had one animal/sex.

Blood was collected for hematology and clinical chemistry tests before initiation of treatment (Day -7) and on Day 29. In addition, blood for clinical chemistry tests was collected on Days 2, 7, and 14. The animals were sacrificed and necropsied on Day 30; macroscopic observations were recorded, and tissues were preserved in fixative as specified by the protocol. Samples of liver were collected and frozen for determination of hepatic palmitoyl CoA oxidase activity and for determination of PFOS content (by the Sponsor). Samples of liver, testes, and pancreas were collected and preserved in zinc formalin for evaluation of proliferation cell nuclear antigen (PCNA; by Pathology Associates International). Microscopic examinations were done on adrenals, eye, femoral bone marrow, lung, liver, kidney, pancreas, spleen, testes, and thymus from all animals.

Results of clinical pathology tests for the control and low-dose groups were compared statistically.

RESULTS AND DISCUSSION

Mortality

All animals survived to the scheduled sacrifice.

Clinical Pathology

Individual values for hematology and clinical chemistry tests are in Appendix 4. Mean values and the results of statistical comparisons are in Tables 8 through 15.

Day -7. Clinical pathology test results indicated no obvious group or individual health abnormalities.

Days 2, 7, and 14. Administration of the test material had no effects on clinical chemistry test results at these collection intervals.

Statistically significant differences for clinical chemistry results between the control and low-dose groups were inconsistent over time and between the sexes. Several of the differences were similar to differences present at Day -7, and none of the differences exhibited a strong dose relationship (i.e., the high-dose animals did not exhibit notable differences for the same parameters).

Day 29. Administration of the test material had no effects on hematology or clinical chemistry test results at Day 29.

Statistically significant differences for red blood cell count, neutrophil count, monocyte count, and hepatic palmitoyl CoA oxidase were inconsistent between the sexes and exhibited no dose relationship. Statistically significant differences for triglycerides and alkaline phosphatase were similar to differences observed at Day -7.

Anatomical Pathology

Anatomical pathology findings for each animal are in Appendix 5. Incidence summaries of the macroscopic and microscopic observations are in Tables 16 and 17.

Week 5. There were no macroscopic and few microscopic findings in the organs and tissues examined, and there were no major differences between control and treated animals in the incidence of any finding. All microscopic observations were considered incidental and unrelated to the test material.

Robert L. Hall, DVM, PhD
Diplomate, ACVP
Clinical Pathology

Date

Thomas E. Palmer, PhD
Pathologist

Date

COMMENTS ON THE DATA

Various models of calculators, computers, and computer programs were used to analyze data in this study. Because different models round off or truncate numbers differently, values in some tables (e.g., means, standard deviations, or individual values) may differ slightly from those in other tables, from individually calculated data, or from statistical analysis data. Neither the integrity nor the interpretation of the data was affected by these differences.

Some tabular data were compiled using Excel[7] Version 7.0 software.

The summary tables for clinical observations indicate the number of animals for which a condition was observed without regard to the specific nature, severity, reversibility, number of incidences/animal, or the length of time the condition persisted.

Only observations other than normal are indicated on the summary clinical observations tables.

The day of initiation of treatment is "Day 1."

CODES, ABBREVIATIONS, AND UNITS

General Codes and Abbreviations
Codes for Clinical Pathology
Abbreviations and Units for Clinical Hematology
Abbreviations and Units for Clinical Chemistry
Codes for Anatomical Pathology

Note: The following lists of codes, abbreviations, and units are used by Covance. Some, but not necessarily all, of this information may be needed for this report.

General Codes and Abbreviations

WK	Week.
N	Number of measurements in a group.
Mean; MEAN	Arithmetic mean.
CAM	Covariate-adjusted mean.
SD; S.D.; STAND DEV; STANDARD DEV; sd	Standard deviation.
*	Group 2 mean is significantly different from the mean of the control group (Group 1) at p # 0.05.
-; NA	No value; not applicable; not present.
P	Present.
UNSCHED	Unscheduled.
DISPATCH	Observations transferred from the in-life module of the data collection system to the necropsy module for reference during necropsy. Observations are duplicates of the last in-life observations.
MIN	Minute.
OBS	Observation.

Animal Death Codes:

T	Terminal sacrifice.

Codes for Clinical Pathology

GENERAL CODES

NS	No sample
QS/QNS	Quantity not sufficient
NR	No repeat (sample volume not sufficient for repeat analysis)
FS	Fibrin strands
SC	Sample clotted
SH	Slightly hemolyzed
H	Hemolyzed
SL	Slightly lipemic
L	Lipemic
SI	Slightly icteric
I	Icteric
NF	Animal not fasted
U	Unscheduled/moribund bleed
DT/DOT	Animal died on test
DB	Died during bleeding
TJ	Technician judgment to repeat test
TE	Technical error (instrument or technician error that results in unacceptable data, e.g., unacceptable instrument output, sample spilled, entry of invalid data)
RE	Recording error (recorded incorrect data, e.g., wrong number, spelling error, incorrect date)
EE	Entry error (incorrect keyboard entry)
SE	Sampling error
PC	Platelets clumped
PD	Platelets decreased
PI	Platelets increased
PL	Platelets large
PA	Platelets appear adequate
CO	Color interferes with test
HB	Heinz bodies observed
PLASMO	Plasmodium
NO AGG	No aggregation
FR	Fractious
UTD	Unable to determine
NO COAG	No coagulation

Codes for Clinical Pathology (Continued)

RESULTS NOT INCLUDED IN STATISTICAL ANALYSES

Hemolyzed clinical chemistry or coagulation samples
Samples from animals at unscheduled intervals
Prothrombin times (PT) greater than 50 seconds
Activated partial thromboplastin times (PTT) greater than 110 seconds
Bleed times (BLETIME) greater than 30 minutes

CODES FOR BLOOD CELL MORPHOLOGY

The following scale was used to measure the degree of anisocytosis (ANISO), poikilocytosis (POIK), polychromasia (POLY), hypochromasia (HYPO), and toxic neutrophils (TOXNEUT):

Scale	Degree	Presence
-	Normal for the species	Not present
1	Slight	Rare
2	Moderate	Few
3	Marked	Moderate
4	Not applicable	Many

Abbreviations and Units for Clinical Hematology

Test	Abbreviation (Units)
Red blood cell count	RBC (E6/UL or $X10^6/\Phi L$)
Hemoglobin	HGB (G/DL)
Hematocrit	HCT (%)
Mean corpuscular volume	MCV (FL)
Mean corpuscular hemoglobin	MCH (PG)
Mean corpuscular hemoglobin concentration	MCHC (%)
Platelet count	PLT (E3/UL or $X10^3/\Phi L$)
Mean platelet volume	MPV (FL)
Reticulocyte count	RETIC (%)
Absolute reticulocyte count	RETIC (E3/UL or $X10^3/\Phi L$)
Heinz body count	HEINZ (%)
Erythrocyte sedimentation rate	ESR (MM/HR)
Prothrombin time	PT (SEC)
Activated partial thromboplastin time	PTT (SEC)
Thrombin time	TT (SEC)
Activated coagulation time	ACT (SEC)
Fibrinogen	FBR (MG/DL)
Fibrin/fibrinogen degradation products	FDP (UG/ML)
Platelet aggregation	
Collagen	PAGG/COL (%)
Adenosine diphosphate	PAGG/ADP (%)
Alpha 2-antiplasmin	ANTIPLAS (%)
Bleeding time	BLE TIME (SEC)
Methemoglobin	METHGB (%)
Plasma hemoglobin	PLA HGB (MG/DL)
Myeloid/erythroid ratio	M/E RATIO
Estimated myeloid/erythroid ratio	EST M/E RATIO
White blood cell count	WBC (E3/UL or $X10^3/\Phi L$)
Differential blood cell count	
Nucleated red blood cell count	NRBC (/100 WBC)
Corrected white blood cell count	COR WBC (E3/UL or $X10^3/\Phi L$)
Segmented neutrophil count	N-SEG (E3/UL or $X10^3/\Phi L$) and %
Band neutrophil count	N-BAND (E3/UL or $X10^3/\Phi L$) and %
Lymphocyte count	LYMPH (E3/UL or $X10^3/\Phi L$) and %
Monocyte count	MONO (E3/UL or $X10^3/\Phi L$) and %
Eosinophil count	EOSIN (E3/UL or $X10^3/\Phi L$) and %
Basophil count	BASO (E3/UL or $X10^3/\Phi L$) and %
Anisocytosis	ANISO (-,1,2,3)
Polychromasia	POLY (-,1,2,3)

Abbreviations and Units for Clinical Hematology (Continued)

Test	Abbreviation (Units)
Poikilocytosis	POIK (-,1,2,3)
Hypochromasia	HYPO (-,1,2,3)
Howell-Jolly bodies	HJBODY (-,1,2,3,4)
Basophilic stippling	BASTIP (-,1,2,3)
Toxic neutrophils	TOXNEUT (-,1,2,3,4)
Atypical lymphocytes	ATYPLYM (-,1,2,3,4)
Aqueous white blood cell count (right eye)	R EYE (WBC/UL)
Aqueous white blood cell count (left eye)	L EYE (WBC/UL)

Abbreviations and Units for Clinical Chemistry

Test	Abbreviation (Units)
Glucose	GLU (MG/DL)
Urea nitrogen	UN (MG/DL)
Urea	UREA (MG/DL)
Creatinine	CREAT (MG/DL)
Total protein	T PRO (G/DL)
Albumin	ALB (G/DL)
Globulin	GLOB (G/DL)
Albumin/globulin ratio	A/G RATIO
Total bilirubin	T BILI (MG/DL)
Direct bilirubin	D BILI (MG/DL)
Indirect bilirubin	I BILI (MG/DL)
Cholesterol	CHOL (MG/DL)
Triglyceride	TRIG (MG/DL)
Urea nitrogen/creatinine ratio	UN/CREAT (RATIO)
Total lipids	T LIPIDS (MG/DL)
Phospholipids	P LIPIDS (MG/DL)
High-density lipoprotein cholesterol	HDL (MG/DL)
Low-density lipoprotein cholesterol	LDL (MG/DL)
Uric acid	UA (MG/DL)
Aspartate aminotransferase	AST/SGOT (IU/L)
Alanine aminotransferase	ALT/SGPT (IU/L)
Alkaline phosphatase	ALK PHOS (IU/L)
Gamma glutamyl transferase	GGT (IU/L)
Sorbitol dehydrogenase	SDH (IU/L)
Lactate dehydrogenase	LDH (IU/L)
Creatine kinase	CK (IU/L)
Amylase	AMYLASE (IU/L)
Lipase	LIPASE (IU/L)
Palmitoyl CoA oxidase	PCOAO (IU/G)
Calcium	CA (MG/DL)
Ionized calcium	ION CA (MG/DL)
Inorganic phosphorus	I PHOS (MG/DL)
Sodium	NA (MMOL/L)
Potassium	K (MMOL/L)
Chloride	CL (MMOL/L)
Magnesium	MG (MEQ/L or MG/DL)
Zinc	ZN (MG/L or PPM)
Strontium	SR (MG/L or PPM)
Iron	FE (UG/DL)

Abbreviations and Units for Clinical Chemistry (Continued)

Test	Abbreviation (Units)
Excess iron	EX FE (UG/DL)
Total iron binding capacity	TIBC (UG/DL)
Unbound iron binding capacity	UIBC (UG/DL)
Percent iron saturation	FE %SAT (%)
Plasma cholinesterase	CHEP (MU/ML)
Red blood cell cholinesterase	CHER (MU/ML)
Brain cholinesterase	CHEB (MU/ML)
Caudate putamen	CAUD PUT (UMOL/G)
Hippocampus	HIPPOCAM (UMOL/G)
Frontal cortex	F CORTEX (UMOL/G)
Cerebellum	CEREBELL (UMOL/G)
Bicarbonate	BICARB (MMOL/L)
Serum hemoglobin	SER HGB (MG/DL)
Serum bile acids	SBA (UMOL/L or MG/DL)
Fecal bile acids	FBA (UG/ML)
Average fecal weight	FCC WGT (G)
Fecal bile acids (calculation)	FBA (MG/Day)
Osmolality	OSMO (MOSM/KG)
Electrophoresis	
Albumin	E ALB (G/DL)
Alpha-1-globulin	E A-1 (G/DL)
Alpha-2-globulin	E A-2 (G/DL)
Beta globulin	E BETA (G/DL)
Gamma globulin	E GAMMA (G/DL)
High-density lipoprotein	E-HDL (%)
Low-density lipoprotein	E-LDL (%)
Very-low-density lipoprotein	E-VLDL (%)
Insulin	INSULIN (UU/ML)
Adrenocorticotropic hormone	ACTH (PG/ML)
Cortisol	CORTISOL (UG/ML)
Glucagon	GLUCAGON (PG/ML)
Triiodothyronine	T3 (NG/DL)
Thyroxine	T4 (UG/DL)
Pancreatic-specific amylase	P AMYL (U/L)
Creatine kinase isoenzymes	
BB	CK-BB (U/L)
MB	CK-MB (U/L)
MM	CK-MM (U/L)

Codes for Anatomical Pathology

MICROSCOPIC CODES

Distribution of Findings
Focal
Diffuse
Multifocal

Grades for Severity or Amount

1	Minimal - the least amount of change that can be observed with the light microscope
2	Slight - less than average amount of change, but readily discernible as abnormal
3	Moderate - the average amount of change that is expected for a lesion
4	Moderately severe (marked) - a marked amount of change with possible loss of function of the affected cells or organs
5	Severe - a great amount of change with probable loss of function of the affected cell or organs and frequently involves large areas of the organ

Table 1

Summary of Clinical Observations
A.M./Weekly

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

DAYS 1-30

		NUMBER OF ANIMALS AFFECTED					
	SEX:	-----MALE----			----FEMALE---		
	GROUP:	1	2	3	1	2	3
CATEGORY	DOSE:	0	0.02	2	0	0.02	2
KEYWORD QUALIFIER	NUMBER:	2	3	1	2	3	1
*** TOP OF LIST ***							
APPEARANCE							
SWOLLEN							
LIP(S)		0	0	0	1	0	0
DISCHARGE							
VOMITUS							
CONTAINING FOOD		0	0	1	0	0	0
APPEARS TO BE MENSTRUATING		0	0	0	0	1	0
DISCHARGE UNKNOWN SOURCE							
FOUND IN PAN							
RED IN COLOR		0	0	1	0	0	0
EXCRETION							
FEW FECES		0	0	0	0	0	1
NON-FORMED FECES		0	0	0	2	0	0
SKIN & PELAGE							
RED SKIN							
LIP(S)		0	0	0	1	0	0
SCAB(S)							
MOUTH		0	0	0	1	0	0
QUALITATIVE FOOD CONSUMPTION							
LOW		0	1	0	1	0	1
*** END OF LIST ***							

Table 2

Summary of Clinical Observations
30 Minutes Postdose

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

	NUMBER OF ANIMALS AFFECTED					
DAYS 1-29						
SEX:	-----MALE----			----FEMALE---		
GROUP:	1	2	3	1	2	3
CATEGORY / DOSE:	0	0.02	2	0	0.02	2
KEYWORD / QUALIFIER / NUMBER:	2	3	1	2	3	1
*** TOP OF LIST ***						
APPEARANCE						
SWOLLEN						
LIP(S)	0	0	0	1	0	0
EXCRETION						
NON-FORMED FECES	0	0	0	1	0	0
SKIN & PELAGE						
RED SKIN						
LIP(S)	0	0	0	1	0	0
SCAB(S)						
MOUTH	0	0	0	1	0	0
*** END OF LIST ***						

Table 3

Summary of Clinical Observations
60 Minutes Postdose

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

DAYS 1-29

		NUMBER OF ANIMALS AFFECTED					
	SEX:	-----MALE----			----FEMALE---		
	GROUP:	1	2	3	1	2	3
CATEGORY	DOSE:	0	0.02	2	0	0.02	2
KEYWORD							
QUALIFIER	NUMBER:	2	3	1	2	3	1
*** TOP OF LIST ***							
APPEARANCE							
SWOLLEN							
LIP(S)		0	0	0	1	0	0
EXCRETION							
MUCOID FECES		1	0	0	0	0	0
SKIN & PELAGE							
RED SKIN							
LIP(S)		0	0	0	1	0	0
SCAB(S)							
MOUTH		0	0	0	1	0	0
*** END OF LIST ***							

Table 4

Summary of Clinical Observations
90 Minutes Postdose

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

DAYS 1-29

NUMBER OF ANIMALS AFFECTED

	SEX:	MALE			FEMALE		
	GROUP:	1	2	3	1	2	3
CATEGORY	DOSE:	0	0.02	2	0	0.02	2
KEYWORD							
QUALIFIER	NUMBER:	2	3	1	2	3	1
*** TOP OF LIST ***							
APPEARANCE							
SWOLLEN							
LIP(S)		0	0	0	1	0	0
SKIN & PELAGE							
RED SKIN							
LIP(S)		0	0	0	1	0	0
SCAB(S)							
MOUTH		0	0	0	1	0	0
*** END OF LIST ***							

Table 5

Summary of Clinical Observations
Unscheduled

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

DAYS 1-30

		NUMBER OF ANIMALS AFFECTED					
	SEX:	-----MALE----			----FEMALE---		
	GROUP:	1	2	3	1	2	3
CATEGORY	DOSE:	0	0.02	2	0	0.02	2
KEYWORD							
QUALIFIER	NUMBER:	2	3	1	2	3	1
*** TOP OF LIST ***							
DISCHARGE							
VOMITUS							
CONTAINING FOOD		0	1	0	0	0	0
*** END OF LIST ***							

Table 6

Summary of Body Weight Data (kg)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

	SEX:	MALE			FEMALE		
	GROUP:	1	2	3	1	2	3
	DOSE:	0	0.02	2	0	0.02	2
DAY	UNITS:	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY
-14	N	2	3	1	2	3	1
	MEAN	2.3	2.3	2.2	2.1	2.1	2.2
	S.D.	0.00	0.21		0.07	0.17	
-10	N	2	3	1	2	3	1
	MEAN	2.3	2.3	2.2	2.1	2.1	2.1
	S.D.	0.07	0.21		0.07	0.10	
-7	N	2	3	1	2	3	1
	MEAN	2.3	2.3	2.2	2.1	2.1	2.2
	S.D.	0.07	0.21		0.00	0.15	
-3	N	2	3	1	2	3	1
	MEAN	2.3	2.3	2.2	2.1	2.1	2.1
	S.D.	0.07	0.21		0.00	0.15	
-1	N	2	3	1	2	3	1
	MEAN	2.3	2.4	2.2	2.1	2.1	2.2
	S.D.	0.00	0.25		0.00	0.20	
1	N	2	3	1	2	3	1
	MEAN	2.3	2.3	2.2	2.1	2.2	2.2
	S.D.	0.14	0.21		0.00	0.15	
5	N	2	3	1	2	3	1
	CAM	2.3	2.3		2.0	2.1	
	MEAN	2.3	2.3	2.2	2.0	2.1	2.1
	S.D.	0.07	0.17		0.00	0.15	

Table 6

Summary of Body Weight Data (kg)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

	SEX:	MALE			FEMALE		
	GROUP:	1	2	3	1	2	3
	DOSE:	0	0.02	2	0	0.02	2
DAY	UNITS:	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY
8	N	2	3	1	2	3	1
	CAM	2.5	2.4		2.2	2.2	
	MEAN	2.5	2.4	2.3	2.2	2.2	2.2
	S.D.	0.07	0.12		0.07	0.20	
12	N	2	3	1	2	3	1
	CAM	2.5	2.3*		2.1	2.1	
	MEAN	2.5	2.3	2.2	2.1	2.2	2.2
	S.D.	0.07	0.12		0.00	0.15	
15	N	2	3	1	2	3	1
	CAM	2.4	2.4		2.2	2.2	
	MEAN	2.4	2.4	2.3	2.2	2.2	2.1
	S.D.	0.14	0.06		0.07	0.20	
19	N	2	3	1	2	3	1
	CAM	2.5	2.4		2.1	2.3	
	MEAN	2.5	2.4	2.3	2.1	2.3	2.3
	S.D.	0.07	0.06		0.00	0.17	
22	N	2	3	1	2	3	1
	CAM	2.5	2.4		2.2	2.2	
	MEAN	2.5	2.4	2.1	2.2	2.2	2.1
	S.D.	0.07	0.10		0.07	0.15	
26	N	2	3	1	2	3	1
	CAM	2.5	2.4		2.2	2.2	
	MEAN	2.5	2.4	2.1	2.2	2.2	2.1
	S.D.	0.07	0.10		0.07	0.15	
29	N	2	3	1	2	3	1
	CAM	2.4	2.4		2.1	2.1	
	MEAN	2.4	2.4	2.0	2.1	2.1	2.1
	S.D.	0.07	0.06		0.00	0.15	

Table 7

Summary of Rectal Body Temperature Data (°C)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

	SEX:	MALE			FEMALE		
	GROUP:	1	2	3	1	2	3
	DOSE:	0	0.02	2	0	0.02	2
DAY	UNITS:	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY
-14	N	2	3	1	2	3	1
	MEAN	39.8	39.2	39.6	40.2	40.1	40.0
	S.D.	0.28	0.57		0.28	0.50	
-10	N	2	3	1	2	3	1
	MEAN	40.0	39.2	39.5	39.8	39.7	39.8
	S.D.	0.35	0.40		0.49	0.55	
-7	N	2	3	1	2	3	1
	MEAN	39.8	39.0	39.1	39.9	40.0	39.9
	S.D.	0.57	0.72		0.21	0.38	
-3	N	2	3	1	2	3	1
	MEAN	39.6	39.2	39.2	39.8	39.8	39.7
	S.D.	0.28	0.45		0.49	0.10	
1	N	2	3	1	2	3	1
	MEAN	39.0	39.4	39.4	39.6	39.9	39.5
	S.D.	0.57	0.30		0.35	0.29	
5	N	2	3	1	2	3	1
	MEAN	38.9	39.1	39.9	39.0	39.8	39.7
	S.D.	0.07	0.59		0.35	0.25	
8	N	2	3	1	2	3	1
	MEAN	38.5	39.2	39.6	39.1	39.8	39.9
	S.D.	0.35	0.40		0.42	0.21	

Table 7

Summary of Rectal Body Temperature Data (°C)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

	SEX:	MALE			FEMALE		
	GROUP:	1	2	3	1	2	3
	DOSE:	0	0.02	2	0	0.02	2
DAY	UNITS:	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY
12	N	2	3	1	2	3	1
	MEAN	39.0	39.1	40.0	39.2	39.8	39.7
	S.D.	0.07	0.47		0.14	0.25	
15	N	2	3	1	2	3	1
	MEAN	39.7	39.7	39.7	39.7	40.0	39.8
	S.D.	0.00	0.42		0.57	0.20	
19	N	2	3	1	2	3	1
	MEAN	38.7	38.7	38.9	39.0	39.3	39.3
	S.D.	0.21	0.64		0.35	0.21	
22	N	2	3	1	2	3	1
	MEAN	39.4	39.5	39.4	39.6	39.8	39.4
	S.D.	0.21	0.57		0.42	0.25	
26	N	2	3	1	2	3	1
	MEAN	38.8	39.2	39.2	39.0	39.6	39.1
	S.D.	0.07	0.38		0.35	0.15	
29	N	2	3	1	2	3	1
	MEAN	38.5	38.8	38.9	38.8	39.1	39.2
	S.D.	0.42	0.35		0.14	0.38	

Table 8

Summary of Clinical Hematology Data

Males Day -7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		RBC $X10^6/\mu L$	HGB G/DL	HCT %	MCV FL	MCH PG	MCHC %	PLT $X10^3/\mu L$	RETIC %	RETIC $X10^3/\mu L$
0										
	MEAN	5.64	14.0	42.6	75.4	24.8	32.9	502	.9	51
	S.D.	.332	1.41	3.82	2.26	1.06	.42	138.6	.00	2.8
	N	2	2	2	2	2	2	2	2	2
0.02										
	MEAN	5.18	12.6	39.1	75.4	24.4	32.4	454	.9	46
	S.D.	.272	.31	.90	2.21	1.10	.91	88.1	.53	26.1
	N	3	3	3	3	3	3	3	3	3
2.0										
	MEAN	5.91	12.8	41.0	69.4	21.7	31.2	531	.7	41
	N	1	1	1	1	1	1	1	1	1

Table 8

Summary of Clinical Hematology Data

Males Day -7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		WBC $X10^3/\mu L$	N-SEG $X10^3/\mu L$	LYMPH $X10^3/\mu L$	MONO $X10^3/\mu L$	EOSIN $X10^3/\mu L$	BASO $X10^3/\mu L$	N-SEG%	LYMPH%	MONO%	EOSIN%	BASO%
0												
	MEAN	8.4	3.4	4.6	.4	.1	.0	40	54	4	1	0
	S.D.	.99	1.06	.07	.07	.14	.00	7.8	7.1	.7	1.4	.0
	N	2	2	2	2	2	2	2	2	2	2	2
0.02												
	MEAN	9.2	2.9	5.8	.4	.1	.0	31	63	4	1	0
	S.D.	1.00	1.33	1.46	.20	.10	.00	16.5	14.6	2.0	1.0	.0
	N	3	3	3	3	3	3	3	3	3	3	3
2.0												
	MEAN	8.2	2.8	4.8	.6	.0	.0	34	58	8	0	0
	N	1	1	1	1	1	1	1	1	1	1	1

Table 8

Summary of Clinical Hematology Data

Females Day -7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		RBC $X10^6/\mu L$	HGB G/DL	HCT %	MCV FL	MCH PG	MCHC %	PLT $X10^3/\mu L$	RETIC %	RETIC $X10^3/\mu L$
0										
	MEAN	5.25	13.3	40.4	76.9	25.4	33.1	478	.8	45
	S.D.	.325	1.34	3.96	2.69	.92	.00	180.3	.21	14.1
	N	2	2	2	2	2	2	2	2	2
0.02										
	MEAN	5.00	12.8	39.1	78.2	25.6	32.7	430	.7	35
	S.D.	.241	.21	.21	3.30	1.55	.56	121.3	.17	8.5
	N	3	3	3	3	3	3	3	3	3
2.0										
	MEAN	5.53	13.4	40.2	72.7	24.2	33.3	505	.8	44
	N	1	1	1	1	1	1	1	1	1

Table 8

Summary of Clinical Hematology Data

Females Day -7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		WBC $X10^3/\mu L$	N-SEG $X10^3/\mu L$	LYMPH $X10^3/\mu L$	MONO $X10^3/\mu L$	EOSIN $X10^3/\mu L$	BASO $X10^3/\mu L$	N-SEG%	LYMPH%	MONO%	EOSIN%	BASO%
0												
	MEAN	9.0	3.6	5.1	.2	.0	.0	38	58	2	0	0
	S.D.	1.48	1.91	.14	.28	.07	.00	14.8	11.3	3.5	.7	.0
	N	2	2	2	2	2	2	2	2	2	2	2
0.02												
	MEAN	10.2	3.5	6.2	.4	.1	.0	36	59	4	1	0
	S.D.	1.97	3.29	4.05	.12	.10	.00	34.2	32.9	1.5	1.0	.0
	N	3	3	3	3	3	3	3	3	3	3	3
2.0												
	MEAN	11.7	6.2	4.8	.4	.2	.0	53	42	4	1	0
	N	1	1	1	1	1	1	1	1	1	1	1

Table 9

Summary of Clinical Hematology Data

Males Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		RBC $X10^6/\mu L$	HGB G/DL	HCT %	MCV FL	MCH PG	MCHC %	PLT $X10^3/\mu L$	RETIC %	RETIC $X10^3/\mu L$
0										
	MEAN	6.02	14.0	44.0	72.9	23.3	31.9	440	.8	48
	S.D.	.035	.64	1.84	2.69	.99	.21	116.7	.14	8.5
	N	2	2	2	2	2	2	2	2	2
0.02										
	MEAN	5.12 *	12.6	39.1	76.4	24.6	32.2	392	.5	28
	S.D.	.262	.78	2.18	1.69	.61	.26	92.1	.35	19.8
	N	3	3	3	3	3	3	3	3	3
2.0										
	MEAN	5.69	13.2	41.5	73.1	23.1	31.7	503	.2	11
	N	1	1	1	1	1	1	1	1	1

Table 9

Summary of Clinical Hematology Data

Males Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		WBC $X10^3/\mu L$	N-SEG $X10^3/\mu L$	LYMPH $X10^3/\mu L$	MONO $X10^3/\mu L$	EOSIN $X10^3/\mu L$	BASO $X10^3/\mu L$	N-SEG%	LYMPH%	MONO%	EOSIN%	BASO%
0												
	MEAN	9.2	1.6	6.8	.6	.2	.0	18	74	6	2	0
	S.D.	.21	.49	.78	.21	.14	.00	5.7	7.1	2.8	1.4	.0
	N	2	2	2	2	2	2	2	2	2	2	2
0.02												
	MEAN	8.8	1.0	6.9	.6	.2	.0	13	78	6	2	0
	S.D.	2.44	.15	2.27	.38	.10	.00	6.1	5.5	2.3	1.0	.0
	N	3	3	3	3	3	3	3	3	3	3	3
2.0												
	MEAN	5.8	.9	4.4	.4	.0	.0	16	77	7	0	0
	N	1	1	1	1	1	1	1	1	1	1	1

Table 9

Summary of Clinical Hematology Data

Females Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		RBC $X10^6/\mu L$	HGB G/DL	HCT %	MCV FL	MCH PG	MCHC %	PLT $X10^3/\mu L$	RETIC %	RETIC $X10^3/\mu L$
0										
	MEAN	5.14	13.2	40.5	78.9	25.6	32.5	511	1.2	59
	S.D.	.170	.78	2.33	2.12	.71	.00	182.4	.21	12.7
	N	2	2	2	2	2	2	2	2	2
0.02										
	MEAN	5.13	13.1	41.1	80.1	25.5	31.9	425	.8	41
	S.D.	.116	.87	1.74	3.93	1.80	.81	116.7	.26	14.0
	N	3	3	3	3	3	3	3	3	3
2.0										
	MEAN	4.81	12.3	36.7	76.4	25.6	33.6	529	1.0	48
	N	1	1	1	1	1	1	1	1	1

Table 9

Summary of Clinical Hematology Data

Females Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		WBC $X10^3/\mu L$	N-SEG $X10^3/\mu L$	LYMPH $X10^3/\mu L$	MONO $X10^3/\mu L$	EOSIN $X10^3/\mu L$	BASO $X10^3/\mu L$	N-SEG%	LYMPH%	MONO%	EOSIN%	BASO%
0												
	MEAN	11.1	3.8	6.2	1.0	.0	.0	36	54	10	0	0
	S.D.	2.69	.14	2.55	.21	.00	.00	10.6	10.6	.7	.0	.0
	N	2	2	2	2	2	2	2	2	2	2	2
0.02												
	MEAN	10.0	2.2 *	7.1	.6 *	.1	.0	22	70	6	1	0
	S.D.	2.55	.45	2.67	.06	.00	.00	7.6	9.2	2.1	.0	.0
	N	3	3	3	3	3	3	3	3	3	3	3
2.0												
	MEAN	15.7	7.2	7.9	.5	.1	.0	46	50	3	1	0
	N	1	1	1	1	1	1	1	1	1	1	1

Table 10

Summary of Clinical Chemistry Data

Males Day -7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
0											
	MEAN	82	24	1.0	8.2	5.2	3.0	.2	8	155	64
	S.D.	19.1	1.4	.07	.00	.00	.00	.07	.7	62.2	24.7
	N	2	2	2	2	2	2	2	2	2	2
0.02											
	MEAN	61	29	1.0	7.7	4.8	3.0	.3	9	161	85
	S.D.	13.2	2.0	.06	.06	.29	.32	.06	1.5	35.4	22.2
	N	3	3	3	3	3	3	3	3	3	3
2.0											
	MEAN	54	28	1.0	8.2	5.0	3.2	.4	10	150	68
	N	1	1	1	1	1	1	1	1	1	1

Table 10

Summary of Clinical Chemistry Data

Males Day -7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
0										
	MEAN	48	40	612	88	4	228	424	64	291
	S.D.	4.9	9.2	36.1	4.9	.7	102.5	99.7	37.5	69.3
	N	2	2	2	2	2	2	2	2	2
0.02										
	MEAN	50	58	681	101	6	214	315	62	223
	S.D.	7.6	13.0	81.1	36.7	1.2	17.2	63.1	61.2	50.1
	N	3	3	3	3	3	3	3	3	3
2.0										
	MEAN	54	50	1086	117	5	220	244	7	144
	N	1	1	1	1	1	1	1	1	1

Table 10

Summary of Clinical Chemistry Data

Males Day -7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0						
	MEAN	10.7	7.2	162	5.8	110
	S.D.	.14	.57	2.1	.07	.0
	N	2	2	2	2	2
0.02						
	MEAN	10.6	7.7	159	5.6	112
	S.D.	.52	.71	5.0	.47	4.6
	N	3	3	3	3	3
2.0						
	MEAN	11.4	8.7	162	5.9	111
	N	1	1	1	1	1

Table 10

Summary of Clinical Chemistry Data

Females Day -7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
0											
	MEAN	76	24	1.0	8.0	5.1	2.8	.5	4	142	76
	S.D.	8.5	.0	.14	.49	.42	.07	.28	5.7	15.6	14.1
	N	2	2	2	2	2	2	2	2	2	2
0.02											
	MEAN	64	26	.9	7.9	4.9	3.0	.4	9	154	69
	S.D.	9.0	4.6	.06	.30	.26	.10	.06	2.1	34.6	35.8
	N	3	3	3	3	3	3	3	3	3	3
2.0											
	MEAN	71	27	1.0	8.2	4.9	3.3	.3	12	141	67
	N	1	1	1	1	1	1	1	1	1	1

Table 10

Summary of Clinical Chemistry Data

Females Day -7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
0										
	MEAN	99	53	593	80	6	1907	334	10	232
	S.D.	76.4	21.2	66.5	2.1	4.9	2286.8	31.1	10.6	21.9
	N	2	2	2	2	2	2	2	2	2
0.02										
	MEAN	58	58	828	74	4	385	324	64	215
	S.D.	6.7	14.2	65.5	10.1	1.0	163.0	44.1	81.8	19.4
	N	3	3	3	3	3	3	3	3	3
2.0										
	MEAN	53	55	683	110	3	1094	315	89	224
	N	1	1	1	1	1	1	1	1	1

Table 10

Summary of Clinical Chemistry Data

Females Day -7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0						
	MEAN	11.0	7.4	159	7.2	113
	S.D.	.49	1.27	2.8	1.91	2.8
	N	2	2	2	2	2
0.02						
	MEAN	11.0	8.0	158	5.8	114
	S.D.	.59	1.72	6.7	.64	4.0
	N	3	3	3	3	3
2.0						
	MEAN	11.3	6.8	165	6.0	115
	N	1	1	1	1	1

Table 11

Summary of Clinical Chemistry Data

Males Day 2

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
0											
	MEAN	57	25	.9	7.4	5.0	2.4	.4	16	142	80
	S.D.	7.1	5.7	.00	.07	.07	.00	.07	4.2	64.3	48.8
	N	2	2	2	2	2	2	2	2	2	2
0.02											
	MEAN	62	24	.8	7.0 *	4.5 *	2.6	.3	10 *	163	69
	S.D.	6.0	2.3	.06	.12	.12	.23	.06	.6	18.3	18.6
	N	3	3	3	3	3	3	3	3	3	3
2.0											
	MEAN	58	21	.9	7.3	4.7	2.6	.4	9	151	50
	N	1	1	1	1	1	1	1	1	1	1

Table 11

Summary of Clinical Chemistry Data

Males Day 2

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
0										
	MEAN	75	56	726	84	2	899	412	31	256
	S.D.	14.1	21.2	48.8	6.4	.7	5.7	69.3	5.7	40.3
	N	2	2	2	2	2	2	2	2	2
0.02										
	MEAN	41	56	599	88	2	579	289	40	180
	S.D.	2.5	14.8	82.7	31.8	.0	391.1	51.3	19.6	30.7
	N	3	3	3	3	3	3	3	3	3
2.0										
	MEAN	54	55	1028	105	2	219	302	11	139
	N	1	1	1	1	1	1	1	1	1

Table 11

Summary of Clinical Chemistry Data

Males Day 2

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0						
	MEAN	10.2	6.8	152	5.2	106
	S.D.	.14	1.06	1.4	.07	.7
	N	2	2	2	2	2
0.02						
	MEAN	9.5 *	6.7	147	4.7	108
	S.D.	.26	.31	2.5	.25	4.0
	N	3	3	3	3	3
2.0						
	MEAN	10.0	7.0	152	5.0	104
	N	1	1	1	1	1

Table 11

Summary of Clinical Chemistry Data

Females Day 2

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
0											
	MEAN	70	19	.8	7.4	4.9	2.5	.4	8	145	42
	S.D.	14.1	.0	.07	.42	.28	.14	.07	.7	2.8	11.3
	N	2	2	2	2	2	2	2	2	2	2
0.02											
	MEAN	57	24	.8	7.3	4.7	2.6	.5	16 *	133	69
	S.D.	3.5	3.5	.06	.15	.30	.23	.06	1.0	28.2	33.7
	N	3	3	3	3	3	3	3	3	3	3
2.0											
	MEAN	68	27	1.0	7.5	4.7	2.8	.4	17	136	47
	N	1	1	1	1	1	1	1	1	1	1

Table 11

Summary of Clinical Chemistry Data

Females Day 2

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
0										
	MEAN	58	72	578	81	2	523	502	39	324
	S.D.	18.4	43.1	123.0	5.7	.7	15.6	138.6	5.7	96.9
	N	2	2	2	2	2	2	2	2	2
0.02										
	MEAN	54	57	805	69	2	426	351	31	208
	S.D.	4.5	16.9	65.3	8.1	.6	133.3	46.2	9.2	24.7
	N	3	3	3	3	3	3	3	3	3
2.0										
	MEAN	46	55	672	100	2	308	291	84	184
	N	1	1	1	1	1	1	1	1	1

Table 11

Summary of Clinical Chemistry Data

Females Day 2

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0						
	MEAN	10.2	6.7	153	5.4	108
	S.D.	.71	.28	4.2	.64	.0
	N	2	2	2	2	2
0.02						
	MEAN	10.0	7.6	151	4.9	105
	S.D.	.25	.85	6.2	.21	2.3
	N	3	3	3	3	3
2.0						
	MEAN	10.0	6.5	151	4.7	106
	N	1	1	1	1	1

Table 12

Summary of Clinical Chemistry Data

Males Day 7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
0											
	MEAN	81	20	.8	7.8	4.8	3.0	.2	10	138	52
	S.D.	4.2	.0	.07	.28	.21	.07	.07	4.9	65.8	7.1
	N	2	2	2	2	2	2	2	2	2	2
0.02											
	MEAN	68 *	21	.8	7.5	4.5 *	3.1	.3	10	156	51
	S.D.	3.1	1.5	.06	.25	.06	.25	.00	1.2	19.3	1.5
	N	3	3	3	3	3	3	3	3	3	3
2.0											
	MEAN	63	18	.8	7.5	4.6	2.9	.4	7	137	50
	N	1	1	1	1	1	1	1	1	1	1

Table 12

Summary of Clinical Chemistry Data

Males Day 7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
0										
	MEAN	51	46	770	80	0	249	397	33	272
	S.D.	15.6	13.4	78.5	.0	.0	79.2	67.9	7.1	48.1
	N	2	2	2	2	2	2	2	2	2
0.02										
	MEAN	39	57	556	85	0	399	327	31	225
	S.D.	3.8	15.0	106.4	34.6	.0	415.4	35.6	13.5	24.1
	N	3	3	3	3	3	3	3	3	3
2.0										
	MEAN	46	49	1012	98	0	270	260	0	139
	N	1	1	1	1	1	1	1	1	1

Table 12

Summary of Clinical Chemistry Data

Males Day 7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0						
	MEAN	10.2	7.0	156	5.2	112
	S.D.	.35	.49	3.5	.21	.0
	N	2	2	2	2	2
0.02						
	MEAN	9.8	7.0	152	4.8	112
	S.D.	.32	.35	3.6	.29	2.5
	N	3	3	3	3	3
2.0						
	MEAN	10.3	6.6	156	5.1	112
	N	1	1	1	1	1

Table 12

Summary of Clinical Chemistry Data

Females Day 7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
0											
	MEAN	86	20	.8	8.0	4.6	3.5	.2	7	130	32
	S.D.	9.2	6.4	.00	.07	.49	.42	.07	1.4	2.1	13.4
	N	2	2	2	2	2	2	2	2	2	2
0.02											
	MEAN	73	19	.8	8.0	4.8	3.2	.3	8	147	38
	S.D.	4.6	1.5	.10	.17	.31	.15	.06	.0	31.3	6.8
	N	3	3	3	3	3	3	3	3	3	3
2.0											
	MEAN	73	18	.8	7.9	4.6	3.3	.3	12	117	44
	N	1	1	1	1	1	1	1	1	1	1

Table 12

Summary of Clinical Chemistry Data

Females Day 7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
0										
	MEAN	46	52	558	69	0	142	434	30	303
	S.D.	.7	13.4	94.0	8.5	.7	55.2	26.9	10.6	26.9
	N	2	2	2	2	2	2	2	2	2
0.02										
	MEAN	49	57	775	68	0	218	356 *	25	231
	S.D.	8.1	6.9	108.2	9.6	.6	27.8	18.9	5.1	34.1
	N	3	3	3	3	3	3	3	3	3
2.0										
	MEAN	45	57	674	90	0	166	349	101	238
	N	1	1	1	1	1	1	1	1	1

Table 12

Summary of Clinical Chemistry Data

Females Day 7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0						
	MEAN	11.0	6.1	156	6.4	112
	S.D.	.78	.57	2.1	.92	.7
	N	2	2	2	2	2
0.02						
	MEAN	10.7	7.3	155	5.5	113
	S.D.	.40	.78	6.1	.20	1.5
	N	3	3	3	3	3
2.0						
	MEAN	10.6	6.4	155	5.3	113
	N	1	1	1	1	1

Table 13

Summary of Clinical Chemistry Data

Males Day 14

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
0											
	MEAN	80	19	.8	7.7	5.0	2.7	.4	8	141	38
	S.D.	13.4	1.4	.07	.42	.28	.14	.00	2.1	58.0	7.1
	N	2	2	2	2	2	2	2	2	2	2
0.02											
	MEAN	63	19	.7	7.2	4.5	2.7	.4	8	150	44
	S.D.	3.8	1.0	.23	.45	.17	.32	.00	2.1	12.2	9.5
	N	3	3	3	3	3	3	3	3	3	3
2.0											
	MEAN	64	15	.7	7.4	4.8	2.6	.4	6	132	27
	N	1	1	1	1	1	1	1	1	1	1

Table 13

Summary of Clinical Chemistry Data

Males Day 14

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
0										
	MEAN	47	40	761	80	4	162	394	35	262
	S.D.	7.1	9.2	33.9	7.8	2.1	43.8	30.4	8.5	20.5
	N	2	2	2	2	2	2	2	2	2
0.02										
	MEAN	36	49	519	77	3	111	306	35	203
	S.D.	5.7	8.0	131.9	37.0	.6	35.2	40.8	18.6	28.9
	N	3	3	3	3	3	3	3	3	3
2.0										
	MEAN	39	45	908	89	2	245	242	2	123
	N	1	1	1	1	1	1	1	1	1

Table 13

Summary of Clinical Chemistry Data

Males Day 14

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0						
	MEAN	10.2	7.6	151	4.8	106
	S.D.	.21	1.63	1.4	.28	.7
	N	2	2	2	2	2
0.02						
	MEAN	9.7 *	6.7	148	4.5	107
	S.D.	.15	.64	1.0	.30	1.0
	N	3	3	3	3	3
2.0						
	MEAN	10.1	6.4	153	4.8	108
	N	1	1	1	1	1

Table 13

Summary of Clinical Chemistry Data

Females Day 14

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
0											
	MEAN	80	19	.6	7.5	4.6	2.8	.4	7	119	24
	S.D.	3.5	4.2	.07	.14	.21	.35	.07	.0	11.3	4.9
	N	2	2	2	2	2	2	2	2	2	2
0.02											
	MEAN	58	20	.7	7.7	4.8	2.9	.5	8	139	35
	S.D.	9.0	2.5	.20	.25	.30	.06	.15	1.5	24.1	7.0
	N	3	3	3	3	3	3	3	3	3	3
2.0											
	MEAN	59	18	.8	7.8	4.6	3.2	.4	8	107	41
	N	1	1	1	1	1	1	1	1	1	1

Table 13

Summary of Clinical Chemistry Data

Females Day 14

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
0										
	MEAN	46	46	499	64	4	259	428	30	288
	S.D.	8.5	7.8	58.0	.7	.7	144.2	40.3	16.3	36.1
	N	2	2	2	2	2	2	2	2	2
0.02										
	MEAN	47	55	800 *	63	3	307	320 *	39	200 *
	S.D.	7.5	11.3	68.6	10.4	.6	97.5	27.2	24.6	18.8
	N	3	3	3	3	3	3	3	3	3
2.0										
	MEAN	40	51	727	86	3	462	440	309	283
	N	1	1	1	1	1	1	1	1	1

Table 13

Summary of Clinical Chemistry Data

Females Day 14

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0						
	MEAN	10.4	6.8	154	6.0	110
	S.D.	.49	.28	3.5	.71	.7
	N	2	2	2	2	2
0.02						
	MEAN	10.4	6.7	151	5.2	108
	S.D.	.46	.69	6.8	.25	3.6
	N	3	3	3	3	3
2.0						
	MEAN	10.4	6.1	152	5.4	108
	N	1	1	1	1	1

Table 14

Summary of Clinical Chemistry Data

Males Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
0											
	MEAN	81	24	.8	7.6	4.6	3.0	.2	7	140	36
	S.D.	8.5	.0	.07	.14	.00	.14	.07	1.4	65.8	6.4
	N	2	2	2	2	2	2	2	2	2	2
0.02											
	MEAN	73	24	.8	7.5	4.3	3.2	.2	10	151	53 *
	S.D.	7.0	4.0	.15	1.04	.44	.65	.06	3.1	21.5	4.7
	N	3	3	3	3	3	3	3	3	3	3
2.0											
	MEAN	80	15	1.1	8.2	4.8	3.4	.3	8	91	25
	N	1	1	1	1	1	1	1	1	1	1

Table 14

Summary of Clinical Chemistry Data

Males Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
0										
	MEAN	52	46	755	96	4	410	424	37	285
	S.D.	12.7	14.1	60.8	9.2	2.8	93.3	87.0	.0	62.2
	N	2	2	2	2	2	2	2	2	2
0.02										
	MEAN	42	62	564	94	3	314	334	35	228
	S.D.	7.5	26.6	127.2	42.9	1.2	255.2	57.7	33.9	39.5
	N	3	3	3	3	3	3	3	3	3
2.0										
	MEAN	31	38	815	88	1	202	285	3	156
	N	1	1	1	1	1	1	1	1	1

Table 14

Summary of Clinical Chemistry Data

Males Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0						
	MEAN	10.5	7.5	154	5.6	111
	S.D.	.14	.99	2.1	.92	1.4
	N	2	2	2	2	2
0.02						
	MEAN	10.2	6.3	152	5.1	110
	S.D.	.29	.40	3.0	.79	2.0
	N	3	3	3	3	3
2.0						
	MEAN	11.0	6.4	156	6.0	107
	N	1	1	1	1	1

Table 14

Summary of Clinical Chemistry Data

Females Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
0											
	MEAN	86	25	.8	7.6	4.4	3.3	.2	9	121	38
	S.D.	.7	1.4	.07	.35	.07	.42	.00	2.8	19.8	3.5
	N	2	2	2	2	2	2	2	2	2	2
0.02											
	MEAN	62	24	.9	7.9	4.6	3.3	.3	9	143	46
	S.D.	10.8	3.8	.12	.57	.38	.20	.10	1.7	24.8	6.0
	N	3	3	3	3	3	3	3	3	3	3
2.0											
	MEAN	78	24	1.0	8.2	4.6	3.6	.2	17	62	27
	N	1	1	1	1	1	1	1	1	1	1

Table 14

Summary of Clinical Chemistry Data

Females Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
0										
	MEAN	53	46	467	72	6	298	538	130	370
	S.D.	9.9	9.2	69.3	3.5	3.5	51.6	133.6	157.7	99.0
	N	2	2	2	2	2	2	2	2	2
0.02										
	MEAN	45	54	908 *	76	3	273	340	23	218
	S.D.	7.1	5.7	68.8	7.6	1.2	79.2	46.1	14.7	34.0
	N	3	3	3	3	3	3	3	3	3
2.0										
	MEAN	36	47	637	93	2	341	326	18	221
	N	1	1	1	1	1	1	1	1	1

Table 14

Summary of Clinical Chemistry Data

Females Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0						
	MEAN	10.4	6.4	152	5.7	111
	S.D.	.21	1.06	1.4	.42	2.8
	N	2	2	2	2	2
0.02						
	MEAN	10.9	6.9	155	5.5	111
	S.D.	.46	.89	4.4	.10	2.1
	N	3	3	3	3	3
2.0						
	MEAN	11.1	6.5	158	5.7	110
	N	1	1	1	1	1

Table 15

Summary of Clinical Chemistry Data

Males Day 30

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		PCOAO IU/G
0		
	MEAN	0
	S.D.	.7
	N	2
0.02		
	MEAN	4 *
	S.D.	.6
	N	3
2.0		
	MEAN	1
	S.D.	.0
	N	1

Table 15

Summary of Clinical Chemistry Data

Females Day 30

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		PCOAO IU/G
0		
	MEAN	2
	S.D.	2.8
	N	2
0.02		
	MEAN	3
	S.D.	3.5
	N	3
2.0		
	MEAN	1
	S.D.	.0
	N	1

TABLE 16

Incidence of Macroscopic Observations

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---					
	SEX:	-----MALE----			----FEMALE---		
	GROUP:	-1-	-2-	-3-	-1-	-2-	-3-
	NUMBER:	2	3	1	2	3	1
** TOP OF LIST **							
GENERAL COMMENT (GC)	NUMBER EXAMINED:	2	3	1	2	3	1
BONE MARROW SMEAR TAKEN		2	3	1	2	3	1
EYES - DAVIDSONS		2	3	1	2	3	1
STAINS-PERINEUM/PERIANAL		0	0	0	0	1	0
NO MACROSCOPIC LESIONS		2	3	1	2	2	1
** END OF LIST **							

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER OF ANIMALS AFFECTED ---					
SEX:		-----MALE----			----FEMALE---		
GROUP:		-1-	-2-	-3-	-1-	-2-	-3-
NUMBER:		2	3	1	2	3	1
** TOP OF LIST **							
EYE (EY)	NUMBER EXAMINED:	2	3	1	2	3	1
	NOT REMARKABLE:	2	3	1	2	3	1
BONE, FEMUR (FE)	NUMBER EXAMINED:	2	3	1	2	3	1
	NOT REMARKABLE:	2	3	1	2	3	1
MARROW, FEMUR (FM)	NUMBER EXAMINED:	0	1	0	1	2	1
	NOT REMARKABLE:	0	1	0	1	2	1
KIDNEY (KD)	NUMBER EXAMINED:	2	3	1	2	3	1
	NOT REMARKABLE:	2	2	1	1	1	1
--INFILTRATE, LYMPHOPLASMACYTIC		0	1	0	1	2	0
LUNG (LU)	NUMBER EXAMINED:	2	3	1	2	3	1
	NOT REMARKABLE:	2	3	1	2	3	1
LIVER (LI)	NUMBER EXAMINED:	2	3	1	2	3	1
	NOT REMARKABLE:	2	2	1	0	1	1
--INFILTRATE, LYMPHOPLASMACYTIC		0	1	0	1	2	0
--INFLAMMATION, LYMPHOHISTIOCYTIC		0	0	0	1	0	0
--LIPIDOSIS, SUBCAPSULAR (TENSION LIPIDOSIS)		0	0	0	1	0	0

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---					
SEX:		-----MALE----			----FEMALE---		
GROUP:		-1-	-2-	-3-	-1-	-2-	-3-
NUMBER:		2	3	1	2	3	1
SPLEEN (SP)	NUMBER EXAMINED:	2	3	1	2	3	1
	NOT REMARKABLE:	2	3	1	2	3	1
PANCREAS (PA)	NUMBER EXAMINED:	2	3	1	2	3	1
	NOT REMARKABLE:	2	3	1	2	3	1
ADRENAL, CORTEX (AC)	NUMBER EXAMINED:	2	3	1	2	3	1
	NOT REMARKABLE:	2	3	1	2	2	1
--HEMORRHAGE		0	0	0	0	1	0
--THROMBUS		0	0	0	0	1	0
ADRENAL, MEDULLA (MA)	NUMBER EXAMINED:	2	3	1	2	3	1
	NOT REMARKABLE:	2	3	1	2	3	1
THYMUS (TH)	NUMBER EXAMINED:	2	3	1	2	3	1
	NOT REMARKABLE:	2	3	1	2	3	1
TESTIS (TE)	NUMBER EXAMINED:	2	3	1	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0
--IMMATURE		2	3	1	0	0	0

** END OF LIST **

APPENDIX 1

Protocol Deviations
Protocol
Protocol Amendment No. 1
Protocol Amendment No. 2
Protocol Amendment No. 3
Material Safety Data Sheet

Protocol Deviations

Protocol. Group Designations and Dosage Levels. Dose levels were 0, 0.02, and 2.0 mg/kg/day. The control group (Group 1) was to receive an equivalent amount of lactose in gelatin capsules as the total material administered to Group 3. The total material was 20.0 mg/kg/day for each group; however, the low- and high-dose groups were to receive test material triturated with lactose (1:999, w:w, and 1:9, w:w, respectively).

Actual Procedure. Because the capsule broke during dose administration, the following animals may not have received the full amount of dose preparation: Animal No. I05350 (Group 1 male) on Day 1; Animal No. I05367 (Group 1 female) on Days 2, 7, and 14; Animal No. I05344 (Group 2 male) on Day 7; and Animal No. I05369 (Group 3 female) on Day 2.

Protocol. Observation of Animals. Rectal Body Temperatures. "Beginning 2 weeks before initiation of treatment, rectal body temperatures will be taken at approximately 11:00 on two days/week (Monday and Thursday)."

Actual Procedure. Rectal body temperatures were recorded between 12:50 and 13:30 on Day -14 and between 08:17 and 08:40 on Day -10.

Protocol. Serum PFOS Level Determination. Frequency. "Before initiation of treatment (Day -7 or -6), and prior to treatment on Days 2 (approximately 24 hours after the first dose), 7, 14, and 29."

Actual Procedure. On Day 2, incorrect blood collection tubes were used for the collection of blood for clinical chemistry test; therefore, blood collected for serum PFOS level determinations was used for clinical chemistry tests. Remaining serum from clinical chemistry tests was used as the Day 2 sample for serum PFOS level determinations. In addition, whole blood (approximately 2 mL) was collected from a femoral vein of each animal before treatment on Day 3 (approximately 24 hours after the second dose).

Protocol Deviations (Continued)

Protocol. Additional Blood Collection. "At scheduled and unscheduled necropsies, blood (as much as possible, up to 20 mL) will be collected from animals at the time of exsanguination."

Actual Procedure. Additional blood was not collected from Animal Nos. I05364 (Group 2 female), I05365 (Group 2 female), and I05369 (Group 3 female).

Protocol. Postmortem Procedures. Tissue Preservation. "The following tissues (when present) from each animal will be preserved in 10% neutral-buffered formalin, unless otherwise specified, for possible future microscopic examination:"

Actual Procedure. Femoral bone marrow from Animal Nos. I05349 and I05350 (Group 1 males), I05344 and I05348 (Group 2 males), I05345 (Group 3 male), I05366 (Group 1 female), and I05364 (Group 2 female) were insufficient; therefore, these tissues were not examined microscopically. This tissue is listed with the appropriate comments in the pathology data sheets for each individual animal. Summary tables do not include it as having been examined.

These deviations are not expected to have affected the results of the study.

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Protocol Amendment No. 3

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Material Safety Data Sheet

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APPENDIX 2

Individual Animal Fate Data
Individual Clinical Observations
Individual Rectal Body Temperature Data (°C)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	DOSE GROUP	SEX	DEATH CODE	TYPE OF DEATH	DESCRIPTION OF DEATH	DATE OF DEATH	DAY OF STUDY	WEEK OF STUDY
I05349	1	MALE	T	SCHEDULED	TERMINAL SACRIFICE	05/22/98	30	5
I05350	1	MALE	T	SCHEDULED	TERMINAL SACRIFICE	05/22/98	30	5
I05344	2	MALE	T	SCHEDULED	TERMINAL SACRIFICE	05/22/98	30	5
I05347	2	MALE	T	SCHEDULED	TERMINAL SACRIFICE	05/22/98	30	5
I05348	2	MALE	T	SCHEDULED	TERMINAL SACRIFICE	05/22/98	30	5
I05345	3	MALE	T	SCHEDULED	TERMINAL SACRIFICE	05/22/98	30	5
I05366	1	FEMALE	T	SCHEDULED	TERMINAL SACRIFICE	05/22/98	30	5
I05367	1	FEMALE	T	SCHEDULED	TERMINAL SACRIFICE	05/22/98	30	5
I05364	2	FEMALE	T	SCHEDULED	TERMINAL SACRIFICE	05/22/98	30	5
I05365	2	FEMALE	T	SCHEDULED	TERMINAL SACRIFICE	05/22/98	30	5
I05370	2	FEMALE	T	SCHEDULED	TERMINAL SACRIFICE	05/22/98	30	5
I05369	3	FEMALE	T	SCHEDULED	TERMINAL SACRIFICE	05/22/98	30	5

Appendix 2

Individual Clinical Observations

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

CATEGORY GROUP: M1 DOSE: 0 MG/KG/DAY 'C' - COMMENTS LISTED AT END OF OBSERVATIONS FOR SEX/GROUP

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	KEYWORD QUALIFIER	DAYS 1-30	DAY	AM OBS	PM CHECK	30MIN	60MIN	90MIN	DISPATCH	UNSCHED
I05349	T	5	NORMAL									
			NO REMARKABLE OBSERVATIONS		1	P	-	-	-	-	-	-
					8	P	-	-	-	-	-	-
					15	P	-	-	-	-	-	-
					22	P	-	-	-	-	-	-
					29	P	-	-	-	-	-	-
					30	P	-	-	-	-	P	-
I05350	T	5	EXCRETION									
			MUCOID FECES		12	-	-	-	P	-	-	-
			NORMAL									
			NO REMARKABLE OBSERVATIONS		1	P	-	-	-	-	-	-
					8	P	-	-	-	-	-	-
					15	P	-	-	-	-	-	-
					22	P	-	-	-	-	-	-
					29	P	-	-	-	-	-	-
					30	P	-	-	-	-	P	-

Appendix 2

Individual Clinical Observations

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

CATEGORY GROUP: M2 DOSE: 0.02 MG/KG/DAY 'C' - COMMENTS LISTED AT END OF OBSERVATIONS FOR SEX/GROUP

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	KEYWORD QUALIFIER	DAYS 1-30	DAY	AM OBS	PM CHECK	30MIN	60MIN	90MIN	UNSCHED DISPATCH
I05344	T	5	NORMAL								
			NO REMARKABLE OBSERVATIONS		1	P	-	-	-	-	-	-
					8	P	-	-	-	-	-	-
					15	P	-	-	-	-	-	-
					22	P	-	-	-	-	-	-
					29	P	-	-	-	-	-	-
					30	P	-	-	-	-	P	-
I05347	T	5	DISCHARGE								
			VOMITUS								
			CONTAINING FOOD		4	-	-	-	-	-	-	P
			NORMAL								
			NO REMARKABLE OBSERVATIONS		1	P	-	-	-	-	-	-
					8	P	-	-	-	-	-	-
					15	P	-	-	-	-	-	-
					22	P	-	-	-	-	-	-
					29	P	-	-	-	-	-	-
					30	P	-	-	-	-	P	-
I05348	T	5	NORMAL								
			NO REMARKABLE OBSERVATIONS		1	P	-	-	-	-	-	-
					8	P	-	-	-	-	-	-
					15	P	-	-	-	-	-	-
					22	P	-	-	-	-	-	-
					29	P	-	-	-	-	-	-
					30	P	-	-	-	-	P	-
			QUALITATIVE FOOD CONSUMPTION									
			LOW		15	P	-	-	-	-	-	-

Appendix 2

Individual Clinical Observations

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

CATEGORY GROUP: M3 DOSE: 2 MG/KG/DAY 'C' - COMMENTS LISTED AT END OF OBSERVATIONS FOR SEX/GROUP

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	KEYWORD QUALIFIER	DAYS 1-30	DAY	AM OBS	PM CHECK	30MIN	60MIN	90MIN	DISPATCH	UNSCHED
I05345	T	5	DISCHARGE									
			VOMITUS									
			CONTAINING FOOD		24	P	-	-	-	-	-	-
			DISCHARGE UNKNOWN SOURCE									
			FOUND IN PAN									
			RED IN COLOR		15	P	-	-	-	-	-	-
			NORMAL									
			NO REMARKABLE OBSERVATIONS		1	P	-	-	-	-	-	-
					8	P	-	-	-	-	-	-
					22	P	-	-	-	-	-	-
					29	P	-	-	-	-	-	-
					30	P	-	-	-	-	P	-

Appendix 2

Individual Clinical Observations

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

CATEGORY GROUP: F1 DOSE: 0 MG/KG/DAY 'C' - COMMENTS LISTED AT END OF OBSERVATIONS FOR SEX/GROUP

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	KEYWORD QUALIFIER DAYS 1-30	DAY	AM OBS	PM CHECK	30MIN	60MIN	90MIN	DISPATCH	UNSCHED
I05366	T	5	EXCRETION								
			NON-FORMED FECES	23	P	-	P	-	-	-	-
				27	P	-	-	-	-	-	-
				29	P	-	-	-	-	-	-
			NORMAL								
			NO REMARKABLE OBSERVATIONS	1	P	-	-	-	-	-	-
				8	P	-	-	-	-	-	-
				15	P	-	-	-	-	-	-
				22	P	-	-	-	-	-	-
				30	P	-	-	-	-	P	-
I05367	T	5	APPEARANCE								
			SWOLLEN								
			LIP(S)	11	-	-	P	P	P	-	-
				13	-	-	P	P	P	-	-
				14	P	-	-	-	P	-	-
				15	P	-	P	P	P	-	-
				19	P	-	P	P	P	-	-
				20	P	-	P	P	P	-	-
				21	P	-	P	P	P	-	-
				22	P	-	P	P	P	-	-
				23	P	-	-	-	-	-	-
				24	-	-	P	P	P	-	-
				25	-	-	-	P	P	-	-
				26	P	-	P	P	P	-	-
				30	P	-	-	-	-	P	-
			EXCRETION								
			NON-FORMED FECES	15	P	-	-	-	-	-	-
				27	P	-	-	-	-	-	-

Appendix 2

Individual Clinical Observations

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER / DAYS 1-30	DAY	'C' - COMMENTS LISTED AT END OF OBSERVATIONS FOR SEX/GROUP: AM OBS	30MIN PM CHECK	60MIN	90MIN	UNSCHED DISPATCH	
(CONTINUED FROM PREVIOUS PAGE)										
I05367	T	5								
			SKIN & PELAGE							
			RED SKIN							
			LIP(S)	11	-	-	P	P	P	-	-
				13	-	-	P	P	P	-	-
				14	P	-	-	-	P	-	-
				15	P	-	P	P	P	-	-
				19	P	-	P	P	P	-	-
				20	P	-	P	P	P	-	-
			SCAB(S)								
			MOUTH	29	P	-	P	P	P	-	-
			NORMAL								
			NO REMARKABLE OBSERVATIONS	1	P	-	-	-	-	-	-
				8	P	-	-	-	-	-	-
			QUALITATIVE FOOD CONSUMPTION								
			LOW	4	P	-	-	-	-	-	-

Appendix 2

Individual Clinical Observations

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

CATEGORY GROUP: F2 DOSE: 0.02 MG/KG/DAY 'C' - COMMENTS LISTED AT END OF OBSERVATIONS FOR SEX/GROUP

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	KEYWORD QUALIFIER	DAYS 1-30	DAY	AM OBS	PM CHECK	30MIN	60MIN	90MIN	DISPATCH	UNSCHED
I05364	T	5	NORMAL									
			NO REMARKABLE OBSERVATIONS		1	P	-	-	-	-	-	-
					8	P	-	-	-	-	-	-
					15	P	-	-	-	-	-	-
					22	P	-	-	-	-	-	-
					29	P	-	-	-	-	-	-
					30	P	-	-	-	-	P	-
I05365	T	5	DISCHARGE									
			APPEARS TO BE MENSTRUATING		29	P	-	-	-	-	-	-
					30	P	-	-	-	-	P	-
			NORMAL									
			NO REMARKABLE OBSERVATIONS		1	P	-	-	-	-	-	-
					8	P	-	-	-	-	-	-
					15	P	-	-	-	-	-	-
					22	P	-	-	-	-	-	-
I05370	T	5	NORMAL									
			NO REMARKABLE OBSERVATIONS		1	P	-	-	-	-	-	-
					8	P	-	-	-	-	-	-
					15	P	-	-	-	-	-	-
					22	P	-	-	-	-	-	-
					29	P	-	-	-	-	-	-
					30	P	-	-	-	-	P	-

Appendix 2

Individual Clinical Observations

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

CATEGORY GROUP: F3 DOSE: 2 MG/KG/DAY 'C' - COMMENTS LISTED AT END OF OBSERVATIONS FOR SEX/GROUP

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	KEYWORD QUALIFIER	DAYS 1-30	DAY	AM OBS	PM CHECK	30MIN	60MIN	90MIN	DISPATCH	UNSCHED
I05369	T	5	EXCRETION									
			FEW FECES		17	P	-	-	-	-	-	-
			NORMAL									
			NO REMARKABLE OBSERVATIONS		1	P	-	-	-	-	-	-
					8	P	-	-	-	-	-	-
					15	P	-	-	-	-	-	-
					22	P	-	-	-	-	-	-
					29	P	-	-	-	-	-	-
					30	P	-	-	-	-	P	-
			QUALITATIVE FOOD CONSUMPTION									
			LOW		26	P	-	-	-	-	-	-

Appendix 2

Individual Rectal Body Temperature Data (°C)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	DAY -14	DAY -10	DAY -7	DAY -3	DAY 1	DAY 5	DAY 8	DAY 12	DAY 15	DAY 19
GROUP: MALE 1 - 0 MG/KG/DAY										
I05349	40.0	40.2	40.2	39.8	39.4	38.8	38.2	38.9	39.7	38.5
I05350	39.6	39.7	39.4	39.4	38.6	38.9	38.7	39.0	39.7	38.8
GROUP: MALE 2 - 0.02 MG/KG/DAY										
I05344	39.0	39.0	38.4	39.2	39.7	39.3	39.4	39.3	39.8	39.2
I05347	39.8	39.7	39.8	39.7	39.4	39.5	39.4	39.5	40.0	39.0
I05348	38.7	39.0	38.8	38.8	39.1	38.4	38.7	38.6	39.2	38.0
GROUP: MALE 3 - 2 MG/KG/DAY										
I05345	39.6	39.5	39.1	39.2	39.4	39.9	39.6	40.0	39.7	38.9
GROUP: FEMALE 1 - 0 MG/KG/DAY										
I05366	40.0	39.4	39.7	39.4	39.3	38.7	38.8	39.1	39.3	38.7
I05367	40.4	40.1	40.0	40.1	39.8	39.2	39.4	39.3	40.1	39.2
GROUP: FEMALE 2 - 0.02 MG/KG/DAY										
I05364	40.6	40.1	40.3	39.9	40.2	40.0	40.0	40.0	40.2	39.5
I05365	39.6	39.1	39.6	39.7	39.7	39.5	39.6	39.5	40.0	39.1
I05370	40.1	40.0	40.2	39.8	39.7	39.8	39.9	39.8	39.8	39.4
GROUP: FEMALE 3 - 2 MG/KG/DAY										
I05369	40.0	39.8	39.9	39.7	39.5	39.7	39.9	39.7	39.8	39.3

Appendix 2

Individual Rectal Body Temperature Data (°C)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	DAY 22	DAY 26	DAY 29
GROUP: MALE 1 - 0 MG/KG/DAY			
I05349	39.2	38.7	38.2
I05350	39.5	38.8	38.8
GROUP: MALE 2 - 0.02 MG/KG/DAY			
I05344	40.0	39.4	38.8
I05347	39.7	39.5	39.1
I05348	38.9	38.8	38.4
GROUP: MALE 3 - 2 MG/KG/DAY			
I05345	39.4	39.2	38.9
GROUP: FEMALE 1 - 0 MG/KG/DAY			
I05366	39.3	38.7	38.7
I05367	39.9	39.2	38.9
GROUP: FEMALE 2 - 0.02 MG/KG/DAY			
I05364	40.1	39.8	39.3
I05365	39.6	39.5	38.7
I05370	39.8	39.6	39.4
GROUP: FEMALE 3 - 2 MG/KG/DAY			
I05369	39.4	39.1	39.2

APPENDIX 3

Individual Body Weight Data (kg)

Appendix 3

Individual Body Weight Data (kg)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	DAY -14	DAY -10	DAY -7	DAY -3	DAY -1	DAY 1	DAY 5	DAY 8	DAY 12	DAY 15
GROUP: MALE 1 - 0 MG/KG/DAY										
I05349	2.3	2.2	2.2	2.2	2.3	2.2	2.2	2.4	2.4	2.3
I05350	2.3	2.3	2.3	2.3	2.3	2.4	2.3	2.5	2.5	2.5
GROUP: MALE 2 - 0.02 MG/KG/DAY										
I05344	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.5	2.4	2.4
I05347	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.3	2.2	2.3
I05348	2.5	2.5	2.5	2.5	2.6	2.5	2.4	2.5	2.4	2.4
GROUP: MALE 3 - 2 MG/KG/DAY										
I05345	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.2	2.3
GROUP: FEMALE 1 - 0 MG/KG/DAY										
I05366	2.0	2.0	2.1	2.1	2.1	2.1	2.0	2.2	2.1	2.1
I05367	2.1	2.1	2.1	2.1	2.1	2.1	2.0	2.1	2.1	2.2
GROUP: FEMALE 2 - 0.02 MG/KG/DAY										
I05364	2.2	2.1	2.1	2.1	2.1	2.2	2.1	2.2	2.2	2.2
I05365	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.4	2.3	2.4
I05370	1.9	2.0	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0
GROUP: FEMALE 3 - 2 MG/KG/DAY										
I05369	2.2	2.1	2.2	2.1	2.2	2.2	2.1	2.2	2.2	2.1

Appendix 3

Individual Body Weight Data (kg)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	DAY 19	DAY 22	DAY 26	DAY 29
GROUP: MALE 1 - 0 MG/KG/DAY				
I05349	2.4	2.4	2.4	2.3
I05350	2.5	2.5	2.5	2.4
GROUP: MALE 2 - 0.02 MG/KG/DAY				
I05344	2.4	2.5	2.4	2.4
I05347	2.3	2.3	2.3	2.3
I05348	2.4	2.4	2.5	2.4
GROUP: MALE 3 - 2 MG/KG/DAY				
I05345	2.3	2.1	2.1	2.0
GROUP: FEMALE 1 - 0 MG/KG/DAY				
I05366	2.1	2.1	2.1	2.1
I05367	2.1	2.2	2.2	2.1
GROUP: FEMALE 2 - 0.02 MG/KG/DAY				
I05364	2.2	2.2	2.2	2.1
I05365	2.5	2.4	2.4	2.3
I05370	2.2	2.1	2.1	2.0
GROUP: FEMALE 3 - 2 MG/KG/DAY				
I05369	2.3	2.1	2.1	2.1

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	RBC $X10^6/\mu L$	HGB G/DL	HCT %	MCV FL	MCH PG	MCHC %	PLT $X10^3/\mu L$	RETIC %	RETIC $X10^3/\mu L$
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day						
I05349	5.41	13.0	39.9	73.8	24.0	32.6	404	.9	49
I05350	5.88	15.0	45.3	77.0	25.5	33.2	600	.9	53
MEAN	5.64	14.0	42.6	75.4	24.8	32.9	502	.9	51
S.D.	.332	1.41	3.82	2.26	1.06	.42	138.6	.00	2.8
N	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day						
I05344	4.97	12.3	38.5	77.5	24.8	32.0	473	1.3	65
I05347	5.49	12.7	40.1	73.1	23.2	31.7	358	.3	16
I05348	5.09	12.9	38.6	75.7	25.3	33.4	531	1.1	56
MEAN	5.18	12.6	39.1	75.4	24.4	32.4	454	.9	46
S.D.	.272	.31	.90	2.21	1.10	.91	88.1	.53	26.1
N	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day						
I05345	5.91	12.8	41.0	69.4	21.7	31.2	531	.7	41

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	WBC $X10^3/\mu L$	N-SEG $X10^3/\mu L$	LYMPH $X10^3/\mu L$	MONO $X10^3/\mu L$	EOSIN $X10^3/\mu L$	BASO $X10^3/\mu L$	N-SEG%	LYMPH%	MONO%	EOSIN%	BASO%
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day								
I05349	9.1	4.1	4.5	.4	.0	.0	45	49	5	0	0
I05350	7.7	2.6	4.6	.3	.2	.0	34	59	4	2	0
MEAN	8.4	3.4	4.6	.4	.1	.0	40	54	4	1	0
S.D.	.99	1.06	.07	.07	.14	.00	7.8	7.1	.7	1.4	.0
N	2	2	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day								
I05344	10.3	3.2	6.3	.6	.2	.0	31	61	6	2	0
I05347	8.8	1.4	7.0	.4	.1	.0	15	79	4	1	0
I05348	8.4	4.0	4.2	.2	.0	.0	48	50	2	0	0
MEAN	9.2	2.9	5.8	.4	.1	.0	31	63	4	1	0
S.D.	1.00	1.33	1.46	.20	.10	.00	16.5	14.6	2.0	1.0	.0
N	3	3	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day								
I05345	8.2	2.8	4.8	.6	.0	.0	34	58	8	0	0

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	ANISO	POLY	POIK	HYPO	TOXNEUT
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day		
I05349	-	-	-	-	-
I05350	-	-	-	-	-
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day		
I05344	-	-	-	-	-
I05347	-	-	-	-	-
I05348	-	-	-	-	-
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day		
I05345	-	-	-	-	-

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	RBC $X10^6/\mu L$	HGB G/DL	HCT %	MCV FL	MCH PG	MCHC %	PLT $X10^3/\mu L$	RETIC %	RETIC $X10^3/\mu L$
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day						
I05366	5.02	12.4	37.6	75.0	24.8	33.1	351	.7	35
I05367	5.48	14.3	43.2	78.8	26.1	33.1	606	1.0	55
MEAN	5.25	13.3	40.4	76.9	25.4	33.1	478	.8	45
S.D.	.325	1.34	3.96	2.69	.92	.00	180.3	.21	14.1
N	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day						
I05364	4.77	13.0	38.9	81.5	27.2	33.3	355	.6	29
I05365	4.98	12.7	39.0	78.3	25.5	32.6	365	.9	45
I05370	5.25	12.6	39.3	74.9	24.1	32.2	570	.6	32
MEAN	5.00	12.8	39.1	78.2	25.6	32.7	430	.7	35
S.D.	.241	.21	.21	3.30	1.55	.56	121.3	.17	8.5
N	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day						
I05369	5.53	13.4	40.2	72.7	24.2	33.3	505	.8	44

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	WBC $X10^3/\mu L$	N-SEG $X10^3/\mu L$	LYMPH $X10^3/\mu L$	MONO $X10^3/\mu L$	EOSIN $X10^3/\mu L$	BASO $X10^3/\mu L$	N-SEG%	LYMPH%	MONO%	EOSIN%	BASO%
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day								
I05366	7.9	2.2	5.2	.4	.1	.0	28	66	5	1	0
I05367	10.0	4.9	5.0	.0	.0	.0	49	50	0	0	0
MEAN	9.0	3.6	5.1	.2	.0	.0	38	58	2	0	0
S.D.	1.48	1.91	.14	.28	.07	.00	14.8	11.3	3.5	.7	0
N	2	2	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day								
I05364	8.6	1.6	6.2	.5	.2	.0	19	73	6	2	0
I05365	12.4	1.6	10.2	.5	.1	.0	13	82	4	1	0
I05370	9.6	7.3	2.1	.3	.0	.0	75	21	3	0	0
MEAN	10.2	3.5	6.2	.4	.1	.0	36	59	4	1	0
S.D.	1.97	3.29	4.05	.12	.10	.00	34.2	32.9	1.5	1.0	.0
N	3	3	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day								
I05369	11.7	6.2	4.8	.4	.2	.0	53	42	4	1	0

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	ANISO	POLY	POIK	HYPO	TOXNEUT
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day		
I05366	-	-	-	-	-
I05367	-	-	-	-	-
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day		
I05364	-	-	-	-	-
I05365	-	-	-	-	-
I05370	-	-	-	-	-
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day		
I05369	-	-	-	-	-

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	RBC $X10^6/\mu L$	HGB G/DL	HCT %	MCV FL	MCH PG	MCHC %	PLT $X10^3/\mu L$	RETIC %	RETIC $X10^3/\mu L$
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day						
I05349	6.00	13.6	42.7	71.0	22.6	31.8	357	.9	54
I05350	6.05	14.5	45.3	74.8	24.0	32.1	522	.7	42
MEAN	6.02	14.0	44.0	72.9	23.3	31.9	440	.8	48
S.D.	.035	.64	1.84	2.69	.99	.21	116.7	.14	8.5
N	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day						
I05344	4.90	12.2	38.1	77.8	24.9	32.0	448	.5	24
I05347	5.05	12.1	37.6	74.5	23.9	32.1	286	.2	10
I05348	5.41	13.5	41.6	76.8	25.0	32.5	443	.9	49
MEAN	5.12	12.6	39.1	76.4	24.6	32.2	392	.5	28
S.D.	.262	.78	2.18	1.69	.61	.26	92.1	.35	19.8
N	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day						
I05345	5.69	13.2	41.5	73.1	23.1	31.7	503	.2	11

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	WBC $X10^3/\mu L$	N-SEG $X10^3/\mu L$	LYMPH $X10^3/\mu L$	MONO $X10^3/\mu L$	EOSIN $X10^3/\mu L$	BASO $X10^3/\mu L$	N-SEG%	LYMPH%	MONO%	EOSIN%	BASO%
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day								
I05349	9.1	2.0	6.3	.7	.1	.0	22	69	8	1	0
I05350	9.4	1.3	7.4	.4	.3	.0	14	79	4	3	0
MEAN	9.2	1.6	6.8	.6	.2	.0	18	74	6	2	0
S.D.	.21	.49	.78	.21	.14	.00	5.7	7.1	2.8	1.4	.0
N	2	2	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day								
I05344	10.9	.9	8.8	1.0	.2	.0	9	81	9	1	0
I05347	9.3	1.0	7.6	.4	.3	.0	10	82	5	3	0
I05348	6.1	1.2	4.4	.3	.1	.0	20	72	5	2	0
MEAN	8.8	1.0	6.9	.6	.2	.0	13	78	6	2	0
S.D.	2.44	.15	2.27	.38	.10	.00	6.1	5.5	2.3	1.0	.0
N	3	3	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day								
I05345	5.8	.9	4.4	.4	.0	.0	16	77	7	0	0

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	ANISO	POLY	POIK	HYPO	TOXNEUT
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day		
I05349	-	-	-	-	-
I05350	-	-	-	-	-
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day		
I05344	-	-	-	-	-
I05347	-	-	-	-	-
I05348	-	-	-	-	-
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day		
I05345	-	-	-	-	-

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	RBC $X10^6/\mu L$	HGB G/DL	HCT %	MCV FL	MCH PG	MCHC %	PLT $X10^3/\mu L$	RETIC %	RETIC $X10^3/\mu L$
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day						
I05366	5.02	12.6	38.9	77.4	25.1	32.5	382	1.0	50
I05367	5.26	13.7	42.2	80.4	26.1	32.5	640	1.3	68
MEAN	5.14	13.2	40.5	78.9	25.6	32.5	511	1.2	59
S.D.	.170	.78	2.33	2.12	.71	.00	182.4	.21	12.7
N	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day						
I05364	5.15	14.1	43.1	83.7	27.4	32.8	377	1.1	57
I05365	5.01	12.7	40.5	80.7	25.4	31.4	340	.7	35
I05370	5.24	12.5	39.8	75.9	23.8	31.4	558	.6	31
MEAN	5.13	13.1	41.1	80.1	25.5	31.9	425	.8	41
S.D.	.116	.87	1.74	3.93	1.80	.81	116.7	.26	14.0
N	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day						
I05369	4.81	12.3	36.7	76.4	25.6	33.6	529	1.0	48

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	WBC $X10^3/\mu L$	N-SEG $X10^3/\mu L$	LYMPH $X10^3/\mu L$	MONO $X10^3/\mu L$	EOSIN $X10^3/\mu L$	BASO $X10^3/\mu L$	N-SEG%	LYMPH%	MONO%	EOSIN%	BASO%
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day								
I05366	9.2	3.9	4.4	.9	.0	.0	43	47	10	0	0
I05367	13.0	3.7	8.0	1.2	.0	.0	28	62	9	0	0
MEAN	11.1	3.8	6.2	1.0	.0	.0	36	54	10	0	0
S.D.	2.69	.14	2.55	.21	.00	.00	10.6	10.6	.7	.0	.0
N	2	2	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day								
I05364	8.7	1.7	6.2	.6	.1	.0	19	72	7	1	0
I05365	12.9	2.2	10.1	.5	.1	.0	17	78	4	1	0
I05370	8.3	2.6	5.0	.6	.1	.0	31	60	8	1	0
MEAN	10.0	2.2	7.1	.6	.1	.0	22	70	6	1	0
S.D.	2.55	.45	2.67	.06	.00	.00	7.6	9.2	2.1	.0	.0
N	3	3	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day								
I05369	15.7	7.2	7.9	.5	.1	.0	46	50	3	1	0

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	ANISO	POLY	POIK	HYPO	TOXNEUT
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day		
I05366	-	-	-	-	-
I05367	-	-	-	-	-
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day		
I05364	-	-	-	-	-
I05365	-	-	-	-	-
I05370	-	-	-	-	-
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day		
I05369	-	-	-	-	-

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day							
I05349	95	25	1.0	8.2	5.2	3.0	.2	8	111	46
I05350	68	23	1.1	8.2	5.2	3.0	.3	9	199	81
MEAN	82	24	1.0	8.2	5.2	3.0	.2	8	155	64
S.D.	19.1	1.4	.07	.00	.00	.00	.07	.7	62.2	24.7
N	2	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day							
I05344	46	29	.9	7.7	4.6	3.1	.3	11	137	65
I05347	71	27	1.0	7.7	5.1	2.6	.4	9	202	82
I05348	66	31	1.0	7.8	4.6	3.2	.3	8	145	109
MEAN	61	29	1.0	7.7	4.8	3.0	.3	9	161	85
S.D.	13.2	2.0	.06	.06	.29	.32	.06	1.5	35.4	22.2
N	3	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day							
I05345	54	28	1.0	8.2	5.0	3.2	.4	10	150	68

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day						
I05349	52	33	638	91	4	156	353	37	242
I05350	45	46	587	84	3	301	494	90	340
MEAN	48	40	612	88	4	228	424	64	291
S.D.	4.9	9.2	36.1	4.9	.7	102.5	99.7	37.5	69.3
N	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day						
I05344	58	45	606	78	7	200	376	132	275
I05347	43	71	767	143	5	208	318	38	220
I05348	48	59	670	81	5	233	250	17	175
MEAN	50	58	681	101	6	214	315	62	223
S.D.	7.6	13.0	81.1	36.7	1.2	17.2	63.1	61.2	50.1
N	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day						
I05345	54	50	1086	117	5	220	244	7	144

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day		
I05349	10.6	7.6	161	5.7	110
I05350	10.8	6.8	164	5.8	110
MEAN	10.7	7.2	162	5.8	110
S.D.	.14	.57	2.1	.07	.0
N	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day		
I05344	10.3	7.8	159	5.1	111
I05347	11.2	6.9	164	5.8	117
I05348	10.3	8.3	154	6.0	108
MEAN	10.6	7.7	159	5.6	112
S.D.	.52	.71	5.0	.47	4.6
N	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day		
I05345	11.4	8.7	162	5.9	111

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day							
I05366	70	24	.9	7.6	4.8	2.8	.3	8	131	66
I05367 SH	82	24	1.1	8.3	5.4	2.9	.7	0	153	86
MEAN	76	24	1.0	8.0	5.1	2.8	.5	4	142	76
S.D.	8.5	.0	.14	.49	.42	.07	.28	5.7	15.6	14.1
N	2	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day							
I05364	55	23	.9	8.2	5.2	3.0	.4	7	114	47
I05365	73	23	.8	7.9	4.8	3.1	.4	8	169	49
I05370	64	31	.9	7.6	4.7	2.9	.3	11	178	110
MEAN	64	26	.9	7.9	4.9	3.0	.4	9	154	69
S.D.	9.0	4.6	.06	.30	.26	.10	.06	2.1	34.6	35.8
N	3	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day							
I05369	71	27	1.0	8.2	4.9	3.3	.3	12	141	67

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Individual Clinical Chemistry Data

Females Day -7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day						
I05366	45	38	546	81	3	290	356	17	247
I05367 SH	153	68	640	78	10	3524	312	2	216
MEAN	99	53	593	80	6	1907	334	10	232
S.D.	76.4	21.2	66.5	2.1	4.9	2286.8	31.1	10.6	21.9
N	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day						
I05364	60	45	755	62	5	253	281	21	193
I05365	64	73	849	80	4	567	369	158	228
I05370	51	55	881	79	3	334	321	12	225
MEAN	58	58	828	74	4	385	324	64	215
S.D.	6.7	14.2	65.5	10.1	1.0	163.0	44.1	81.8	19.4
N	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day						
I05369	53	55	683	110	3	1094	315	89	224

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Individual Clinical Chemistry Data

Females Day -7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day		
I05366	10.6	6.5	161	5.9	111
I05367 SH	11.3	8.3	157	8.6	115
MEAN	11.0	7.4	159	7.2	113
S.D.	.49	1.27	2.8	1.91	2.8
N	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day		
I05364	10.6	6.4	154	5.1	110
I05365	10.8	7.7	155	6.1	114
I05370	11.7	9.8	166	6.3	118
MEAN	11.0	8.0	158	5.8	114
S.D.	.59	1.72	6.7	.64	4.0
N	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day		
I05369	11.3	6.8	165	6.0	115

Appendix 4

Individual Clinical Chemistry Data

Males Day 2

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day							
I05349	52	29	.9	7.4	5.0	2.4	.4	19	97	45
I05350	62	21	.9	7.3	4.9	2.4	.3	13	188	114
MEAN	57	25	.9	7.4	5.0	2.4	.4	16	142	80
S.D.	7.1	5.7	.00	.07	.07	.00	.07	4.2	64.3	48.8
N	2	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day							
I05344	56	21	.8	7.1	4.4	2.7	.3	10	149	60
I05347	68	25	.8	6.9	4.6	2.3	.3	9	184	56
I05348	62	25	.9	7.1	4.4	2.7	.4	10	157	90
MEAN	62	24	.8	7.0	4.5	2.6	.3	10	163	69
S.D.	6.0	2.3	.06	.12	.12	.23	.06	.6	18.3	18.6
N	3	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day							
I05345	58	21	.9	7.3	4.7	2.6	.4	9	151	50

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Individual Clinical Chemistry Data

Males Day 2

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day						
I05349	65	41	692	88	2	903	363	35	227
I05350	85	71	761	79	3	895	461	27	284
MEAN	75	56	726	84	2	899	412	31	256
S.D.	14.1	21.2	48.8	6.4	.7	5.7	69.3	5.7	40.3
N	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day						
I05344	44	40	531	68	2	139	325	62	205
I05347	39	69	691	125	2	888	311	35	190
I05348	41	60	575	72	2	709	230	24	146
MEAN	41	56	599	88	2	579	289	40	180
S.D.	2.5	14.8	82.7	31.8	.0	391.1	51.3	19.6	30.7
N	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day						
I05345	54	55	1028	105	2	219	302	11	139

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Individual Clinical Chemistry Data

Males Day 2

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day		
I05349	10.1	7.6	151	5.2	107
I05350	10.3	6.1	153	5.1	106
MEAN	10.2	6.8	152	5.2	106
S.D.	.14	1.06	1.4	.07	.7
N	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day		
I05344	9.7	7.0	147	5.0	110
I05347	9.6	6.6	150	4.5	110
I05348	9.2	6.4	145	4.7	103
MEAN	9.5	6.7	147	4.7	108
S.D.	.26	.31	2.5	.25	4.0
N	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day		
I05345	10.0	7.0	152	5.0	104

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Individual Clinical Chemistry Data

Females Day 2

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day							
I05366	80	19	.8	7.1	4.7	2.4	.4	8	143	34
I05367	60	19	.9	7.7	5.1	2.6	.5	9	147	50
MEAN	70	19	.8	7.4	4.9	2.5	.4	8	145	42
S.D.	14.1	.0	.07	.42	.28	.14	.07	.7	2.8	11.3
N	2	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day							
I05364	60	24	.9	7.5	5.0	2.5	.5	15	102	42
I05365	57	28	.8	7.3	4.4	2.9	.5	16	140	59
I05370	53	21	.8	7.2	4.7	2.5	.4	17	157	107
MEAN	57	24	.8	7.3	4.7	2.6	.5	16	133	69
S.D.	3.5	3.5	.06	.15	.30	.23	.06	1.0	28.2	33.7
N	3	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day							
I05369	68	27	1.0	7.5	4.7	2.8	.4	17	136	47

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Individual Clinical Chemistry Data

Females Day 2

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day						
I05366	45	42	491	77	1	534	404	43	256
I05367	71	103	665	85	2	512	600	35	393
MEAN	58	72	578	81	2	523	502	39	324
S.D.	18.4	43.1	123.0	5.7	.7	15.6	138.6	5.7	96.9
N	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day						
I05364	54	43	730	60	2	281	298	21	185
I05365	59	76	833	74	3	543	376	33	204
I05370	50	53	851	74	2	455	380	39	234
MEAN	54	57	805	69	2	426	351	31	208
S.D.	4.5	16.9	65.3	8.1	.6	133.3	46.2	9.2	24.7
N	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day						
I05369	46	55	672	100	2	308	291	84	184

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Individual Clinical Chemistry Data

Females Day 2

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day		
I05366	9.7	6.5	150	5.0	108
I05367	10.7	6.9	156	5.9	108
MEAN	10.2	6.7	153	5.4	108
S.D.	.71	.28	4.2	.64	.0
N	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day		
I05364	10.2	6.7	146	5.1	104
I05365	9.7	7.6	149	4.7	104
I05370	10.0	8.4	158	4.8	108
MEAN	10.0	7.6	151	4.9	105
S.D.	.25	.85	6.2	.21	2.3
N	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day		
I05369	10.0	6.5	151	4.7	106

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Individual Clinical Chemistry Data

Males Day 7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day							
I05349	84	20	.8	7.6	4.7	2.9	.3	7	92	47
I05350	78	20	.9	8.0	5.0	3.0	.2	14	185	57
MEAN	81	20	.8	7.8	4.8	3.0	.2	10	138	52
S.D.	4.2	.0	.07	.28	.21	.07	.07	4.9	65.8	7.1
N	2	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day							
I05344	67	20	.8	7.5	4.4	3.1	.3	11	134	49
I05347	71	21	.7	7.3	4.5	2.8	.3	9	171	51
I05348	65	23	.8	7.8	4.5	3.3	.3	9	162	52
MEAN	68	21	.8	7.5	4.5	3.1	.3	10	156	51
S.D.	3.1	1.5	.06	.25	.06	.25	.00	1.2	19.3	1.5
N	3	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day							
I05345	63	18	.8	7.5	4.6	2.9	.4	7	137	50

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Individual Clinical Chemistry Data

Males Day 7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day						
I05349	62	37	714	80	0	305	349	28	238
I05350	40	56	825	80	0	193	445	38	306
MEAN	51	46	770	80	0	249	397	33	272
S.D.	15.6	13.4	78.5	.0	.0	79.2	67.9	7.1	48.1
N	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day						
I05344	42	40	477	65	0	110	361	42	250
I05347	41	66	677	125	0	875	330	35	222
I05348	35	66	514	65	0	212	290	16	202
MEAN	39	57	556	85	0	399	327	31	225
S.D.	3.8	15.0	106.4	34.6	.0	415.4	35.6	13.5	24.1
N	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day						
I05345	46	49	1012	98	0	270	260	0	139

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Individual Clinical Chemistry Data

Males Day 7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day		
I05349	10.0	7.3	153	5.0	112
I05350	10.5	6.6	158	5.3	112
MEAN	10.2	7.0	156	5.2	112
S.D.	.35	.49	3.5	.21	.0
N	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day		
I05344	9.4	7.3	151	4.5	112
I05347	9.9	7.0	156	5.0	114
I05348	10.0	6.6	149	5.0	109
MEAN	9.8	7.0	152	4.8	112
S.D.	.32	.35	3.6	.29	2.5
N	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day		
I05345	10.3	6.6	156	5.1	112

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Individual Clinical Chemistry Data

Females Day 7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day							
I05366	80	25	.8	8.1	4.9	3.2	.3	6	128	42
I05367	93	16	.8	8.0	4.2	3.8	.2	8	131	23
MEAN	86	20	.8	8.0	4.6	3.5	.2	7	130	32
S.D.	9.2	6.4	.00	.07	.49	.42	.07	1.4	2.1	13.4
N	2	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day							
I05364	74	18	.8	8.1	5.1	3.0	.3	8	111	30
I05365	68	21	.7	7.8	4.5	3.3	.4	8	162	43
I05370	77	19	.9	8.1	4.9	3.2	.3	8	168	40
MEAN	73	19	.8	8.0	4.8	3.2	.3	8	147	38
S.D.	4.6	1.5	.10	.17	.31	.15	.06	.0	31.3	6.8
N	3	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day							
I05369	73	18	.8	7.9	4.6	3.3	.3	12	117	44

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Individual Clinical Chemistry Data

Females Day 7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day						
I05366	45	43	492	75	1	181	415	23	284
I05367	46	62	625	63	0	103	453	38	322
MEAN	46	52	558	69	0	142	434	30	303
S.D.	.7	13.4	94.0	8.5	.7	55.2	26.9	10.6	26.9
N	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day						
I05364	58	65	655	57	0	240	364	21	251
I05365	45	53	805	72	1	228	334	31	192
I05370	43	53	865	75	0	187	369	24	251
MEAN	49	57	775	68	0	218	356	25	231
S.D.	8.1	6.9	108.2	9.6	.6	27.8	18.9	5.1	34.1
N	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day						
I05369	45	57	674	90	0	166	349	101	238

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Individual Clinical Chemistry Data

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day		
I05366	10.4	6.5	155	5.7	112
I05367	11.5	5.7	158	7.0	113
MEAN	11.0	6.1	156	6.4	112
S.D.	.78	.57	2.1	.92	.7
N	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day		
I05364	10.7	6.8	151	5.7	111
I05365	10.3	6.9	152	5.3	113
I05370	11.1	8.2	162	5.5	114
MEAN	10.7	7.3	155	5.5	113
S.D.	.40	.78	6.1	.20	1.5
N	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day		
I05369	10.6	6.4	155	5.3	113

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Individual Clinical Chemistry Data

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4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day							
I05349	89	18	.9	8.0	5.2	2.8	.4	6	100	33
I05350	70	20	.8	7.4	4.8	2.6	.4	9	182	43
MEAN	80	19	.8	7.7	5.0	2.7	.4	8	141	38
S.D.	13.4	1.4	.07	.42	.28	.14	.00	2.1	58.0	7.1
N	2	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day							
I05344	60	18	.6	7.2	4.4	2.8	.4	10	136	37
I05347	61	20	.6	6.7	4.4	2.3	.4	7	158	55
I05348	67	19	1.0	7.6	4.7	2.9	.4	6	156	41
MEAN	63	19	.7	7.2	4.5	2.7	.4	8	150	44
S.D.	3.8	1.0	.23	.45	.17	.32	.00	2.1	12.2	9.5
N	3	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day							
I05345	64	15	.7	7.4	4.8	2.6	.4	6	132	27

Appendix 4

Individual Clinical Chemistry Data

Males Day 14

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day						
I05349	52	34	785	86	6	131	372	41	248
I05350	42	47	737	75	3	193	415	29	277
MEAN	47	40	761	80	4	162	394	35	262
S.D.	7.1	9.2	33.9	7.8	2.1	43.8	30.4	8.5	20.5
N	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day						
I05344	42	41	431	58	3	97	351	52	236
I05347	34	48	671	120	4	85	294	37	188
I05348	31	57	456	54	3	151	272	15	184
MEAN	36	49	519	77	3	111	306	35	203
S.D.	5.7	8.0	131.9	37.0	.6	35.2	40.8	18.6	28.9
N	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day						
I05345	39	45	908	89	2	245	242	2	123

Appendix 4

Individual Clinical Chemistry Data

Males Day 14

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day		
I05349	10.1	8.8	152	4.6	105
I05350	10.4	6.5	150	5.0	106
MEAN	10.2	7.6	151	4.8	106
S.D.	.21	1.63	1.4	.28	.7
N	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day		
I05344	9.7	7.4	148	4.5	108
I05347	9.5	6.4	149	4.2	107
I05348	9.8	6.2	147	4.8	106
MEAN	9.7	6.7	148	4.5	107
S.D.	.15	.64	1.0	.30	1.0
N	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day		
I05345	10.1	6.4	153	4.8	108

Appendix 4

Individual Clinical Chemistry Data

Females Day 14

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day							
I05366	77	22	.7	7.4	4.8	2.6	.4	7	127	27
I05367	82	16	.6	7.6	4.5	3.1	.3	7	111	20
MEAN	80	19	.6	7.5	4.6	2.8	.4	7	119	24
S.D.	3.5	4.2	.07	.14	.21	.35	.07	.0	11.3	4.9
N	2	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day							
I05364	49	20	.9	7.9	5.1	2.8	.5	6	111	28
I05365	57	22	.5	7.4	4.5	2.9	.7	8	150	42
I05370	67	17	.7	7.7	4.8	2.9	.4	9	155	36
MEAN	58	20	.7	7.7	4.8	2.9	.5	8	139	35
S.D.	9.0	2.5	.20	.25	.30	.06	.15	1.5	24.1	7.0
N	3	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day							
I05369	59	18	.8	7.8	4.6	3.2	.4	8	107	41

Appendix 4

Individual Clinical Chemistry Data

Females Day 14

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day						
I05366	40	41	458	64	5	157	399	18	262
I05367	52	52	540	63	4	361	456	41	313
MEAN	46	46	499	64	4	259	428	30	288
S.D.	8.5	7.8	58.0	.7	.7	144.2	40.3	16.3	36.1
N	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day						
I05364	46	48	722	51	3	341	289	31	190
I05365	55	68	852	69	3	383	335	67	189
I05370	40	49	825	69	4	197	337	20	222
MEAN	47	55	800	63	3	307	320	39	200
S.D.	7.5	11.3	68.6	10.4	.6	97.5	27.2	24.6	18.8
N	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day						
I05369	40	51	727	86	3	462	440	309	283

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Individual Clinical Chemistry Data

Females Day 14

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day		
I05366	10.1	6.6	152	5.5	110
I05367	10.8	7.0	157	6.5	109
MEAN	10.4	6.8	154	6.0	110
S.D.	.49	.28	3.5	.71	.7
N	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day		
I05364	10.5	6.3	146	5.2	105
I05365	9.9	6.3	149	5.0	107
I05370	10.8	7.5	159	5.5	112
MEAN	10.4	6.7	151	5.2	108
S.D.	.46	.69	6.8	.25	3.6
N	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day		
I05369	10.4	6.1	152	5.4	108

Appendix 4

Individual Clinical Chemistry Data

Males Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day							
I05349	75	24	.8	7.5	4.6	2.9	.3	6	93	40
I05350	87	24	.9	7.7	4.6	3.1	.2	8	186	31
MEAN	81	24	.8	7.6	4.6	3.0	.2	7	140	36
S.D.	8.5	.0	.07	.14	.00	.14	.07	1.4	65.8	6.4
N	2	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day							
I05344	66	22	.8	7.2	4.0	3.2	.2	9	129	48
I05347	73	22	.7	6.7	4.1	2.6	.2	7	151	55
I05348	80	29	1.0	8.7	4.8	3.9	.3	13	172	57
MEAN	73	24	.8	7.5	4.3	3.2	.2	10	151	53
S.D.	7.0	4.0	.15	1.04	.44	.65	.06	3.1	21.5	4.7
N	3	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day							
I05345	80	15	1.1	8.2	4.8	3.4	.3	8	91	25

Appendix 4

Individual Clinical Chemistry Data

Males Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day						
I05349	61	36	798	103	6	476	362	37	241
I05350	43	56	712	90	2	344	485	37	329
MEAN	52	46	755	96	4	410	424	37	285
S.D.	12.7	14.1	60.8	9.2	2.8	93.3	87.0	.0	62.2
N	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day						
I05344	42	45	477	73	2	134	382	73	263
I05347	34	49	710	143	4	202	350	24	235
I05348	49	93	505	65	2	606	270	8	185
MEAN	42	62	564	94	3	314	334	35	228
S.D.	7.5	26.6	127.2	42.9	1.2	255.2	57.7	33.9	39.5
N	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day						
I05345	31	38	815	88	1	202	285	3	156

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Individual Clinical Chemistry Data

Males Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day		
I05349	10.4	8.2	152	6.3	112
I05350	10.6	6.8	155	5.0	110
MEAN	10.5	7.5	154	5.6	111
S.D.	.14	.99	2.1	.92	1.4
N	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day		
I05344	10.0	6.7	149	4.8	108
I05347	10.0	5.9	152	4.5	112
I05348	10.5	6.3	155	6.0	110
MEAN	10.2	6.3	152	5.1	110
S.D.	.29	.40	3.0	.79	2.0
N	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day		
I05345	11.0	6.4	156	6.0	107

Appendix 4

Individual Clinical Chemistry Data

Females Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	GLU MG/DL	UN MG/DL	CREAT MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	T BILI MG/DL	SBA umol/L	CHOL MG/DL	TRIG MG/DL
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day							
I05366	87	26	.8	7.4	4.4	3.0	.2	11	107	41
I05367	86	24	.9	7.9	4.3	3.6	.2	7	135	36
MEAN	86	25	.8	7.6	4.4	3.3	.2	9	121	38
S.D.	.7	1.4	.07	.35	.07	.42	.00	2.8	19.8	3.5
N	2	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day							
I05364	50	28	1.0	8.5	5.0	3.5	.4	8	114	45
I05365	71	22	.8	7.7	4.4	3.3	.3	8	156	40
I05370	65	21	.8	7.4	4.3	3.1	.2	11	158	52
MEAN	62	24	.9	7.9	4.6	3.3	.3	9	143	46
S.D.	10.8	3.8	.12	.57	.38	.20	.10	1.7	24.8	6.0
N	3	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day							
I05369	78	24	1.0	8.2	4.6	3.6	.2	17	62	27

Appendix 4

Individual Clinical Chemistry Data

Females Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L	GGT IU/L	SDH IU/L	CK IU/L	AMYLASE IU/L	LIPASE IU/L	P AMYL U/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day						
I05366	46	39	418	70	9	335	444	18	300
I05367	60	52	516	75	4	262	633	241	440
MEAN	53	46	467	72	6	298	538	130	370
S.D.	9.9	9.2	69.3	3.5	3.5	51.6	133.6	157.7	99.0
N	2	2	2	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day						
I05364	53	49	926	67	4	215	290	10	193
I05365	44	60	966	79	2	363	348	39	205
I05370	39	52	832	81	2	240	381	20	257
MEAN	45	54	908	76	3	273	340	23	218
S.D.	7.1	5.7	68.8	7.6	1.2	79.2	46.1	14.7	34.0
N	3	3	3	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day						
I05369	36	47	637	93	2	341	326	18	221

Appendix 4

Individual Clinical Chemistry Data

Females Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	CA MG/DL	I PHOS MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day		
I05366	10.3	5.6	151	5.4	109
I05367	10.6	7.1	153	6.0	113
MEAN	10.4	6.4	152	5.7	111
S.D.	.21	1.06	1.4	.42	2.8
N	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day		
I05364	11.2	7.9	152	5.5	109
I05365	10.4	6.6	153	5.4	112
I05370	11.2	6.2	160	5.6	113
MEAN	10.9	6.9	155	5.5	111
S.D.	.46	.89	4.4	.10	2.1
N	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day		
I05369	11.1	6.5	158	5.7	110

Appendix 4

Individual Clinical Chemistry Data

Males Day 30

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	PCOAO IU/G
Group: 1	Dose Level: 0 Dosage Unit: mg/kg/day
I05349	0
I05350	1
MEAN	0
S.D.	.7
N	2
Group: 2	Dose Level: 0.02 Dosage Unit: mg/kg/day
I05344	4
I05347	4
I05348	3
MEAN	4
S.D.	.6
N	3
Group: 3	Dose Level: 2.0 Dosage Unit: mg/kg/day
I05345	1

Appendix 4

Individual Clinical Chemistry Data

Males Day 30

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	PCOAO IU/G
Group: 1	Dose Level: 0 Dosage Unit: mg/kg/day
I05366	0
I05367	4
MEAN	2
S.D.	2.8
N	2
Group: 2	Dose Level: 0.02 Dosage Unit: mg/kg/day
I05364	7
I05365	0
I05370	3
MEAN	3
S.D.	3.5
N	3
Group: 3	Dose Level: 2.0 Dosage Unit: mg/kg/day
I05369	1

APPENDIX 5

Individual Animal Pathology Data

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05349 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/22/98 STUDY DAY OF DEATH: 30 STUDY WEEK OF DEATH: 5 TERMINAL BODY WEIGHT: 2235.0 GRAMS
DATE AND TIME OF NECROPSY: 05/22/98 9:44 PROSECTOR: JILL PAUS RECORDER: WENDY CHERRY
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: NOT AVAILABLE

O B S E R V A T I O N S

NECROPSY

HISTOPATHOLOGY

MARROW, FEMUR (FM) :
>SECTION EXAMINED; TISSUE NOT PRESENT
TESTIS (TE) :
-IMMATURE,-PRESENT

GENERAL COMMENT (GC) :
-BONE MARROW SMEAR TAKEN
-EYES - DAVIDSONS
-NO MACROSCOPIC LESIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH), TESTIS (TE), MARROW, STERNUM (SE), BONE, STERNUM (SB), BRAIN (BR), SPINAL CORD (SC), NERVE, SCIATIC (SN), HEART (HT), MUSCLE, SKELETAL (SM), TRACHEA (TR), ESOPHAGUS (ES), GALLBLADDER (GB), PITUITARY (PI), AORTA (AO), LN, MESENTERIC (MS), THYROID (TY), PARATHYROID (PT), SALIV GL, MANDIB (SG), SKIN (SK), MAMMARY, MALE (MM), STOMACH, GL (ST), DUODENUM (DU), JEJUNUM (JE), ILEUM (IL), CECUM (CE), COLON (CO), RECTUM (RE), URINARY BLADDER (UB), PROSTATE (PR), SEMINAL VESICLES (SV), EPIDIDYMIDES (EP)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
EYE (EY), BONE, FEMUR (FE), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05350 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/22/98 STUDY DAY OF DEATH: 30 STUDY WEEK OF DEATH: 5 TERMINAL BODY WEIGHT: 2295.0 GRAMS
DATE AND TIME OF NECROPSY: 05/22/98 11:00 PROSECTOR: JILL PAUS RECORDER: DONIA MEYER
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: NOT AVAILABLE

O B S E R V A T I O N S

NECROPSY

HISTOPATHOLOGY

MARROW, FEMUR (FM) :
>SECTION EXAMINED; TISSUE NOT PRESENT
TESTIS (TE) :
-IMMATURE,-PRESENT

GENERAL COMMENT (GC) :
-BONE MARROW SMEAR TAKEN
-EYES - DAVIDSONS
-NO MACROSCOPIC LESIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH), TESTIS (TE), MARROW, STERNUM (SE), BONE, STERNUM (SB), BRAIN (BR), SPINAL CORD (SC), NERVE, SCIATIC (SN), HEART (HT), MUSCLE, SKELETAL (SM), TRACHEA (TR), ESOPHAGUS (ES), GALLBLADDER (GB), PITUITARY (PI), AORTA (AO), LN, MESENTERIC (MS), THYROID (TY), PARATHYROID (PT), SALIV GL, MANDIB (SG), SKIN (SK), MAMMARY, MALE (MM), STOMACH, GL (ST), DUODENUM (DU), JEJUNUM (JE), ILEUM (IL), CECUM (CE), COLON (CO), RECTUM (RE), URINARY BLADDER (UB), PROSTATE (PR), SEMINAL VESICLES (SV), EPIDIDYMIDES (EP)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
EYE (EY), BONE, FEMUR (FE), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05344 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/22/98 STUDY DAY OF DEATH: 30 STUDY WEEK OF DEATH: 5 TERMINAL BODY WEIGHT: 2330.0 GRAMS
DATE AND TIME OF NECROPSY: 05/22/98 10:25 PROSECTOR: DAVID SCHUETTE RECORDER: NANCY DIEDRICH
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: NOT AVAILABLE

O B S E R V A T I O N S

NECROPSY	HISTOPATHOLOGY
	MARROW, FEMUR (FM) : >SECTION EXAMINED; TISSUE NOT PRESENT TESTIS (TE) : -IMMATURE,-PRESENT

GENERAL COMMENT (GC) :
-BONE MARROW SMEAR TAKEN
-EYES - DAVIDSONS
-NO MACROSCOPIC LESIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH), TESTIS (TE), MARROW, STERNUM (SE), BONE, STERNUM (SB), BRAIN (BR), SPINAL CORD (SC), NERVE, SCIATIC (SN), HEART (HT), MUSCLE, SKELETAL (SM), TRACHEA (TR), ESOPHAGUS (ES), GALLBLADDER (GB), PITUITARY (PI), AORTA (AO), LN, MESENTERIC (MS), THYROID (TY), PARATHYROID (PT), SALIV GL, MANDIB (SG), SKIN (SK), MAMMARY, MALE (MM), STOMACH, GL (ST), DUODENUM (DU), JEJUNUM (JE), ILEUM (IL), CECUM (CE), COLON (CO), RECTUM (RE), URINARY BLADDER (UB), PROSTATE (PR), SEMINAL VESICLES (SV), EPIDIDYMIDES (EP)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
EYE (EY), BONE, FEMUR (FE), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05347 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/22/98 STUDY DAY OF DEATH: 30 STUDY WEEK OF DEATH: 5 TERMINAL BODY WEIGHT: 2125.0 GRAMS
DATE AND TIME OF NECROPSY: 05/22/98 11:00 PROSECTOR: DAVID SCHUETTE RECORDER: NANCY DIEDRICH
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: NOT AVAILABLE

O B S E R V A T I O N S

NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-INFILTRATE, LYMPHOPLASMACYTIC,-MINIMAL
TESTIS (TE) :
-IMMATURE,-PRESENT

GENERAL COMMENT (GC) :
-BONE MARROW SMEAR TAKEN
-EYES - DAVIDSONS
-NO MACROSCOPIC LESIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH), TESTIS (TE), MARROW, STERNUM (SE), BONE, STERNUM (SB), BRAIN (BR), SPINAL CORD (SC), NERVE, SCIATIC (SN), HEART (HT), MUSCLE, SKELETAL (SM), TRACHEA (TR), ESOPHAGUS (ES), GALLBLADDER (GB), PITUITARY (PI), AORTA (AO), LN, MESENTERIC (MS), THYROID (TY), PARATHYROID (PT), SALIV GL, MANDIB (SG), SKIN (SK), MAMMARY, MALE (MM), STOMACH, GL (ST), DUODENUM (DU), JEJUNUM (JE), ILEUM (IL), CECUM (CE), COLON (CO), RECTUM (RE), URINARY BLADDER (UB), PROSTATE (PR), SEMINAL VESICLES (SV), EPIDIDYMIDES (EP)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05348 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/22/98 STUDY DAY OF DEATH: 30 STUDY WEEK OF DEATH: 5 TERMINAL BODY WEIGHT: 2285.0 GRAMS
DATE AND TIME OF NECROPSY: 05/22/98 10:19 PROSECTOR: DENNIS HOFFMAN RECORDER: DONIA MEYER
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: NOT AVAILABLE

O B S E R V A T I O N S

NECROPSY

HISTOPATHOLOGY

MARROW, FEMUR (FM) :
>SECTION EXAMINED; TISSUE NOT PRESENT
KIDNEY (KD) :
-INFILTRATE, LYMPHOPLASMACYTIC,-SLIGHT, FOCAL
TESTIS (TE) :
-IMMATURE,-PRESENT

GENERAL COMMENT (GC) :
-BONE MARROW SMEAR TAKEN
-EYES - DAVIDSONS
-NO MACROSCOPIC LESIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH), TESTIS (TE), MARROW, STERNUM (SE), BONE, STERNUM (SB), BRAIN (BR), SPINAL CORD (SC), NERVE, SCIATIC (SN), HEART (HT), MUSCLE, SKELETAL (SM), TRACHEA (TR), ESOPHAGUS (ES), GALLBLADDER (GB), PITUITARY (PI), AORTA (AO), LN, MESENTERIC (MS), THYROID (TY), PARATHYROID (PT), SALIV GL, MANDIB (SG), SKIN (SK), MAMMARY, MALE (MM), STOMACH, GL (ST), DUODENUM (DU), JEJUNUM (JE), ILEUM (IL), CECUM (CE), COLON (CO), RECTUM (RE), URINARY BLADDER (UB), PROSTATE (PR), SEMINAL VESICLES (SV), EPIDIDYMIDES (EP)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
EYE (EY), BONE, FEMUR (FE), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05345 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/22/98 STUDY DAY OF DEATH: 30 STUDY WEEK OF DEATH: 5 TERMINAL BODY WEIGHT: 1870.0 GRAMS
DATE AND TIME OF NECROPSY: 05/22/98 11:10 PROSECTOR: WENDY CHERRY RECORDER: DENNIS HOFFMAN
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: NOT AVAILABLE

O B S E R V A T I O N S

NECROPSY

HISTOPATHOLOGY

MARROW, FEMUR (FM) :
>SECTION EXAMINED; TISSUE NOT PRESENT
TESTIS (TE) :
-IMMATURE,-PRESENT

GENERAL COMMENT (GC) :
-BONE MARROW SMEAR TAKEN
-EYES - DAVIDSONS
-NO MACROSCOPIC LESIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH), TESTIS (TE), MARROW, STERNUM (SE), BONE, STERNUM (SB), BRAIN (BR), SPINAL CORD (SC), NERVE, SCIATIC (SN), HEART (HT), MUSCLE, SKELETAL (SM), TRACHEA (TR), ESOPHAGUS (ES), GALLBLADDER (GB), PITUITARY (PI), AORTA (AO), LN, MESENTERIC (MS), THYROID (TY), PARATHYROID (PT), SALIV GL, MANDIB (SG), SKIN (SK), MAMMARY, MALE (MM), STOMACH, GL (ST), DUODENUM (DU), JEJUNUM (JE), ILEUM (IL), CECUM (CE), COLON (CO), RECTUM (RE), URINARY BLADDER (UB), PROSTATE (PR), SEMINAL VESICLES (SV), EPIDIDYMIDES (EP)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
EYE (EY), BONE, FEMUR (FE), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID
POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05366 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/22/98 STUDY DAY OF DEATH: 30 STUDY WEEK OF DEATH: 5 TERMINAL BODY WEIGHT: 2000.0 GRAMS
DATE AND TIME OF NECROPSY: 05/22/98 9:40 PROSECTOR: DENNIS HOFFMAN RECORDER: DONIA MEYER
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: NOT AVAILABLE

O B S E R V A T I O N S

NECROPSY	HISTOPATHOLOGY
	MARROW, FEMUR (FM) : >SECTION EXAMINED; TISSUE NOT PRESENT LIVER (LI) : -INFLAMMATION, LYMPHOHISTIOCYTIC,-SLIGHT, FOCAL

GENERAL COMMENT (GC) :
-BONE MARROW SMEAR TAKEN
-EYES - DAVIDSONS
-NO MACROSCOPIC LESIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH), MARROW, STERNUM (SE), BONE, STERNUM (SB), BRAIN (BR), SPINAL CORD (SC), NERVE, SCIATIC (SN), HEART (HT), MUSCLE, SKELETAL (SM), TRACHEA (TR), ESOPHAGUS (ES), GALLBLADDER (GB), PITUITARY (PI), AORTA (AO), LN, MESENTERIC (MS), THYROID (TY), PARATHYROID (PT), SALIV GL, MANDIB (SG), SKIN (SK), MAMMARY, FEMALE (MF), STOMACH, GL (ST), DUODENUM (DU), JEJUNUM (JE), ILEUM (IL), CECUM (CE), COLON (CO), RECTUM (RE), URINARY BLADDER (UB), OVARY (OV), UTERUS (UT), CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
EYE (EY), BONE, FEMUR (FE), KIDNEY (KD), LUNG (LU), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05367 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/22/98 STUDY DAY OF DEATH: 30 STUDY WEEK OF DEATH: 5 TERMINAL BODY WEIGHT: 2085.0 GRAMS
DATE AND TIME OF NECROPSY: 05/22/98 9:47 PROSECTOR: DAVID SCHUETTE RECORDER: NANCY DIEDRICH
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: NOT AVAILABLE

O B S E R V A T I O N S

NECROPSY

HISTOPATHOLOGY

KIDNEY (KD) :
-INFILTRATE, LYMPHOPLASMACYTIC,-MINIMAL
LIVER (LI) :
-INFILTRATE, LYMPHOPLASMACYTIC,-MINIMAL
-LIPIDOSIS, SUBCAPSULAR (TENSION LIPIDOSIS),-SLIGHT, FOCAL

GENERAL COMMENT (GC) :
-BONE MARROW SMEAR TAKEN
-EYES - DAVIDSONS
-NO MACROSCOPIC LESIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH), MARROW, STERNUM (SE), BONE, STERNUM (SB), BRAIN (BR), SPINAL CORD (SC), NERVE, SCIATIC (SN), HEART (HT), MUSCLE, SKELETAL (SM), TRACHEA (TR), ESOPHAGUS (ES), GALLBLADDER (GB), PITUITARY (PI), AORTA (AO), LN, MESENTERIC (MS), THYROID (TY), PARATHYROID (PT), SALIV GL, MANDIB (SG), SKIN (SK), MAMMARY, FEMALE (MF), STOMACH, GL (ST), DUODENUM (DU), JEJUNUM (JE), ILEUM (IL), CECUM (CE), COLON (CO), RECTUM (RE), URINARY BLADDER (UB), OVARY (OV), UTERUS (UT), CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), LUNG (LU), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05364 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/22/98 STUDY DAY OF DEATH: 30 STUDY WEEK OF DEATH: 5 TERMINAL BODY WEIGHT: 2080.0 GRAMS
DATE AND TIME OF NECROPSY: 05/22/98 8:09 PROSECTOR: DENNIS HOFFMAN RECORDER: DONIA MEYER
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: NOT AVAILABLE

O B S E R V A T I O N S

NECROPSY

GENERAL COMMENT (GC) :
-BONE MARROW SMEAR TAKEN
-EYES - DAVIDSONS
-NO MACROSCOPIC LESIONS

HISTOPATHOLOGY

MARROW, FEMUR (FM) :
>SECTION EXAMINED; TISSUE NOT PRESENT
KIDNEY (KD) :
-INFILTRATE, LYMPHOPLASMACYTIC,-SLIGHT
ADRENAL, CORTEX (AC) :
-HEMORRHAGE,-MODERATE, FOCAL
-THROMBUS,-PRESENT
>NOTE:>UNILATERAL MICROSCOPIC FINDINGS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH), MARROW, STERNUM (SE), BONE, STERNUM (SB), BRAIN (BR), SPINAL CORD (SC), NERVE, SCIATIC (SN), HEART (HT), MUSCLE, SKELETAL (SM), TRACHEA (TR), ESOPHAGUS (ES), GALLBLADDER (GB), PITUITARY (PI), AORTA (AO), LN, MESENTERIC (MS), THYROID (TY), PARATHYROID (PT), SALIV GL, MANDIB (SG), SKIN (SK), MAMMARY, FEMALE (MF), STOMACH, GL (ST), DUODENUM (DU), JEJUNUM (JE), ILEUM (IL), CECUM (CE), COLON (CO), RECTUM (RE), URINARY BLADDER (UB), OVARY (OV), UTERUS (UT), CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
EYE (EY), BONE, FEMUR (FE), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, MEDULLA (MA), THYMUS (TH)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05365 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/22/98 STUDY DAY OF DEATH: 30 STUDY WEEK OF DEATH: 5 TERMINAL BODY WEIGHT: 2245.0 GRAMS
DATE AND TIME OF NECROPSY: 05/22/98 8:08 PROSECTOR: DAVID SCHUETTE RECORDER: NANCY DIEDRICH
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: NOT AVAILABLE

O B S E R V A T I O N S

NECROPSY

HISTOPATHOLOGY

KIDNEY (KD) :
-INFILTRATE, LYMPHOPLASMACYTIC,-MODERATE
LIVER (LI) :
-INFILTRATE, LYMPHOPLASMACYTIC,-MINIMAL

GENERAL COMMENT (GC) :
-BONE MARROW SMEAR TAKEN
-EYES - DAVIDSONS
-STAINS-PERINEUM/PERIANAL; DARK RED AND MOIST

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH), MARROW, STERNUM (SE), BONE, STERNUM (SB), BRAIN (BR), SPINAL CORD (SC), NERVE, SCIATIC (SN), HEART (HT), MUSCLE, SKELETAL (SM), TRACHEA (TR), ESOPHAGUS (ES), GALLBLADDER (GB), PITUITARY (PI), AORTA (AO), LN, MESENTERIC (MS), THYROID (TY), PARATHYROID (PT), SALIV GL, MANDIB (SG), SKIN (SK), MAMMARY, FEMALE (MF), STOMACH, GL (ST), DUODENUM (DU), JEJUNUM (JE), ILEUM (IL), CECUM (CE), COLON (CO), RECTUM (RE), URINARY BLADDER (UB), OVARY (OV), UTERUS (UT), CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), LUNG (LU), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05370 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/22/98 STUDY DAY OF DEATH: 30 STUDY WEEK OF DEATH: 5 TERMINAL BODY WEIGHT: 1940.0 GRAMS
DATE AND TIME OF NECROPSY: 05/22/98 10:18 PROSECTOR: JILL PAUS RECORDER: WENDY CHERRY
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: NOT AVAILABLE

O B S E R V A T I O N S

NECROPSY	HISTOPATHOLOGY
	LIVER (LI) : -INFILTRATE, LYMPHOPLASMACYTIC,-SLIGHT

GENERAL COMMENT (GC) :
-BONE MARROW SMEAR TAKEN
-EYES - DAVIDSONS
-NO MACROSCOPIC LESIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH), MARROW, STERNUM (SE), BONE, STERNUM (SB), BRAIN (BR), SPINAL CORD (SC), NERVE, SCIATIC (SN), HEART (HT), MUSCLE, SKELETAL (SM), TRACHEA (TR), ESOPHAGUS (ES), GALLBLADDER (GB), PITUITARY (PI), AORTA (AO), LN, MESENTERIC (MS), THYROID (TY), PARATHYROID (PT), SALIV GL, MANDIB (SG), SKIN (SK), MAMMARY, FEMALE (MF), STOMACH, GL (ST), DUODENUM (DU), JEJUNUM (JE), ILEUM (IL), CECUM (CE), COLON (CO), RECTUM (RE), URINARY BLADDER (UB), OVARY (OV), UTERUS (UT), CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH)

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05369 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/22/98 STUDY DAY OF DEATH: 30 STUDY WEEK OF DEATH: 5 TERMINAL BODY WEIGHT: 1970.0 GRAMS
DATE AND TIME OF NECROPSY: 05/22/98 8:08 PROSECTOR: JILL PAUS RECORDER: WENDY CHERRY
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: NOT AVAILABLE

O B S E R V A T I O N S

NECROPSY

GENERAL COMMENT (GC) :
-BONE MARROW SMEAR TAKEN
-EYES - DAVIDSONS
-NO MACROSCOPIC LESIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH), MARROW, STERNUM (SE), BONE, STERNUM (SB), BRAIN (BR), SPINAL CORD (SC), NERVE, SCIATIC (SN), HEART (HT), MUSCLE, SKELETAL (SM), TRACHEA (TR), ESOPHAGUS (ES), GALLBLADDER (GB), PITUITARY (PI), AORTA (AO), LN, MESENTERIC (MS), THYROID (TY), PARATHYROID (PT), SALIV GL, MANDIB (SG), SKIN (SK), MAMMARY, FEMALE (MF), STOMACH, GL (ST), DUODENUM (DU), JEJUNUM (JE), ILEUM (IL), CECUM (CE), COLON (CO), RECTUM (RE), URINARY BLADDER (UB), OVARY (OV), UTERUS (UT), CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
EYE (EY), BONE, FEMUR (FE), MARROW, FEMUR (FM), KIDNEY (KD), LUNG (LU), LIVER (LI), SPLEEN (SP), PANCREAS (PA), ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (MA), THYMUS (TH)

HISTOPATHOLOGY

APPENDIX 6

Summary and Individual Hormone Analyses Data
Figure 1 - Mean Estradiol Data - Males
Figure 2 - Mean Estradiol Data - Females
Figure 3 - Mean Triiodothyronine Data - Males
Figure 4 - Mean Triiodothyronine Data - Females

NOTE: This appendix of the report contains information supplied by Ani Lytics Inc. and has been reviewed by the Quality Assurance Unit of Ani Lytics Inc.

Appendix 6

Summary and Individual Hormone Analyses Data

Males Day -7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	ESTRADIOL pg/mL	ESTRONE pg/mL	ESTRIOL pg/mL	THYROID STIMULATING ΦU/mL	TRIIODOTHYRONINE ng/dL	THYROXIN Φg/dL
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day			
I05349	34.86	38.62	0.00	2.33	160.41	4.01
I05350	29.20	17.83	0.00	3.30	119.07	6.84
MEAN	32.03	28.23	0.00	2.82	139.74	5.43
S.D.	4.002	14.701	0.000	0.686	29.232	2.001
N	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day			
I05344	24.95	18.44	0.00	2.62	152.65	3.90
I05347	34.14	17.74	0.00	2.49	148.40	4.43
I05348	26.73	15.79	0.00	1.21	66.41	4.52
MEAN	28.61	17.32	0.00	2.11	122.49	4.28
S.D.	4.874	1.373	0.000	0.779	48.610	0.335
N	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day			
I05345	28.71	13.98	0.00	1.71	97.61	3.86

Appendix 6

Summary and Individual Hormone Analyses Data

Females Day -7

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	ESTRADIOL pg/mL	ESTRONE pg/mL	ESTRIOL pg/mL	THYROID STIMULATING ΦU/mL	TRIIODOTHYRONINE ng/dL	THYROXIN Φg/dL
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day			
I05366	45.43	25.12	0.00	1.26	172.31	5.55
I05367	45.13	32.42	0.00	7.48	92.99	4.21
MEAN	45.28	28.77	0.00	4.37	132.65	4.88
S.D.	0.212	5.162	0.000	4.398	56.088	0.948
N	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day			
I05364	28.17	21.98	0.00	3.07	148.92	5.71
I05365	70.25	26.58	0.00	3.65	176.45	4.94
I05370	45.95	42.65	0.00	0.80	67.89	3.62
MEAN	48.12	30.40	0.00	2.51	131.09	4.76
S.D.	21.124	10.852	0.000	1.506	56.434	1.057
N	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day			
I05369	37.37	29.50	0.00	1.41	122.38	3.60

Appendix 6

Summary and Individual Hormone Analyses Data

Males Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	ESTRADIOL pg/mL	ESTRONE pg/mL	ESTRIOL pg/mL	THYROID STIMULATING ΦU/mL	TRIIODOTHYRONINE ng/dL	THYROXIN Φg/dL
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day			
I05349	33.04	25.02	0.00	0.73	181.44	3.32
I05350	32.75	18.84	0.00	3.57	191.25	5.31
MEAN	32.90	21.93	0.00	2.15	186.35	4.32
S.D.	0.205	4.370	0.000	2.008	6.937	1.407
N	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day			
I05344	25.19	10.24	0.00	3.27	195.89	3.86
I05347	37.25	14.20	0.00	3.58	209.96	3.82
I05348	40.32	19.73	0.00	2.45	159.16	4.90
MEAN	34.25	14.72	0.00	3.10	188.34	4.19
S.D.	7.998	4.767	0.000	0.584	26.229	0.612
N	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day			
I05345	18.16	20.12	0.00	0.95	90.73	3.18

Appendix 6

Summary and Individual Hormone Analyses Data

Females Day 29

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	ESTRADIOL pg/mL	ESTRONE pg/mL	ESTRIOL pg/mL	THYROID STIMULATING ΦU/mL	TRIIODOTHYRONINE ng/dL	THYROXIN Φg/dL
Group: 1	Dose Level: 0		Dosage Unit: mg/kg/day			
I05366	67.67	24.46	0.00	2.57	141.93	4.57
I05367	39.27	27.47	0.00	3.32	183.46	3.95
MEAN	53.47	25.97	0.00	2.95	162.70	4.26
S.D.	20.082	2.128	0.000	0.530	29.366	0.438
N	2	2	2	2	2	2
Group: 2	Dose Level: 0.02		Dosage Unit: mg/kg/day			
I05364	31.90	32.66	0.00	2.50	179.61	5.26
I05365	87.09	30.94	0.00	4.64	196.25	3.79
I05370	57.17	31.23	0.00	1.14	165.89	3.09
MEAN	58.72	31.61	0.00	2.76	180.58	4.05
S.D.	27.628	0.921	0.000	1.764	15.203	1.108
N	3	3	3	3	3	3
Group: 3	Dose Level: 2.0		Dosage Unit: mg/kg/day			
I05369	19.82	25.85	0.00	3.92	90.17	3.38

Figure 1

GRAPH - Mean Estradiol Data - Males

Figure 2

GRAPH - Mean Estradiol Data - Females

Figure 3

GRAPH - Mean Triiodothyronine Data - Males

Figure 4

GRAPH - Mean Triiodothyronine Data - Females

APPENDIX 7

Dose Analysis

NOTE: This appendix of the report contains information supplied by the Sponsor and has been reviewed by the Quality Assurance Unit of 3M.

Dose Analysis
(to be provided by the Sponsor)

APPENDIX 8

Serum and Liver PFOS Level Determinations

NOTE: This appendix of the report contains information supplied by the Sponsor and has been reviewed by the Quality Assurance Unit of 3M.

Serum and Liver PFOS Level Determinations
(to be provided by the Sponsor)

APPENDIX 9

Cell Proliferation Evaluation

NOTE: This appendix of the report contains information supplied by Pathology Associates International and has been reviewed by the Quality Assurance Unit of Pathology Associates International.

Cell Proliferation Evaluation
(to be provided by Pathology Associates International)

Pathology Associates International
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An Employee-Owned Company

DRAFT
CELL PROLIFERATION REPORT

T-6295.6

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS
COVANCE STUDY NUMBER 6329-222

PREPARED FOR:

3M
TOXICOLOGY SERVICES
BUILDING 220-2E-02, 3M CENTER
ST. PAUL, MN 55144-1000

PREPARED BY:

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15 WORMAN'S MILL COURT, SUITE I
FREDERICK, MD 21701

SEPTEMBER 30, 1998

CELL PROLIFERATION REPORT

4-WEEK CAPSULE TOXICITY STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295) IN CYNOMOLGUS MONKEYS
COVANCE STUDY NUMBER 6329-222

PURPOSE

The purpose of the study was to provide data for determining an estimated maximum-tolerated dose and lower dose levels to be used in a chronic toxicity study and to assess the effect of the test material on critical enzyme levels, hormones, and other selected biochemical parameters.

This report, submitted by Pathology Associates International (PAI) to the study Sponsor, 3M, represents the cell proliferation findings and interpretation for Covance Study Number 6329-222 entitled "4-Week Capsule Toxicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295) in Cynomolgus Monkeys". All aspects of the tasks associated with PAI's portion of this study were conducted in compliance with the Environmental Protection Agency Good Laboratory Practice (GLP) Regulations as set forth in Title 40 of the US Code of Federal Regulations, Part 792, issued November 29, 1983 (effective December 29, 1983), and with any applicable amendments.

MATERIALS AND METHODS

Tissue Collection for Cell Proliferation

Two animals per sex in control group 1, three animals per sex in dose group 2 (0.02 mg/kg/day) and one animal per sex in dose group 3 (2.0 mg/kg/day) were sacrificed after four weeks on diet. A representative sample of the liver, testes (males only) and pancreas from each animal was fixed in zinc formalin, processed and embedded to paraffin block by Covance per protocol specifications. Tissue blocks were then shipped to PAI for sectioning and staining. From each block, a slide was prepared for H&E evaluation and immunohistochemical detection of proliferating cell nuclear antigen (PCNA), a marker of cell proliferation.

Immunohistochemistry for Cell Proliferation

Sections of paraffin-embedded tissues were cut at 5 µm and placed on positively charged slides (Superfrost Plus, Fisher Scientific, Pittsburgh, PA) to ensure adhesion during processing for PCNA. Standard immunohistochemical methods were used to stain tissues for PCNA (PAI's Standard Operating Procedure for Immunohistochemical Staining (SOP #707). Briefly, tissue sections were incubated with a monoclonal antibody to PCNA (DAKO, lot #016, PAI No. A1723) and reagents required for the avidin-biotin peroxidase (ABC Kit, lot #PK-6100, PAI No. K 324) method for the detection of the antigen-antibody complex. PCNA expression in cells was localized by the chromagen 3,3'-diaminobenzidine (DAB; Sigma Chemical Co., lot #18H8201). Tissue sections were counterstained with hematoxylin.

Cell Proliferation Measurements

The percentage of proliferating cells (proliferating index, PI) was determined by scoring at least 3000 hepatocytes in 10 fields of liver, at least 500 Leydig cells of the testes (males only), and at least 2000 acinar cells of the pancreas per animal. A negative control slide was included in the staining run and consisted of study tissue that was not incubated with the primary antibody.

For cell proliferation evaluations, slides were first perused at low magnification (100X) to judge quality of staining, processing and sectioning, potential patterns of cellular proliferation, and histomorphologic changes. Cell proliferation was then quantified at higher magnification (200X for liver, and 400X for testes and pancreas) as described above. Histomorphology was further assessed by evaluating the H&E slide prepared from the same tissue block for each animal evaluated for cell proliferation.

Statistical Analysis

Due to the small sample size, statistical analysis was not performed.

RESULTS

Cell Proliferation

Individual animal cell proliferation data are presented in Section II (Table 1). Cell proliferation in the liver, testes and pancreas of control and test material-treated animals was similar.

Histopathology

Sections from the same tissue blocks used for preparation of PCNA-stained slides were stained with hematoxylin and eosin (H&E) for histopathologic evaluation to facilitate the interpretation of the immunostained slides. Individual animal findings are presented in Appendix I.

Single sections of liver, pancreas, and testes from 6 young adult male monkeys and single sections of liver and pancreas from 6 young adult female monkeys representing control, low-dose (0.02 mg/kg/day), and high-dose (2.0 mg/kg/day) treatment groups were evaluated histologically. Each tissue section was stained with hematoxylin and eosin. The purpose of this evaluation was to determine whether or not morphologic changes were occurring in these tissues which may alter or confound the specificity of the PCNA staining observed in these animals.

The results showed that no significant changes were observed in either the liver, pancreas, or testicular tissues from male monkeys or the liver and pancreas tissues from female monkeys, which would alter the interpretation of the PCNA staining in this study.

DISCUSSION

In the present study, cell proliferation was measured within the liver, testes and pancreas of male monkeys, and the liver and pancreas of female monkeys from control (0 mg/kg/day), low dose (0.02 mg/kg/day), and high dose (2.0 mg/kg/day) groups after four weeks on study to determine an estimated maximun-tolerated dose and lower dose levels to be used in a chronic toxicity study and to assess the effect of the test material on critical enzyme levels, hormones, and other selected biological parameters, to include cell proliferation.

There did not appear to be a cell proliferative response to the test material in the liver, testes or pancreas, as determined by proliferating indices which were similar in all animals.

SUMMARY

In the present study, cell proliferation, as determined by measuring the proliferating index, was not increased in the liver, testes or pancreas of monkeys.

II. TABLE

COVANCE STUDY NO. 6329-222
TABLE 1. CELL PROLIFERATION IN MONKEYS

Group	Sex	Animal Number	Proliferating Index Liver	Proliferating Index Testes	Proliferating Index Pancreas
1 - 0 mg/kg/day (Control)	M	IO5349	0.025%	20.3%	62.30%
1 - 0 mg/kg/day (Control)	M	IO5350	0.087%	22.9%	50.30%
2 - 0.02 mg/kg/day (Low dose)	M	IO5344	0.056%	18.5%	66.30%
2 - 0.02 mg/kg/day (Low dose)	M	IO5347	0.298%	33.6%	55.50%
2 - 0.02 mg/kg/day (Low dose)	M	IO5348	0.106%	16.5%	63.90%
3 - 2.0 mg/kg/day (High dose)	M	IO5345	0.026%	17.6%	44.90%
1 - 0 mg/kg/day (Control)	F	IO5366	0.000%	NA	50.20%
1 - 0 mg/kg/day (Control)	F	IO5367	0.086%	NA	65.60%
2 - 0.02 mg/kg/day (Low dose)	F	IO5364	0.000%	NA	39.60%
2 - 0.02 mg/kg/day (Low dose)	F	IO5365	0.083%	NA	43.60%
2 - 0.02 mg/kg/day (Low dose)	F	IO5370	0.143%	NA	60.20%
3 - 2.0 mg/kg/day (High dose)	F	IO5369	0.000%	NA	40.90%

APPENDIX I

Individual Animal Histopathology Findings - Male Monkeys
4-week Capsule Toxicity Study

Animal Number	Liver	Testes	Pancreas
I05349	No significant findings	No significant findings	No significant findings
I05350	No significant findings	No significant findings	No significant findings
I05344	No significant findings	No significant findings	No significant findings
I05347	No significant findings	No significant findings	No significant findings
I05348	No significant findings	No significant findings	No significant findings
I05345	No significant findings	No significant findings	No significant findings

Individual Animal Histopathology Findings - Female Monkeys
4-week Capsule Toxicity Study

Animal Number	Liver	Pancreas
I05366	No significant findings	No significant findings
I05367	No significant findings	No significant findings
I05364	No significant findings	No significant findings
I05365	No significant findings	No significant findings
I05370	No significant findings	No significant findings
I05369	No significant findings	No significant findings

III. SIGNATURE PAGE

4-Week Capsule Toxicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295) in Cynomolgus Monkeys (Covance Study Number 6329-222)

Submitted by:

PAI Project Manager:

Sandra R. Eldridge, Ph.D. — Date: 9/30/98

PAI Project Pathologist:

Carolyn Moyer, D.V.M., Diplomate, A.C.V.P. — Date: 9/30/98

IV. QUALITY ASSURANCE STATEMENT