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COVANCE
THE DEVELOPMENT SERVICES COMPANY

Sponsor:

3M
St. Paul, Minnesota

FINAL REPORT

Study Title:

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

Author:

Peter J. Thomford, PhD

Study Completion Date:

April 9, 2002

Performing Laboratory:

Covance Laboratories Inc.
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Madison, Wisconsin 53704-2595

Laboratory Project Identification:

Covance 6329-222

Sponsor Project Identification:

3M Study No. T-6295.6

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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 (GLP) Standards, 40 CFR 792. However, during the timeframe of March 10, 1998, through April 16, 1998, prestudy procedures such as general husbandry, health screening activities, and testing for assignment to study were conducted. The protocol was finalized on April 17, 1998. While the performance of these prestudy events without a final protocol represents a GLP deviation, they did not affect either the outcome or the interpretation of the data.

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

05 Apr. 2002
Date

Andrew M. Seacat, PhD
Study Monitor
3M

Date

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QUALITY ASSURANCE STATEMENT

This report has been reviewed by the Quality Assurance Unit of Covance Laboratories Inc. The following inspections were conducted and findings reported to the study director (SD) and associated management.

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
05/21/98	05/21/98	Clinical Laboratory Inspection	05/21/98
06/01/98	06/01/98	Postlife	06/01/98
07/08/98	07/13/98	Data Review	07/13/98
08/14/98	08/14/98	Protocol Amendment Review	08/14/98
08/10/98	08/18/98	Report Review	08/18/98
06/04/99	06/04/99	Protocol Amendment Review	06/04/99
03/27/02	03/27/02	Protocol Amendment Review	03/27/02
03/27/02	03/27/02	Report Review	03/27/02

Nathan Swanson
Representative
Quality Assurance Unit

09 April 2002
Date

000139

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)
Sponsor	3M Toxicology Services Building 220-2E-02, 3M Center St. Paul, Minnesota 55144-1000
Study Monitor	Andrew M. Seacat, PhD 3M 651.575.3161
Alternate Study Monitor	Marvin T. Case, DVM, PhD 3M 651.733.5180
Study Location	Covance Laboratories Inc. 3301 Kinsman Boulevard Madison, Wisconsin 53704-2595
Study Director	Peter J. Thomford, PhD Covance Laboratories Inc. 3301 Kinsman Boulevard Madison, Wisconsin 53704-2595 608.241.7207
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	April 8, 2002

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KEY PERSONNEL

Study Director	Peter J. Thomford, PhD
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Anatomical Pathologist	Thomas E. Palmer, PhD
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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.

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

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.

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, VEHICLE, AND SOLVENT

Test Material

The test material, Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295), Lot No. 217, is a white to off-white powder and is 86.9% pure. 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. The Certificate of Analysis is in Appendix 7.

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.

Solvent
The solvent was acetone, USP (Spectrum, Gardena, California), Lot No. LH0253 (expiration date June 2000), and is 99.8% pure. It was received at Covance on June 23, 1997. The vehicle was stored at room temperature.

Information on synthesis methods, purity, composition, or other characteristics that define the solvent 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 were 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 29°C, 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 4. 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 (see Protocol Deviations for exceptions).

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 (see Protocol Deviations for exceptions).

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 these analyses will be reported separately by the Sponsor.

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. PCNA evaluation (including examination of slides stained with hematoxylin and eosin) was done on the samples. Results of the evaluation provided by Pathology Associates International are in Appendix 8.

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 will be reported separately by the Sponsor.

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 and Ani Lytics Inc.) will be sent to the Sponsor (Andrew Seacat, PhD, 3M).

Pathology Associates International (PAI) is responsible for the maintenance of any raw data or specimens produced by PAI.

RESULTS

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

Dose analysis results indicate that the average ± standard deviation for the 2.0 mg/kg/day dose level prepared at a 1:9 dilution was 80 ± 02% of target. The average ± standard deviation for the 0.02 mg/kg/day dose level prepared at a 1:999 dilution was 54% ± 02% of target. The stability samples obtained from the middle of each mixture on May 22, 1998, were 79% and 71% of target for the 2.0 and 0.02 mg/kg/day preparations, respectively. Inherent variability and lack of sufficient sensitivity in the analytical method for measuring (PFOS; T-6295) resulted in stability and routine analysis data that were outside of the generally recognized as acceptable standard limits of ± 15%.

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.

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 8.

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

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.

SIGNATURES

Patricia K. McKee Pesik, BS, LAT
Study Coordinator
Covance Laboratories Inc.

09 April 2002
Date

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

05 Apr 2002
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.

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04 April 2002
Date

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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® 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 $p \leq 0.05$.
-; 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.

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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 $X10^6/\mu L$)
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 $X10^3/\mu L$)
Mean platelet volume	MPV (FL)
Reticulocyte count	RETIC (%)
Absolute reticulocyte count	RETIC (E3/UL or $X10^3/\mu L$)
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 $X10^3/\mu L$)
Differential blood cell count	
Nucleated red blood cell count	NRBC (/100 WBC)
Corrected white blood cell count	COR WBC (E3/UL or $X10^3/\mu L$)
Segmented neutrophil count	N-SEG (E3/UL or $X10^3/\mu L$) and %
Band neutrophil count	N-BAND (E3/UL or $X10^3/\mu L$) and %
Lymphocyte count	LYMPH (E3/UL or $X10^3/\mu L$) and %
Monocyte count	MONO (E3/UL or $X10^3/\mu L$) and %
Eosinophil count	EOSIN (E3/UL or $X10^3/\mu L$) and %
Basophil count	BASO (E3/UL or $X10^3/\mu L$) 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)

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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

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							
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

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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

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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

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

		--- NUMBER-OF-ANIMALS-AFFECTED ---					
	SEX:	-----MALE----			----FEMALE---		
	GROUP:	-1-	-2-	-3-	-1-	-2-	-3-
ORGAN AND KEYWORD(S) OR PHRASE	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
Protocol Amendment No. 4
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. Dose Analysis. Stability. "One set of samples (approximately 1 g each) will be taken from the low- and high-dose test material/lactose preparations at the end of the in-life phase and analyzed for test material content."

Actual Procedure. Two reserve samples (10 g) were shipped to the sponsor for stability analysis. The samples for stability analysis (1 g) were retained as reserve samples, until shipped to the Sponsor on March 19, 2002.

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."

Protocol Deviations (Continued)

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. 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.

COVANCE
THE DEVELOPMENT SERVICES COMPANY

Sponsor:

3M
St. Paul, Minnesota

PROTOCOL

Study Title:

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

Date:

April 17, 1998

Performing Laboratory:

Covance Laboratories Inc.
3301 Kinsman Boulevard
Madison, Wisconsin 53704-2595

Laboratory Study Identification:

Proposal No. 90545A

Covance 6329-222

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

Purpose
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

Sponsor
3M
Toxicology Services
Building 220-2E-02, 3M Center
St. Paul, Minnesota 55144-1000

Study Monitor
Andrew M. Seacat, PhD
3M
Telephone No.: 612.575.3161
Facsimile No.: 612.733.1773

Alternate Study Monitor
Paul Lieder, PhD, DABT
3M
Telephone No.: 612.737.2678
Facsimile No.: 612.733.1733

Study Location
Covance Laboratories Inc.
3301 Kinsman Boulevard
Madison, Wisconsin 53704-2595

Mailing Address: PO Box 7545
Madison, Wisconsin 53707-7545

000234

Study Director
Peter J. Thomford, PhD
Covance Laboratories Inc.
Telephone No.: 608.241.7207
Facsimile No.: 608.242.2736

Study Toxicologist
Dale Aldridge, BS
Covance Laboratories Inc.

Proposed Study Timetable
In-Life Start Date: April 23, 1998
In-Life End Date: May 22, 1998
Audited Draft Report Date: September 3, 1998

Regulatory Compliance
This study will be conducted in compliance with the Environmental Protection Agency Good Laboratory Practice 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.

Animal Care and Use Statement
All procedures in this protocol are in compliance with the Animal Welfare Act Regulations, 9 CFR 1-4. In the opinion of the Sponsor and study director, the study does not unnecessarily duplicate any previous work.

Quality Assurance
The protocol, study conduct, and final report will be audited by the Covance Quality Assurance Unit (QAU). The proliferation cell nuclear antigen evaluation data and report will be audited by the QAU of Pathology Associates International. The dose analysis and plasma and liver PFOS analysis and report will be audited by the QAU of 3M Environmental Laboratories. The blood hormone determinations and report will be audited by the QAU of AniLytics Inc.

Test Material

Identification
Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295)

Lot Number
The lot number will be maintained in the raw data.

Purity
Responsibility of the Sponsor

Stability
Responsibility of the Sponsor

Storage Conditions
At room temperature

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

Vehicle

Identification
Lactose

Lot Number
The lot number will be maintained in the raw data.

Purity
On file with the manufacturer

Stability
On file with the manufacturer

Storage Conditions

At room temperature

Gelatin Capsules

Capsules (Size No. 2) obtained from Torpac, Inc. (Fairfield, New Jersey); lot number will be supplied by the manufacturer. Gelatin capsules will be stored at room temperature. A copy of the Certificate of Analysis provided by the manufacturer will be maintained in the data.

Reserve (Archive) Samples

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

Disposition of Test Material

Any remaining test material will be retained at Covance for use in possible future studies.

Animals

Species

Cynomolgus monkey (purpose-bred)

Source

Covance Research Products Inc., Alice, Texas

Age at Initiation of Treatment

Young adult/adult

Weight at Initiation of Treatment

Approximately 2 to 4 kg

Number and Sex

Six males and six females

Identification

Collar tag

000237

Husbandry

Housing
Individual; animals will be housed in suspended, stainless steel cages.

Diet
Certified primate diet (#8726C, Harlan Teklad) once or twice daily. The diet is routinely analyzed by the manufacturer for nutritional components and environmental contaminants. Results of specified nutrient and contaminant analyses are on file at Covance-Madison. Fruit, vegetables, or other supplements may be provided but will not require analysis.

Water
Ad libitum. Samples of the water are routinely analyzed for specified microorganisms and environmental contaminants. The results are on file at Covance-Madison.

Contaminants
There are no known contaminants in the diet or water at levels that might interfere with this study.

Environment
Environmental controls for the animal room will be set to maintain 18 to 29°C, a relative humidity of 30 to 70%, and a 12-hour light/12-hour dark cycle.

Acclimation
Minimum of 4 weeks

Randomization
Animals will be weighed, stratified by body weight, and allocated to the number of blocks equal to the number of animals to be selected for each group. Animals in each block will then be assigned to groups using computer-generated random numbers.

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.

Group Designations and Dosage Levels

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) will receive an equivalent amount of lactose in gelatin capsules as the total material administered to Group 3.
b The low-dose (Group 2) will receive the test material triturated with lactose (1:999, w:w).
c The high-dose (Group 3) will receive the test material triturated with lactose (1:9, w:w).

Dosing Procedures

Method of Administration

Orally by gelatin capsules, daily (7 days/week) for 28 days

Reason for Dosing Route

To compare with data from previous toxicology studies using the oral route, which is the most likely route of exposure

Dose Preparation

Capsules will be prepared at least twice weekly. The size and number of capsules will depend on the physical characteristics of the test material, the dose level, and the weight of the monkey. Individual daily doses will be based on the most recent individual body weights, with the exception of body weight collection days when the previous body weight will be used. Dose levels will be based on the vehicle as

supplied for Group 1. For the Groups 2 and 3 dose preparations, the test material will be triturated with lactose (1:999 and 1:9, w:w, respectively) once before initiation of treatment. Trituration with lactose is necessary to facilitate capsule preparation. All dose preparations will be stored at room temperature until dosed.

Dose Analysis

Dose analyses will be done by the Sponsor.

Homogeneity

Samples (approximately 1 g each) will be collected from the top, middle, and bottom of the test material/lactose preparations for the low- and high-dose groups and analyzed for test material content. All samples will be stored at room temperature until analyzed.

Stability

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

Sample Shipping

Samples will be shipped under ambient conditions to:

Kris J. Hansen, PhD
3M E.T. & S
Bldg. 2-3E-09
935 Bush Avenue
St. Paul, Minnesota 55106
Telephone: 612.778.6018
Facsimile: 612.778.6176

Kris J. Hansen or her alternate will be notified regarding the shipment of the samples. Analysis of for test material content will be done on the samples. Results will be provided for inclusion in the final report.

Observation of Animals

Clinical Observations

Each animal will be observed twice daily (a.m. and p.m.) for mortality and moribundity; findings will be recorded as they are observed.

Each animal will be observed daily and food consumption will be assessed qualitatively; abnormal findings will be recorded. Once weekly, each animal will be observed; abnormal findings, or an indication that the animal is normal will be recorded. During treatment, each animal will be observed for signs of poor health or abnormal behavior approximately 30, 60, and 90 minutes postdose.

Additional findings will be recorded as they are observed.

Body Weights

Beginning two weeks before initiation of treatment, twice weekly (Monday and Thursday), on the first day of treatment, and twice weekly thereafter. An additional body weight will be recorded on Day -1 for the Day 1 dose calculations.

Rectal Body Temperatures

Using nonanesthetized animals. Beginning 2 weeks before initiation of treatment, rectal body temperatures will be taken at approximately 11:00 on two days/week (Monday and Thursday).

Clinical Pathology

Frequency

Unscheduled Collections

When possible, blood will be collected for clinical pathology tests from animals sacrificed at unscheduled intervals

Scheduled Collections

Hematology and clinical chemistry will be done once before initiation of treatment (Day -7 or -6) and on Day 29. Clinical chemistry will also be done prior to the daily dose on Days 2, 7, and 14.

Method of Collection

Animals will be fasted overnight; blood will be collected from a femoral vein. Anticoagulant will be potassium EDTA for hematology tests. No anticoagulant is used for clinical chemistry tests.

Tests

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
- blood cell morphology
- reticulocyte count

Clinical Chemistry

- glucose
- urea nitrogen
- creatinine
- total protein
- albumin
- globulin
- total bilirubin
- direct bilirubin (if total bilirubin is greater than 2.0 mg/dL)
- cholesterol
- triglycerides
- alanine aminotransferase
- alkaline phosphatase
- aspartate aminotransferase
- gamma glutamyltransferase
- sorbitol dehydrogenase
- creatine kinase
- calcium
- inorganic phosphorus
- sodium
- potassium
- chloride
- serum bile acids
- amylase
- lipase
- pancreatic-specific amylase

Blood Hormone Determination

Frequency
Before initiation of treatment (Day -7 or -6) and prior to treatment on Day 29; blood will be collected between 7:00 a.m. and 9:00 a.m.

Number of Animals
All

Method of Collection
Animals will be fasted overnight; blood will be collected from a femoral vein. Approximately 5 mL of blood will be collected without anticoagulant and allowed to clot for serum samples.

Sample Handling
Samples for serum will be centrifuged within 1 hour after collection, and serum will be harvested. Serum will be stored in a freezer set to maintain -60 to -80°C until packed on dry ice and shipped to:

Dr. Das
AniLytics Inc.
200 Girard Street, Suite 200
Gaithersburg, Maryland 20877
Telephone No.: 301.921.0168
Facsimile No.: 301.977.0433

AniLytics Inc. will be notified regarding shipment of samples.

Tests
Samples will be analyzed by AniLytics Inc., for estradiol, estrone, estriol, thyroid stimulating hormone, triiodothyronine (T3), and thyroxin (T4).

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

Number of Animals
All

Method of Collection
Animals will be fasted overnight; blood (approximately 2 mL) will be collected from a femoral vein without an anticoagulant.

Sample Handling
Samples will be centrifuged within 1 hour after collection, and serum will be harvested. Serum samples will be stored in a freezer set to maintain -60 to -80°C.

Sample Shipping
Serum samples will be packed on dry ice and shipped to:

Kris J. Hansen, PhD
3M E.T. & S
Bldg. 2-3E-09
935 Bush Avenue
St. Paul, Minnesota 55106
Telephone: 612.778.6018
Facsimile: 612.778.6176

Kris J. Hansen or her alternate will be notified regarding the shipment of the samples. Analysis of serum for PFOS will be done on the samples. Results will be provided for inclusion in the final report.

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. Blood from each animal will be transferred into containers (approximately 5 mL each) and stored in a freezer set to maintain -60 to -80°C until shipped to the Sponsor for possible future analysis.

Termination

Unscheduled Sacrifices and Deaths

Necropsies will be done. Animals to be sacrificed will be anesthetized with sodium pentobarbital, weighed, bled for required tests, and exsanguinated.

Scheduled Sacrifice

After at least 4 weeks of treatment, all surviving animals will be fasted overnight, then anesthetized with sodium pentobarbital, weighed, bled for required tests, exsanguinated, and necropsied.

Postmortem Procedures

Necropsy

The necropsy will include examination of:

all orifices
cranial cavity
external surface of the brain; the external surface of the spinal cord and cut surfaces of the brain and spinal cord will be examined whenever tissue trimming is performed
cervical tissues and organs
thoracic, abdominal, and pelvic cavities and viscera
external surface of the body
nasal cavity and paranasal sinuses

Palmitoyl CoA Oxidase Determinations

A sample of the right lateral lobe of liver will be collected from each animal at the scheduled sacrifice. The sample will be 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 will be collected and preserved in zinc formalin.

After fixation, samples for proliferation cell nuclear antigen (PCNA) evaluation will be embedded in paraffin and shipped to:

Sandra R. Eldridge, PhD
Pathology Associates International
15 Worman's Mill Court
Suite I
Frederick, Maryland 21701
Telephone: 301.663.1644 ext. 2201
Facsimile: 301.663.8994

Pathology Associates International will be notified regarding shipment of samples. PCNA evaluation will be done on the samples. Results will be provided for inclusion in the final report.

Liver PFOS Determination

A sample of liver (any non-formalin treated liver remaining after sampling for histopathology) will be collected from each animal at the scheduled sacrifice, weighed, flash-frozen in liquid nitrogen, and stored in a freezer set to maintain -60 to -80°C until shipped with plasma samples to 3M (Kris Hansen) for analysis. Analysis of liver for PFOS will be done on the samples. Results will be provided for inclusion in the final report.

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:

adrenal (2)
aorta
brain
cecum
cervix
colon
duodenum
epididymis (2)
esophagus
eye [(2) to be preserved in Davidson's fixative]
femur with bone marrow (articular surface of the distal end)
gallbladder
mesenteric lymph node
pancreas
pituitary
prostate
rectum
salivary gland [mandibular (2)]
sciatic nerve
seminal vesicle (2)
skeletal muscle (thigh)
skin
spinal cord (cervical, thoracic, and lumbar)
spleen
sternum with bone marrow

heart
ileum
jejunum
kidney (2)
lesions
liver
lung
mammary gland (females only)
ovary (2)
stomach
testis (2)
thymus
thyroid (2) with parathyroid
trachea
urinary bladder
uterus
vagina

Bone Marrow Smear

From the sternum of each animal at unscheduled and scheduled sacrifices (made and held for possible future examination)

Histopathology

The adrenals, eye, femoral bone marrow, lung, liver, kidney, pancreas, spleen, testes, and thymus from each animal will be embedded in paraffin, sectioned, stained with hematoxylin and eosin, and examined microscopically.

Reports

A draft report that includes the following information will be prepared and submitted:

Experimental Design and Methods

Results

mortality
clinical observations
body weights
food consumption
rectal body temperatures
clinical pathology results
palmitoyl CoA oxidase activities
hormone analyses (provided by AniLytics)
dose analyses (provided by 3M)
plasma and liver PFOS levels (provided by 3M)
macroscopic observations
microscopic observations
cell proliferation evaluations (provided by Pathology Associates International)
dose analyses (provided by 3M)

Statistical Evaluation

Levene's test will be done to test for variance homogeneity. In the case of heterogeneity of variance at $p \leq 0.05$, transformations will be used to stabilize the variance. Comparison tests will take variance heterogeneity into consideration.

One-way analysis of variance (ANOVA) will be used (if applicable) to analyze initial body weights, rectal body temperature, palmitoyl CoA oxidase activities, and continuous clinical pathology values. If the ANOVA is significant, Dunnett's t-test will be used for control versus treated group comparisons.

One-way analysis of covariance (ANCOVA) will be used to analyze body weights, with initial body weights as the covariate. If the ANCOVA is significant, covariate-adjusted means will be used for control versus treated group comparisons.

Group comparisons (Group 2 versus Group 1) will be evaluated at the 5.0% two-tailed probability level. Only data collected on or after the first day of treatment will be analyzed statistically.

At the end of 1 year after issuance of the audited draft report, if no requested revisions or instructions to finalize have been communicated by the Sponsor, then the audited draft report will be considered 'final' and issued as the final report, signed by the study director, and submitted to the Sponsor.

Any modifications or changes to the audited draft report requested 1 year after issuance will be performed at additional cost to the Sponsor.

Record Retention

All raw data, documentation, records, protocol, specimens, and final report generated as a result of this study will be archived in the storage facilities of Covance for a period of 1 year following submission of the final report to the Sponsor. One year after submission of the final report, all of the aforementioned materials will be sent to the Sponsor, and a return fee will be charged. The Sponsor may elect to have the materials retained in the Covance archives for an additional period of time, and Covance will charge a storage fee. If the Sponsor chooses to have Covance dispose of the materials, a disposal fee will be charged. All raw data stored on magnetic media will be retained by Covance.

protocol and protocol amendments
dose preparation records
in-life records
  animal receipt
  acclimation
  animal room maintenance
  randomizations
  dose administration
  clinical observations
  body weights
  food consumption
  sample collection
clinical pathology records
anatomical pathology records
statistical analyses
study correspondence
tissue specimens (wet and in paraffin)
blood and tissue slides
final report (original signed copy)

The following supporting records will be retained at Covance-Madison but will not be archived with the study data.

feed analysis records
water analysis records
animal room environment records
refrigerator and freezer temperature records
room temperature records for test material storage
instrument calibration and maintenance records.

PROTOCOL APPROVAL

Andrew M. Seacat, PhD
Study Monitor
3M

4/21/98
Date

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

4/17/98
Date

000250

COVANCE
THE DEVELOPMENT SERVICES COMPANY

PROTOCOL AMENDMENT NO. 1

Covance 6329-222

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

Sponsor:	3M, St. Paul, Minnesota
Study Monitor:	Andrew M. Seacat, PhD
Testing Facility:	Covance Laboratories Inc., Madison, Wisconsin
Study Director:	Peter J. Thomford, PhD

This amendment modifies the following portions of the protocol:

Effective April 17, 1998

1. **Page 7, Dosing Procedures, Method of Administration.** To more precisely define the duration of treatment, delete the text in this section replace with the following:

   Orally by gelatin capsules, daily (7 days/week) for at least 28 days

2. **Page 11, Blood Hormone Determination, Sample Handling, Sentence 2.** To modify the sample handling method, delete this sentence and replace with the following:

   Serum will be divided into two approximately equal aliquots and stored in a freezer set to maintain -60 to -80°C until packed on dry ice and shipped to:

3. **Page 14, Postmortem Procedures, Tissue Preservation.** To correct an error in the protocol, delete "mammary gland (females only)" and replace with the following:

mammary gland

Effective April 28, 1998

4. **Page 2, Alternate Study Monitor.** To change the alternate study monitor, delete the text in this section and replace with the following:

Marvin T. Case, DVM, PhD
3M
Toxicology Services
Telephone No.: 612.733.5180
Facsimile No.: 612.733.1773

AMENDMENT APPROVAL

Andrew M. Seacat, PhD
Study Monitor
3M

Date 5/12/98

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

Date 5/7/98

000252

COVANCE
THE DEVELOPMENT SERVICES COMPANY

PROTOCOL AMENDMENT NO. 2

Covance 6329-222

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

Sponsor:	3M, St. Paul, Minnesota
Study Monitor:	Andrew M. Seacat, PhD
Testing Facility:	Covance Laboratories Inc., Madison, Wisconsin
Study Director:	Peter J. Thomford, PhD

This amendment modifies the following portions of the protocol:

Effective May 15, 1998

1. **Page 13, Termination, Unscheduled Sacrifices and Deaths.** To change the anesthetic to be used before exsanguination because the barbiturate may interfere with tissue analyses, delete the text in this section and replace with the following:

   Necropsies will be done. Animals to be sacrificed will be anesthetized with ketamine and xylazine, weighed, bled for required tests, and exsanguinated.

2. **Page 13, Termination, Scheduled Sacrifice.** To change the anesthetic to be used before exsanguination because the barbiturate may interfere with tissue analyses, delete the text in this section and replace with the following:

   After at least 4 weeks of treatment, all surviving animals will be fasted overnight, then anesthetized with ketamine and xylazine, weighed, bled for required tests, exsanguinated, and necropsied.

AMENDMENT APPROVAL

Andrew M. Seacat, PhD (1.)
Study Monitor
3M

Date

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

Date 5/24/02

① Monitor did not return a signed copy of Protocol Amendment No. 2

PJT 27 Mar. 2002

000255

PROTOCOL AMENDMENT NO. 3

Covance 6329-222

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

Sponsor:	3M, St. Paul, Minnesota
Study Monitor:	Andrew M. Seacat, PhD
Testing Facility:	Covance Laboratories Inc., Madison, Wisconsin
Study Director:	Peter J. Thomford, PhD

This amendment modifies the following portions of the protocol.

Effective April 17, 1998

1. **Page 5, Vehicle, Storage Conditions.** To include the solvent used to dissolve the test material before mixing with the lactose, add the following after this section.

Solvent

Identification
Acetone

Lot Numbers
The lot numbers will be maintained in the raw data.

Purity
On file with the manufacturer

Stability
On file with the manufacturer

Storage Conditions
At room temperature

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

2. **Page 7, Dosing Procedures, Dose Preparation, Sentence 5.** To include the use of acetone in the preparation of the doses, delete this sentence and replace with the following.

   For the Group 2 and 3 dose preparations, the test material will be dissolved in acetone and triturated with lactose (1:999 and 1:9, w:w, respectively) once before initiation of treatment.

Effective April 17, 1998 and April 26, 1999

3. **Page 16, Record Retention.** To correct an omission in the protocol and to specify the record retention requirements for Ani Lytics Inc. and 3M E.T. & S (effective April 17, 1998) and to clarify the requirement for Pathology Associates International (effective April 26, 1999), add the following.

   Within 1 year after submission of the final report, all of the aforementioned materials (as appropriate) from Ani Lytics Inc. and 3M E.T. & S will be sent to the Sponsor (Andrew Seacat, PhD, 3M). Pathology Associates International (PAI) is responsible for the maintenance of any raw data or specimens produced by PAI.

Effective December 15, 1998

4. **Page 13, Postmortem Procedures, Cell Proliferation Evaluation, Paragraph 3, Sentence 2.** To include evaluation of slides stained with hematoxylin and eosin in the PCNA evaluation, delete this sentence and replace with the following.

   PCNA evaluation (including examination of slides stained with hematoxylin and eosin) will be done on the samples.

AMENDMENT APPROVAL

Andrew M. Seacat

Andrew M. Seacat, PhD
Study Monitor
3M

6/21/99
Date

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

18 June 1999
Date

000258

COVANCE
THE DEVELOPMENT SERVICES COMPANY

PROTOCOL AMENDMENT NO. 4

Covance 6329-222

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

Sponsor:	3M, St. Paul, Minnesota
Study Monitor:	Andrew M. Seacat, PhD
Testing Facility:	Covance Laboratories Inc., Madison, Wisconsin
Study Director:	Peter J. Thomford, PhD

This amendment modifies the following portions of the protocol.

Effective July 18, 2000

1. **Page 12, Serum PFOS Level Determination, Sample Shipping, Paragraph 3, Sentence 2.** To reflect the sponsor's decision to report the results of analysis of tissues for compound levels separately, delete this sentence and replace with the following.

   Results will be reported separately by the sponsor.

2. **Page 14, Liver PFOS Determination, Sentence 3.** To reflect the sponsor's decision to report the results of analysis of tissues for compound levels separately, delete this sentence and replace with the following.

   Results will be reported separately by the sponsor.

3. **Page 15, Reports, Results.** To reflect the sponsor's decision to report the results of analysis of tissues for compound levels separately, delete the following.

   plasma and liver PFOS levels (provided by 3M)

AMENDMENT APPROVAL

Andrew M. Seacat, PhD
Study Monitor
3M

7/31/2000
Date

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

24 July 2000
Date

000260

MATERIAL SAFETY DATA SHEET

3M
3M Center
St. Paul, Minnesota
55144-1000
(612) 733-1110

DIVISION: SPECIALTY CHEMICALS DIVISION
TRADE NAME:
FC-95 FLUORAD Brand Fluorochemical Surfactant
ID NUMBER/U.P.C.:
98-0207-0103-7 00-51135-09054-1 98-0207-0104-5 00-51135-09055-8
98-0211-0888-5 00-51135-09362-7 98-0211-3916-1 00-51135-02311-2
ZF-0002-1044-1 - - -
ISSUED: February 19, 1997
SUPERSEDES: August 23, 1996
DOCUMENT: 10-3796-9

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

2. PHYSICAL DATA

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

000261

3. FIRE AND EXPLOSION HAZARD DATA

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

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

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

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

4. REACTIVITY DATA

STABILITY: Stable

INCOMPATIBILITY - MATERIALS/CONDITIONS TO AVOID:
Not applicable.

HAZARDOUS POLYMERIZATION: Hazardous polymerization will not occur.

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

5. ENVIRONMENTAL INFORMATION

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

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

5. ENVIRONMENTAL INFORMATION (continued)

accept chemical waste.

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

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

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

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

RCRA HAZARD CLASS:
IRE HAZARD: No PRESSURE: No REACTIVITY: No ACUTE: Yes CHRONIC: Yes

6. SUGGESTED FIRST AID

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

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

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

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

7. PRECAUTIONARY INFORMATION

PROTECTION:
Avoid eye contact. Wear vented goggles.

7. PRECAUTIONARY INFORMATION (continued)

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

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

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

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

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

FIRE AND EXPLOSION AVOIDANCE:
Nonflammable.

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

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

EXPOSURE LIMITS

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

FC-95 FLUORAD Brand Fluorochemical Surfactant
Jary 19, 1997

EXPOSURE LIMITS (continued)

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

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

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

8. HEALTH HAZARD DATA

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

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

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

INHALATION:
May be harmful if inhaled.

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

Single overexposure, above recommended guidelines, may cause:

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

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

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

May be harmful if swallowed.

TAGENICITY:
utagenicity assays indicate the product is not mutagenic.

8. HEALTH HAZARD DATA (continued)

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

OTHER HEALTH HAZARD INFORMATION:
A Product Toxicity Summary Sheet is available.

SECTION CHANGE DATES

PRECAUTIONARY INFO. SECTION CHANGED SINCE August 23, 1996 ISSUE

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

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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

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER	GROUP: M1 DOSE: 0 MG/KG/DAY DAYS 1-30	DAY	'C' - COMMENTS LISTED AT END OF OBSERVATIONS FOR SEX/GROUP 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

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	DISPATCH	UNSCHED
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

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M3 DOSE: 2 MG/KG/DAY) DAYS 1-30	DAY	'C' - COMMENTS LISTED AT END OF OBSERVATIONS FOR SEX/GROUP: 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

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

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY 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	-	-	-	-	-	-

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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 (GROUP: F1 DOSE: 0 MG/KG/DAY 'C' - COMMENTS LISTED AT END OF OBSERVATIONS FOR SEX/GROUP)	DAYS 1-30 DAY	AM OBS	PM CHECK	30MIN	60MIN	90MIN	DISPATCH	UNSCHED
(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

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	CATEGORY 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	-

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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 (GROUP: F3 DOSE: 2 MG/KG/DAY, DAYS 1-30)	DAY	'C' - COMMENTS LISTED AT END OF OBSERVATIONS FOR SEX/GROUP: 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

APPENDIX 4

Individual Clinical Hematology Data
Individual Clinical Chemistry Data

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Individual Clinical Hematology Data

Males Day -7

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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Individual Clinical Hematology Data

Males Day -7

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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Individual Clinical Hematology Data

Males Day -7

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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Individual Clinical Hematology Data

Females Day -7

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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Individual Clinical Hematology Data

Females Day -7

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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Individual Clinical Hematology Data

Females Day -7

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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Individual Clinical Hematology Data

Males Day 29

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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Individual Clinical Hematology Data

Males Day 29

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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Individual Clinical Hematology Data

Males Day 29

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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Individual Clinical Hematology Data

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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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Individual Clinical Hematology Data

Females Day 29

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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Individual Clinical Hematology Data

Females Day 29

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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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	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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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	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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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	10.6	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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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	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

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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	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

000303

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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

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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	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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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

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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	10.0	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

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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	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

Appendix 4

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	10.4	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

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	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

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

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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	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

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	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

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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	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

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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	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 PERFLUCROOCTANE 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)

000333

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

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

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), 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

HISTOPATHOLOGY

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)

APPENDIX 6

Quality Assurance Statement
Summary and Individual Hormone Analyses Data
Figure 1 - Mean Estradiol Data (pg/mL) - Males
Figure 2 - Mean Estradiol Data (pg/mL) - Females
Figure 3 - Mean Triiodothyronine Data (ng/dL) - Males
Figure 4 - Mean Triiodothyronine Data (ng/dL) - 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.

ANALYTICS INCORPORATED
200 Girard Street, Suite 200, Gaithersburg, MD 20877
301-921-0168 800-237-2815

The reports listed below was reviewed for compliance with the FDA Good Laboratory Practices and with the EPA Good Laboratory Practices. The final report and all associated raw data were reviewed for accuracy and consistency and the findings were reported to management.

The methods used were the methods described and the report accurately reflects the data. Therefore, these studies were done in compliance with the FDA and EPA Good Laboratory Practices.

Franklin B. Newman
QA Auditor

SPONSOR: COVANCE LABS INC STUDY: 6329-222

REPORT TYPE:	AUDIT DATE:	REPORT TO MGMT:	AUDIT #:
E1, E2, E3, T3 T4, TSH	6-14-98	6-15-98	98-391

MANAGEMENT 6/15/98

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 ng/mL	THYROID STIMULATING µIU/mL	TRIIODOTHYRONINE ng/dL	THYROXIN µg/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 ng/mL	THYROID STIMULATING µIU/mL	TRIIODOTHYRONINE ng/dL	THYROXIN µg/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 ng/mL	THYROID STIMULATING µIU/mL	TRIIODOTHYRONINE ng/dL	THYROXIN µg/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

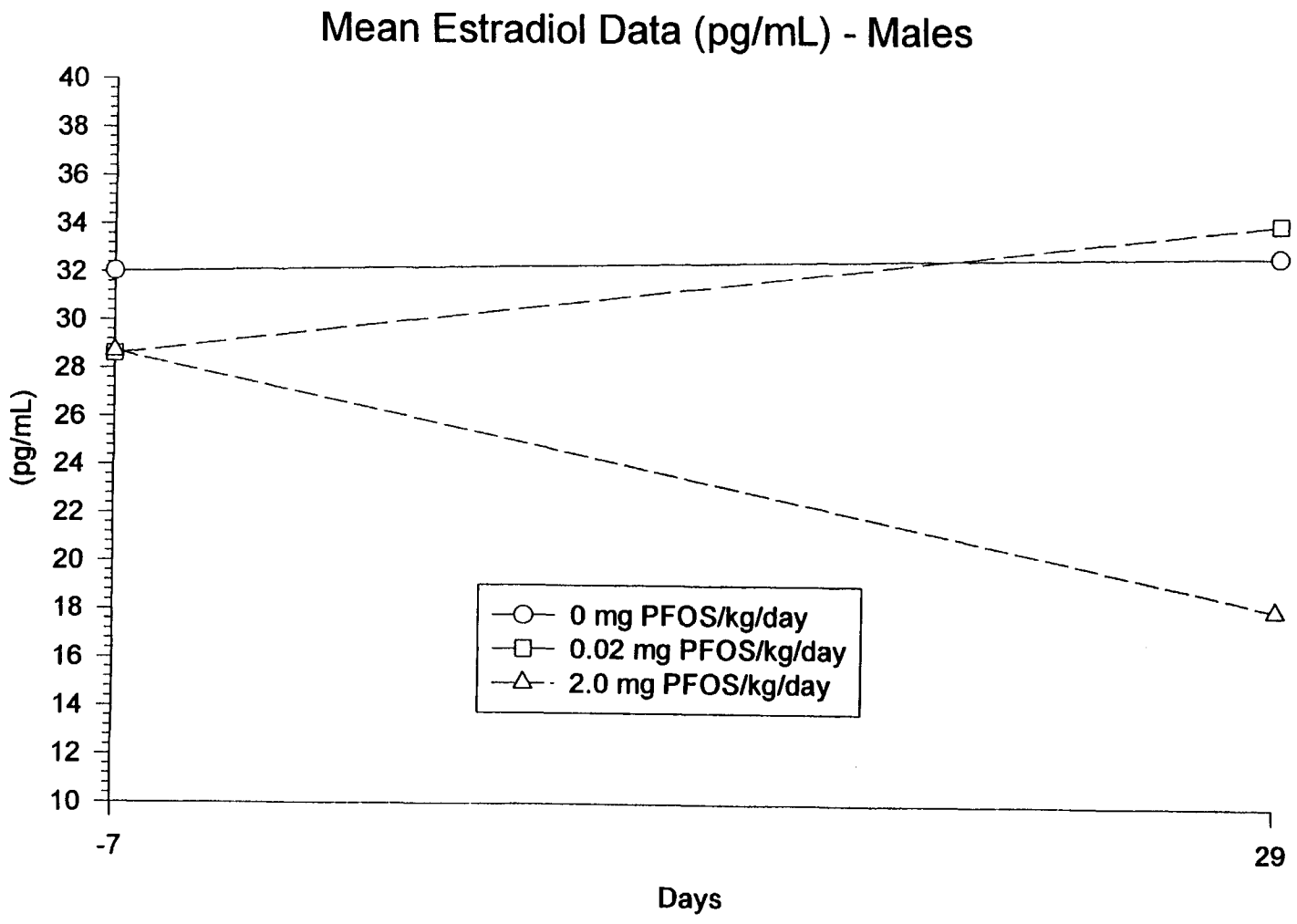
Females Day 29

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 ng/mL	THYROID STIMULATING µIU/mL	TRIIODOTHYRONINE ng/dL	THYROXIN µg/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

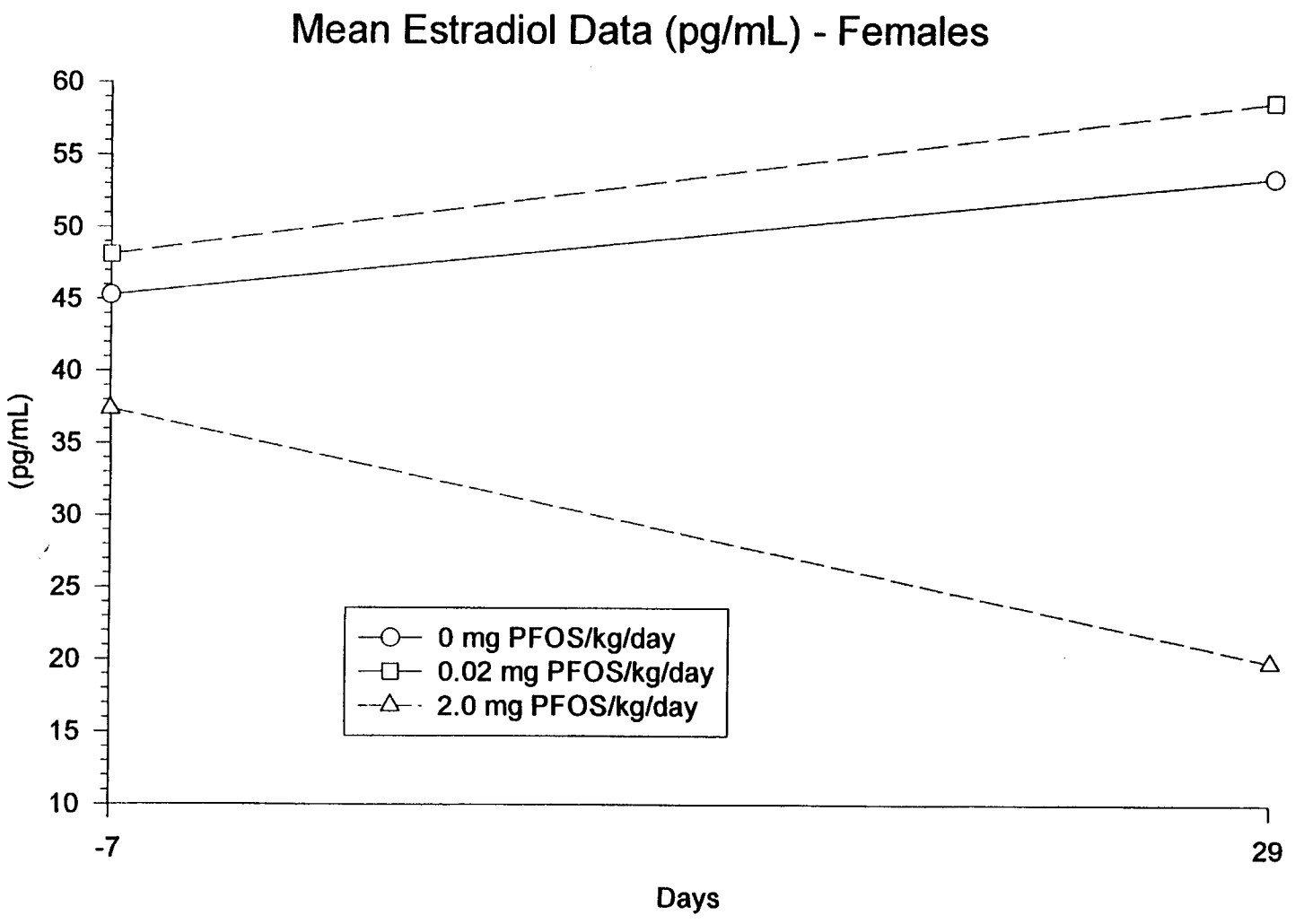
Covance 6329-222
3M T-6295.6



000345

Figure 2

Covance 6329-222
3M T-6295.6

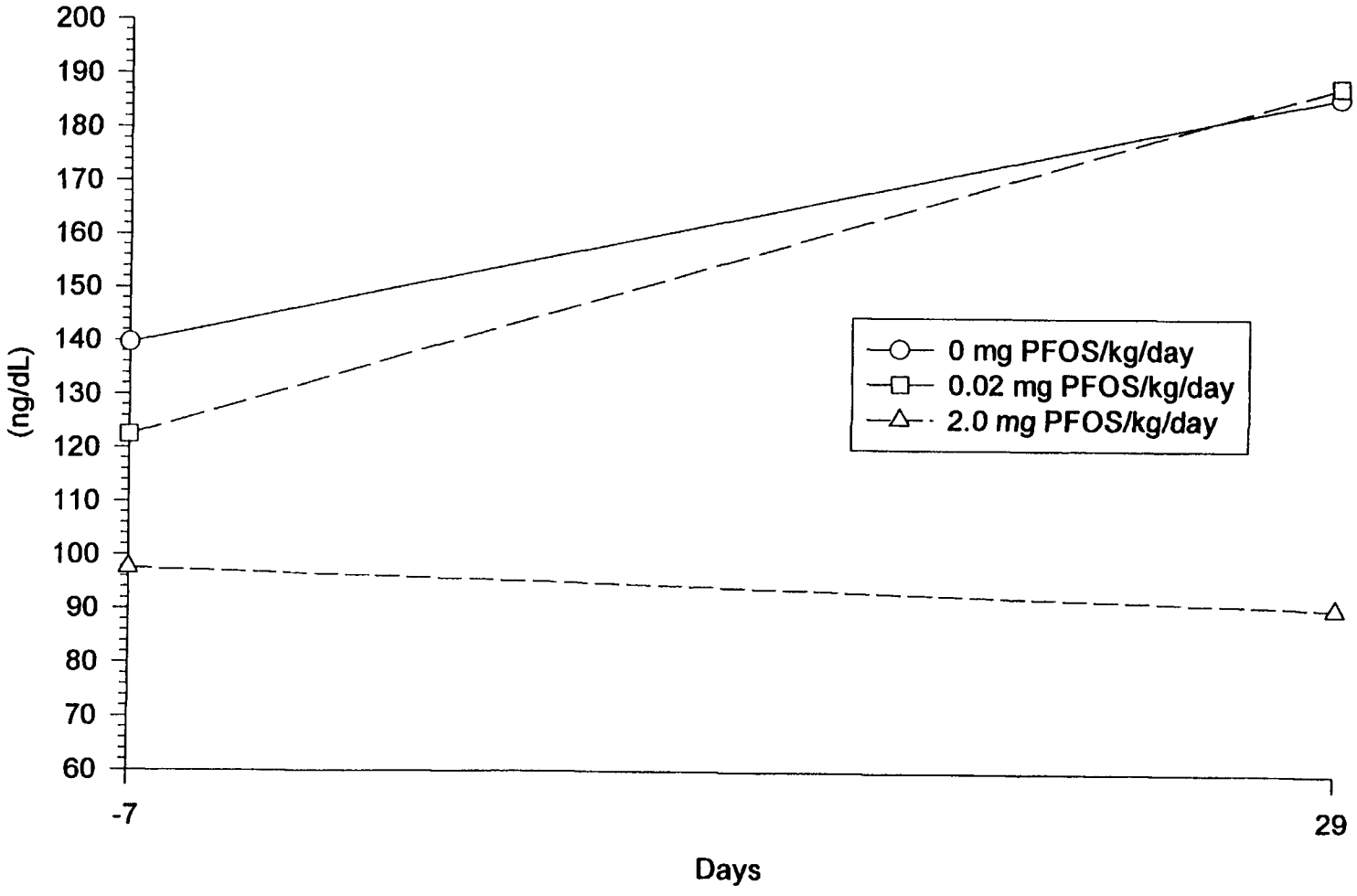


000346

Figure 3

Covance 6329-222
3M T-6295.6

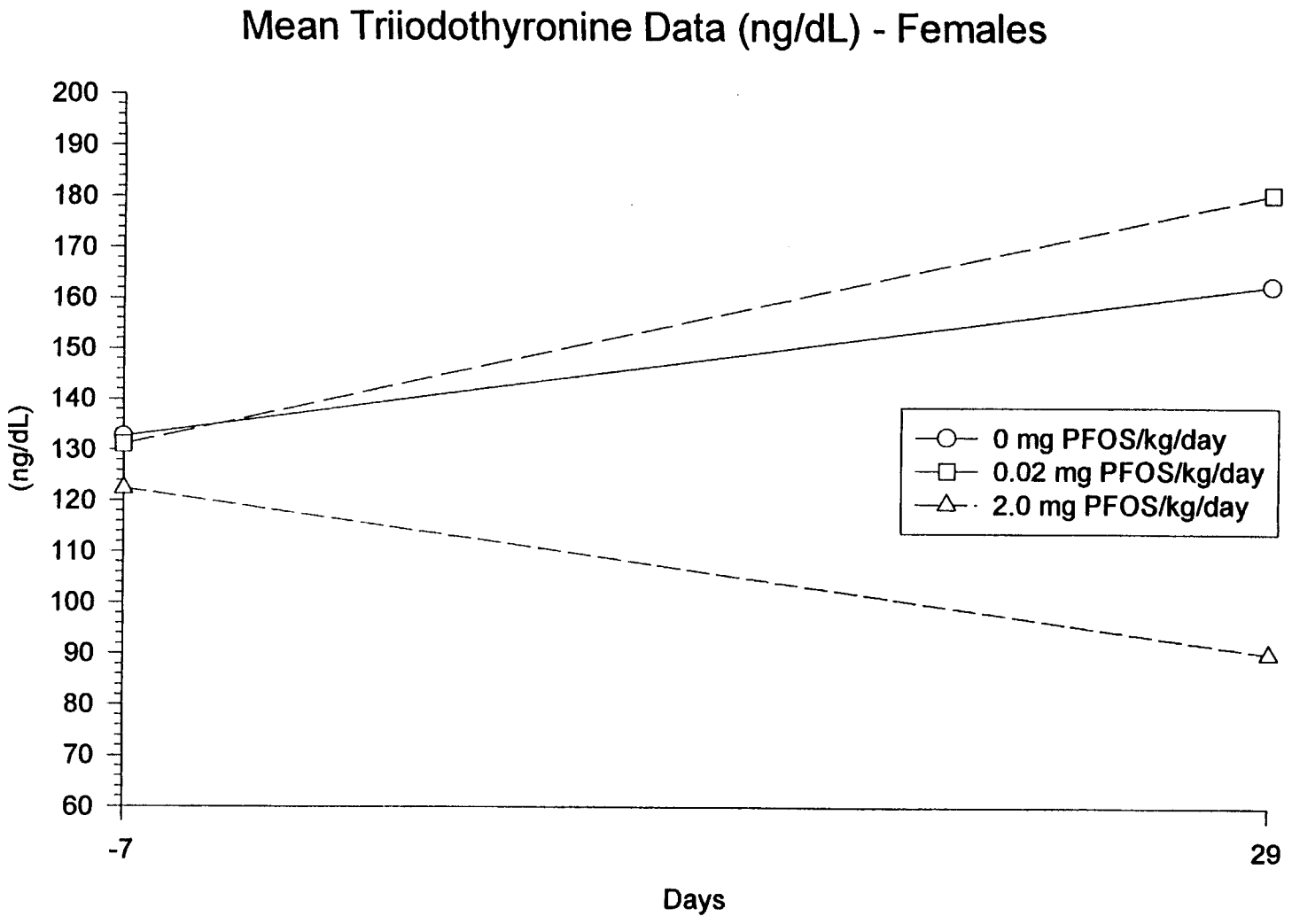
Mean Triiodothyronine Data (ng/dL) - Males



0003427

Figure 4

Covance 6329-222
3M T-6295.6



APPENDIX 7

Dose Confirmation Analysis Report
Compound Stability Report
Certificate of Analysis
Quality of Assurance Statement

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

Dose Confirmation Analysis Report for Study title: 4-Week Capsule Toxicity Study with Perfluorooctanesulfonic Acid Potassium Salt (PFOS) in Cynomolgus Monkeys Covance 6329-222, (3M Medical Dept number: T- 6295.6).

Author: Andrew M. Seacat

Final Report Date: 2/28/01

Introduction

Dose confirmation analysis were performed on samples of perfluorooctanesulfonic acid potassium salt (KPFOS) triturated in lactose. The 2.0 mg/kg/day dose level was prepared at 1:9 w:w PFOS: lactose, and the 0.02 mg/kg/day dose level was prepared at 1:999 w:w PFOS:lactose (sample numbers: CLI # 1205A1, and CLI# 1206A1, respectively). These samples were prepared at Covance on 4-13-98 at the initiation of the in-life phase of the study. Eight samples were collected. Samples from the top, middle and bottom of each mixture were collected on 4-13-98 and sent to 3M Environmental Lab. Additional samples were collected to assess compound stability in the dosing vehicle from the middle of each mixture on 5-22-98, and were sent to the 3M Environmental Lab for analysis.

Method summary

The dose confirmation data were collected according to a method described fully in the Analytical Laboratory Report (1). Briefly, dose confirmation was performed by diluting the lactose dose samples 1000-fold with Milli-Q water, which were then extracted using the ion-pair reagent tetrabutylammonium hydrogen sulfate according to the procedure (1). The extracts from CLI # 1205A1 and CLI# 1206A1 were then diluted 1:200 and 1:2, respectively, to bring the PFOS levels in the linear range of the instrument. For each sample, (top, middle and bottom), the average PFOS spiked matrix extract value was used as correction factor for calculating the percent recovery. In all cases, samples were analyzed versus an unextracted curve using HPLC-ESMS/MS.

Results

The results indicated that the average ± SD for the 2.0 mg/kg/day dose level prepared at a 1:9 dilution in lactose was 80 ± 0.02% of the target concentration. The average ± SD for the 0.02 mg/kg/day dose level prepared at a 1:999 dilution in lactose was 54 ± 0.02% of the target concentration (See Table 1 and calculations in the appendix).

The stability samples that were obtained from the middle of each mixture on 5-22-98 were 79% and 71% of the target concentration for the 2.0 and the 0.02 mg/kg/day dose level preparations respectively. Thus the dose preparations were stable for the entire dosing period.

Signature:

Andrew M. Seacat

Andrew M. Seacat Ph.D.

000350

Reference:

1. Hansen K. J. Analytical Laboratory Report from the 26-Week Capsule Toxicity Study with Perfluorooctanesulfonic Acid Potassium Salt (PFOS) in Cynomolgus Monkeys on the Determination of the Presence and Concentration of Perfluorooctanesulfonate (PFOS) in Liver and Serum Samples. Project Identification: Covance 6329-222, 6329-223, 3M Medical Dept number: T- 6295.7, Analytical study: FACT TOX030, 3M Laboratory request No. U2279. 214 pp, 2000.

Covance: 6329-222
3M T-6295.6

Dose Analysis Report

Appendix

Table 1

Study:	Covance 6329-222,		
Product Number(Test Substance)	0		
Matrix:	Dosing Vehicle	Filename:	See Attachments
Method/Revision:	FACT-M-3.0 and ETS-8-5.1- unextracted curves	R-Squared Value:	See Attachments
Analytical Equipment System Number:	Soup 020199	Slope:	See Attachments
Instrument Software/Version:	Masslynx 3.4	Y-Intercept:	See Attachments
Date of Extraction/Analyst:	10/23/00 RWW		
Date of Analysis/Analyst:	10/24/00 KJH		
Date of Data Reduction/Analyst:	10/25/00 KJH		

Lactose Dosing Confirmation

Group Dose	Sample #	Expected Conc. PFOS ng/mL	PFOS-Bckgrnd Conc. ng/mL	PFOS % Recovery Accuracy	Avg	SD
Method Blk	Lact102300-WBlk-1	0.00	NA	NA		
	Lact102300-WBlk-2	0.00	NA	NA		
QC	CLI1205A1(1:9)-MS-1	252	216	86%		
	CLI1205A1(1:9)-MSD-1	252	200	80%		
	CLI1206A1(1:999)-MS-1	251	265	106%		
	CLI1206A1(1:999)-MSD-1	251	276	110%		
Dose	CLI1205A1(1:9)	535	NA	79%		
	CLI1206A1(1:999)	544	NA	71%		
	CLI1206A1 G2-Top (1:999)	510	NA	54%	54%	2%
	CLI1206A1 G2-Middle (1:999)	502	NA	52%		
	CLI1206A1 G2-Bottom (1:999)	509	NA	57%		
	CLI1205A1 G3-Top (1:9)	511	NA	81%	80%	2%
	CLI1205A1 G3-Middle (1:9)	507	NA	81%		
	CLI1205A1 G3-Bottom (1:9)	513	NA	78%		

Limit of Quantitation Limit (LOQ): PFOS = 5.01 ng/mL on 9/19/00 and 25.1 ng/mL on 9/26/00

PFOS = Perfluorooctanesulfonate

NR = Sample not received nor reported.
NA = Not Applicable

Date Entered/Analyst: 11/02/00 LAC
Date Verified/Analyst: kjh 12/22/00

0003352

Covance: 6329-222
3M T-6295.6

Dose Analysis Report

Example Calculations:

Sample 1:9 G3 Top	1 mg PFOS / 10 mg lactose mix	102.1 mg lactose mix / 100 mL H2O	= 0.1021 mg PFOS / mL H2O	x 1000 ug / 1 mg	Dilution x 1 / 200	0.511 ug / mL
Sample 1 999 G2 Top	1 mg PFOS / 1000 mg lactose mix	101.9 mg lactose mix / 100 mL H2O	= 0.001019 mg PFOS / mL H2O	x 1000 ug / 1 mg	Dilution x 1 / 2	0.510 ug / mL
Matrix Spike 1:9	1006 ug / mL	x 0.05 mL / 1 mL	Dilution x 1 / 200	0.252 ug / mL		
Matrix Spike 1:999	50.1 ug / mL	x 0.01 mL / 1 mL	Dilution x 1 / 2	0.251 ug / mL		

Matrix Spike Curve and Spike are absolute and do not need purity/salt correction

[PFOS spkd sample] ng/mL	x extraction dilution factor		"=" [PFOS Corrected spkd sample] (ng/mL)
[PFOS Corrected spkd sample] (ng/mL) -	[PFOS Corrected sample] ng/mL		"=" [PFOS spike] measured (ng/mL)
[PFOS spike] measured / [Expected PFOS]	x 100 %		"=" % Recovery
Sample [Expected PFOS] (ng/mL)	x Salt and Purity Correction		= [Corrected, expected PFOS] ng/mL
[Measured PFOS] ng/mL	x Purity Correction Factor	x Extraction Dil Factor	= [Corrested, measured PFOS]
[Corrested, measured PFOS] ng/mL / [Corrected, expected PFOS] ng/mL	x 100%		= % Recovery

Covance: 6329-222
3M T-6295.6

Dose Analysis Report

CL1205A-MS-1		
486 ng/mL	x 1.25	= 608 ng/mL
608 ng/mL-	(314 ng/mL x 1.25)	= 215.5 ng/mL
215.5 ng/mL / 252 ng/mL	x 100	= 86%

G2 Top		
510 ng/mL	x 0.9275 x 0.8690	=411 ng/mL
203 ng/mL	x .8690 x 1.25	= 220 ng/mL
220 ng/mL / 411 ng/mL	x 100 %	= 54%

Corporate Health Physics
Corporate Occupational Medicine
Corporate Product Responsibility
Corporate Toxicology
3M Medical Department

3M Center, 220-2E-02
PO Box 33220
St. Paul, MN 55133-3220
651 733 1110

September 6, 2000

3M

Peter J. Thomford, Ph.D.
Study Director, Toxicology
Covance Laboratories Inc.
3301 Kinsman Blvd.
Madison WI 53704

Re. Covance 6329-222 (T-6295.6), 6329-223 (T-6295.7). Perfluorooctanesulfonate Compound Stability Report

Peter:

The perfluorooctanesulfonic acid potassium salt (PFOS, FC-95 Lot 217) used in Covance 6329-222, 6329-223, has remained stable for the entire duration of the study. A Certificate of Analysis (C of A) dated March 9, 2000 (1), identified the compound as being 90.49% C8F17SO3-K+ by a combination of LC/MS, ^{1}H-NMR, ^{19}F-NMR, and elemental analysis techniques. Previously, on December 1st 1997, ^{19}F-NMR was used to characterize FC-95 lot 217 and showed that the isomer distribution was identical to the C of A sent to you earlier this year (2). Additionally, ^{19}F-NMR and 1H NMR conducted on August 24th 2000 (3) were compared to the ^{19}F-NMR completed on December 1st 1997 and indicated that there was no significant differences in the composition of this lot of PFOS over intervening 3 and a half year time period. Thus, PFOS, FC-95 Lot 217 used was stable for greater the time period during which these studies were conducted.

Sincerely,

Andrew M. Seacat

Andrew M. Seacat Ph.D.
Toxicology Specialist

000355

References:

1. Payfer R.M. Certificate Of Analysis FC-95, Lot 217. 3M Specialty Chemicals Division. March 9, 2000

2. Kestner T. Fluorochemical Isomer Distribution by ^{19}F-NMR Spectroscopy. FC-95, lot 217 Analytical Request 53030 . SA&C Analytical Lab. December 1, 1997

3. Kestner T. Chemical Characterization of PFOS (FC-95, lot 217) by ^{1}H-NMR & ^{19}F-NMR Spectroscopy. Comparison to FC-95/217 analysis from Req.#53030-Request No. 61886. 3M SA&C Analytical Lab - 236-2B-11. August 24, 2000.

Centre Analytical Laboratories, Inc.
3048 Research Drive State College, PA 16801 www.centrelab.com
Phone: (814) 231-8032 Fax: (814) 231-1253 or (814) 231-1580

INTERIM CERTIFICATE OF ANALYSIS

Revision 3

Centre Analytical Laboratories COA Reference #: 023-018A
3M Product: PFOS, Lot 217
Reference #: SD-018
Purity: 86.9%

Test Name	Specifications	Result
Purity[1]		**86.9%**
Appearance	White Crystalline Powder	Conforms
Identification NMR		Positive
Metals (ICP/MS) 1. Calcium 2. Magnesium 3. Sodium 4. Potassium[2] 5. Nickel 6. Iron 7. Manganese		1. 0.005 wt./wt.% 2. 0.001 wt./wt.% 3. 1.439 wt./wt.% 4. 6.849 wt./wt.% 5. <0.001 wt./wt.% 6. 0.005 wt./wt.% 7. <0.001 wt./wt.%
Total % Impurity (NMR)		1.91 wt./wt.%
Total % Impurity (LC/MS)		8.41 wt./wt.%
Total % Impurity (GC/MS)		None Detected
Related Compounds – POAA		0.33 wt./wt.%
Residual Solvents (TGA)		None Detected
Purity by DSC		Not Applicable[3]
Inorganic Anions (IC) 1. Chloride 2. Fluoride 3. Bromide 4. Nitrate 5. Nitrite 6. Phosphate 7. Sulfate[4]		1. <0.015 wt./wt.% 2. 0.59 wt./wt.% 3. <0.040 wt./wt.% 4. <0.009 wt./wt.% 5. <0.006 wt./wt.% 6. <0.007 wt./wt.% 7. 8.76 wt./wt.%
Organic Acids [5] (IC) 1. TFA 2. PFPA 3. HFBA 4. NFPA		1. <0.1 wt./wt.% 2. <0.1 wt./wt.% 3. 0.10 wt./wt.% 4. 0.28 wt./wt.%
Elemental Analysis[6]: 1. Carbon 2. Hydrogen 3. Nitrogen 4. Sulfur 5. Fluorine	1. Theoretical Value = 17.8% 2. Theoretical Value = 0% 3. Theoretical Value = 0% 4. Theoretical Value = 5.95% 5. Theoretical Value = 60%	1. 12.48 wt./wt.% 2. 0.244 wt./wt.% 3. 1.74 wt./wt.% 4. 8.84 wt./wt.% 5. 54.1 wt./wt.%

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Phone: (814) 231-8032 Fax: (814) 231-1253 or (814) 231-1580

INTERIM CERTIFICATE OF ANALYSIS

Revision 3

Centre Analytical Laboratories COA Reference #: 023-018A

Date of Last Analysis: 08/31/00

Expiration Date: 08/31/06

Storage Conditions: Frozen ≤-10°C

Re-assessment Date: 08/31/06

[1]Purity = 100% - (sum of metal impurities, 1.45% +LC/MS impurities, 8.41%+Inorganic Fluoride, 0.59%+NMR impurities, 1.905%+organic acid impurities, 0.38%+POAA, 0.33%)

Total impurity from all tests = 13.07%
Purity = 100% - 13.07% = 86.9%

[2]Potassium is expected in this salt form and is therefore not considered an impurity.

[3]Purity by DSC is generally not applicable to materials of low purity. No endotherm was observed for this sample.

[4]Sulfur in the sample appears to be converted to SO_4 and hence detected using the inorganic anion method conditions. The anion result agrees well with the sulfur determination in the elemental analysis, lending confidence to this interpretation. Based on the results, the SO_4 is not considered an impurity.

[5]TFA	Trifluoroacetic acid
HFBA	Heptafluorobutyric acid
NFPA	Nonafluoropentanoic acid
PFPA	Pentafluoropropanoic acid

[6]Theoretical value calculations based on the empirical formula, $C_8F_{17}SO_3^-K^+$ (MW=538)

This work was conducted under EPA Good Laboratory Practice Standards (40 CFR 160).

Centre Analytical Laboratories, Inc.
3048 Research Drive State College, PA 16801 www.centrelab.com
Phone: (814) 231-8032 Fax: (814) 231-1253 or (814) 231-1580

INTERIM CERTIFICATE OF ANALYSIS

Revision 3

Centre Analytical Laboratories COA Reference #: 023-018A

LC/MS Purity Profile:

Impurity	wt./wt. %
C4	1.22
C5	1.33
C6	4.72
C7	1.14
Total	**8.41**

Note: The C4 and C6 values were calculated using the C4 and C6 standard calibration curves, respectively. The C5 value was calculated using the average result from the C4 and C6 standard curves. Likewise, the C7 value was calculated using the average result from the C6 and C8 standard curves.

Prepared By: _____ 10/11/01
Charles Simons Date
Scientist, Centre Analytical Laboratories

Reviewed By: _____ 10/11/01
John Flaherty Date
Laboratory Manager, Centre Analytical Laboratories

3M ENVIRONMENTAL LABORATORY

Note to File

Project or Study Number: FACT-TCR-001

Associated Study Number: LIMS # E00-1682

The expiration dates for PFOS lots 171 and 217 (SD009 and SD018) may be extended 5 years (08/31/06) as stability was demonstrated by studies W1878 (hydrolysis), W2775 (photolysis), and E01-0444 (biodegradation).

LAC 08/03/01

Recorded By:
Lisa Clemen Lisa A Clemen

Date
08/03/01 08/03/01

Form ETS-4-15.0

Exact Copy of Original
LAC 10/19/01
Initial Date

Sponsor Protocol No.: FACT-TCR001
Centre Study No.: 023-018

QUALITY ASSURANCE STATEMENT

Centre Study Number 023-018, entitled, "Characterization Study of PFOS, Lot 217 and Lot 171" was reviewed by Centre Analytical Laboratories' Quality Assurance Unit. All reviewed phases were reviewed for conduct according to Centre Analytical Laboratories' Standard Operating Procedures, the Study Protocol, and all applicable Good Laboratory Practice Standards. All findings were reported to the Study Director and to management.

Phase	Date Inspected	Date Reported to Study Director and Centre Management	Date Reported to Sponsor Management
1. Protocol Review	5/19/00	5/19/00	7/14/00
2. Label Checks (solubility)	7/14/00	7/17/00	Pending
3. Standard Solution Preparation and analysis by instrumentation	6/20,21/00 6/22/00	6/22/00 6/22/00	7/14/00 7/14/00
4. Raw Data Review (NMR)	7/11-13/00	7/15/00	Pending
5. Standard Solution Preparation (Solubility)	7/14/00	7/20/00	Pending
6. Standard Solution Preparation	6/29, 30/00 7/26/00	6/30/00 7/27/00	7/14/00 Pending
7. Report Review (DSC/TGA)	8/8/00	8/8/00	Pending
8. Data Review and Interim Report Review	8/8,9/00	8/9/00	Pending

Lisa Manning
Quality Assurance Officer

8-9-00
Date

THIS IS AN EXACT COPY OF
THE ORIGINAL DOCUMENT

BY CS DATE 12/4/01

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APPENDIX 8

Cell Proliferation Report

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.

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FINAL

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

PREPARED FOR:

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

PREPARED BY:

PATHOLOGY ASSOCIATES INTERNATIONAL
15 WORMAN'S MILL COURT, SUITE I
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NOVEMBER 11, 1999

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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%

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Final Cell Proliferation Report
Covance Study Number 6329-222

APPENDIX I

Covance Study Number 6329-222

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

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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: 11-12-99

PAI Project Pathologist:

Carolyn Moyer, D.V.M., Diplomate, A.C.V.P. — Date: 11/11/99

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Final Cell Proliferation Report
Covance Study Number 6329-222

IV. QUALITY ASSURANCE STATEMENT

Pathology Associates International
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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

QUALITY ASSURANCE STATEMENT

This cell proliferation project has been inspected and audited by the PAI Quality Assurance Unit (QAU) as required by the Good Laboratory Practice (GLP) regulations promulgated by the U.S. Environmental Protection Agency (TSCA). The cell proliferation report is an accurate reflection of the recorded data. The following table is a record of the inspections/audits performed and reported by the QAU.

Date of Inspection	Phase Inspected	Date Findings Reported to PAI Management/Study Pathologist
06/24/98	Tissue Labeling	06/26/98
08/27;09/08,10/98	Study Data and Supporting Documentation	09/10/98
08/27;09/08,10/98	Draft Cell Proliferation Report	09/10/98
11/11/99	Final Cell Proliferation Report	11/11/99

Karen E. Butler
Quality Assurance Specialist

11/11/99
Date

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