Final Report

26-Week Capsule Toxicity Study with Ammonium Perfluorooctanoate (APFO) in Cynomolgus Monkeys

PREPARED FOR:
APME Ad-Hoc APFO Toxicology Working Group

COVANCE STUDY NUMBER:
6329-231

COVANCE.
THE DEVELOPMENT SERVICES COMPANY

Sponsors:

APME Ad-Hoc APFO Toxicology Working Group

FINAL REPORT

Study Title:

26-Week Capsule Toxicity Study with Ammonium Perfluorooctanoate (APFO) in Cynomolgus Monkeys

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Study Completion Date:

December 18, 2001

Testing Facility:

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

Laboratory Study Identification:

Covance 6329-231

Sponsor Study Identification:

3M T-6889.3

COMPLIANCE STATEMENT

26-Week Capsule Toxicity Study with Ammonium Perfluorooctanoate (APFO)
in Cynomolgus Monkeys

All aspects of this study were in accordance with the Environmental Protection Agency Good Laboratory Practice Standards, 40 CFR 792, except that bile acid and palmitoyl CoA oxidase determinations done by the University of Dundee were not done in compliance with GLPs and will be reported separately by the University of Dundee.

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

18 DEC. 2001
Date

Paul Lieder, PhD
Diplomate, ABT
Study Monitor
3M

20 December 2001
Date

QUALITY ASSURANCE STATEMENT

This report, with exception of appendices 6, 7, and 8, has been reviewed by the Quality Assurance Unit of Covance Laboratories Inc., in accordance with the Environmental Protection Agency (EPA) Good Laboratory Practice Standards, 40 CFR 792. The following inspections were conducted and findings reported to the study director and study director management.

Inspection Dates			Date Reported to Study Director and
From	To	Phase	Study Director Management
09/24/98	09/24/98	Protocol Review	09/24/98
10/07/98	10/07/98	Analytical Laboratory Inspection	10/07/98
01/05/99	01/05/99	Body Weight	01/05/99
04/01/99	04/01/99	Protocol Amendment Review	04/01/99
05/03/99	05/03/99	Clinical Laboratory Inspection	05/03/99
06/18/99	06/18/99	Data Review	06/23/99
07/29/99	07/29/99	Protocol Amendment Review	07/29/99
08/11/99	08/11/99	Protocol Amendment Review	08/11/99
09/02/99	10/01/99	Data Review	10/01/99
09/13/99	10/01/99	Report Review	10/01/99
11/15/99	11/15/99	Protocol Amendment Review	11/18/99
01/15/01	01/15/01	Protocol Amendment Review	01/15/01
02/26/01	02/27/01	Report Review	03/01/01
12/04/01	12/04/01	Report Review	12/05/01

Mark R. Sullivan
Representative
Quality Assurance Unit

18 Dec 2001
Date

STUDY IDENTIFICATION

26-Week Capsule Toxicity Study with Ammonium Perfluorooctanoate (APFO) in Cynomolgus Monkeys

Test Material	Ammonium Perfluorooctanoate (APFO)
Sponsors	APME Ad-Hoc APFO Toxicology Working Group
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Alternate Study Monitor	John Butenhoff, PhD, DABT 3M Toxicology Services Building 220-2E-02, 3M Center St. Paul, Minnesota 55144-1000 612.733.1962
Sponsor's Representative	David Farrar, PhD ICI Chemicals & Polymers Limited Occupational Health The Heath, Runcorn, PO Box 13 Cheshire, WA7 4QF 01928.513953
Study Location	Covance Laboratories Inc. 3301 Kinsman Boulevard Madison, Wisconsin 53704-2595
Study Director	Peter J. Thomford, PhD Covance Laboratories Inc. PO Box 7545 Madison, Wisconsin 53707-7545 608.241.7207

STUDY IDENTIFICATION (Continued)

26-Week Capsule Toxicity Study with Ammonium Perfluorooctanoate (APFO)
in Cynomolgus Monkeys

Study Timetable

Study Initiation Date	September 23, 1998
In-Life (Experimental) Start Date	September 29, 1998
In-Life Termination Date	July 2, 1999
Experimental Termination Date	December 18, 2001

KEY PERSONNEL

26-Week Capsule Toxicity Study with Ammonium Perfluorooctanoate (APFO) in Cynomolgus Monkeys

Study Director	Peter J. Thomford, PhD
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Supervisor, Dose Formulation	Dixie Bushee, BS, LATG
Associate Director, Laboratory Animal Medicine	Donna J. Clemons, DVM, MS Diplomate, ACLAM
Clinical Pathologist	Robert L. Hall, DVM, PhD Diplomate, ACVP (Clinical Pathology)
Supervisor, Clinical Pathology	Ronald Markevitch, BS, MT (ASCP)
Anatomic Pathologist	Johnnie J. Eighmy, DVM, MS Diplomate, ACVP Diplomate, ABT
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ABSTRACT

The purpose of this study was to assess the effect of the test material, ammonium perfluorooctanoate (APFO), on critical enzyme levels, hormones, and other selected biochemical parameters when administered daily by capsule to cynomolgus monkeys for at least 26 weeks.

Male cynomolgus monkeys were assigned to four groups (six animals/group in Groups 1, 3, and 4, and four animals in Group 2). Animals in Group 1 received empty gelatin capsules. Animals in Groups 2 and 3 received gelatin capsules containing 3 and 10 mg APFO/kg of weight/day (mg/kg/day), respectively. Animals in Group 4 received gelatin capsules containing 30 mg APFO/kg/day on Days 1 through 11; dose administration was discontinued for Days 12 through 21 due to signs of toxicity. Beginning on Day 22 and continuing throughout the remainder of the study, Group 4 males were administered 20 mg APFO/kg/day with the exception that dosing for three animals was discontinued between Days 43 and 81; hereafter, the high dose will be referred to as 30/20 mg/kg/day. Animals were administered APFO daily for at least 26 weeks; two animals in Groups 1 and 3 were treated for 26 weeks, then treatment was discontinued and the animals were observed for reversibility, persistence, or delayed occurrence of toxic effects for 13 weeks posttreatment.

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. Ophthalmic examinations were done before initiation of treatment and during Weeks 27 and 40. Body weight data were collected weekly before initiation of treatment, on the first day of treatment, and weekly thereafter. Blood samples for hormone analyses were collected at selected intervals during treatment and recovery. Blood, urine, and fecal samples were collected during Week 2 and every 2 weeks thereafter during treatment and recovery for APFO concentration analyses. Blood and urine samples were collected for clinical hematology, coagulation, clinical chemistry, and urinalysis tests at selected intervals during treatment and recovery. After 26 weeks of treatment, four animals/group in Groups 1 through 3, and all surviving animals in Group 4 were anesthetized, weighed, exsanguinated, and necropsied. After 26 weeks of treatment and 13 weeks without treatment, two animals/group in Groups 1 and 3 were anesthetized, weighed, exsanguinated, and necropsied. At necropsy, macroscopic observations were recorded, selected organs were weighed, and selected

tissues were collected and preserved. In addition, the right lateral lobe of liver was collected from each animal for palmitoyl CoA oxidase activity analyses. Representative samples of liver, right and left testes, and pancreas were collected from each animal for cell proliferation evaluation using proliferation cell nuclear antigen (PCNA). Bile was collected from each animal for bile acid determination. A sample of liver was collected from each animal for APFO concentration analyses. Microscopic examinations were done on tissues from each animal.

One male given 30/20 mg/kg/day and one male given 3 mg/kg/day were sacrificed in moribund condition on Days 29 and 137, respectively. Test material-related observations noted for the male given 30/20 mg/kg/day included hypoactive behavior, entire body cold to the touch, few or no feces, low or no food consumption, and weight loss. Clinical observations noted for the male given 3 mg/kg/day included limited use and paralysis of the hind limbs, ataxic and hypoactive behavior, few feces, and no food consumption.

During Week 1, males given 30 mg/kg/day had observations of few feces, low food consumption, and lost weight. Based on decreased food consumption and body weight loss, the dose level was lowered to 20 mg/kg/day beginning on Day 22. After the dose level was lowered, only two animals tolerated the dose level for remaining 23 weeks of dose administration; one of these animals continued to have test material-related observations of few feces and low food consumption. Dose administration was discontinued for three males given 30/20 mg/kg/day between Days 43 (Week 7) and 81 (Week 12). Test material-related observations noted for these animals included thin appearance, few or no feces, low or no food consumption, and weight loss (17.5 to 23.1%). These animals appeared to recover from the test material-related effects within 3 weeks after dose administration was discontinued.

There were no effects on estrone, estradiol, estriol, thyroid stimulating hormone, or testosterone that were clearly dose-related or consistent in their effects over time. Thyroid hormones in general were decreased beginning on Day 35 in animals administered 10 or 20 mg APFO/kg and in general exhibited recovery in the last 3 months of dosing or during the recovery phase. No alterations in cholecystokinin concentrations were observed at any of the time points.

Administration of APFO at dose levels of 3 or 10 mg/kg/day had no apparent effects on hematology, coagulation, clinical chemistry, or urinalysis results. Of uncertain relationship to administration of APFO at 30/20 mg/kg/day were mildly increased

triglyceride concentration and mildly to moderately decreased absolute neutrophil count, total protein concentration, and albumin concentration. In addition, two animals given APFO at 30/20 mg/kg/day exhibited moderately to markedly increased serum enzyme activities (i.e., aspartate aminotransferase, alanine aminotransferase, sorbitol dehydrogenase, and creatine kinase) and mildly increased serum bile acid concentration prior to the unscheduled sacrifice of one of the animals and the cessation of treatment for the other animal because of poor health. These findings, although not observed for most of the animals given 30/20 mg/kg/day, may also have been caused by the test material.

During recovery, there was no evidence of persistent or delayed toxic effects on clinical pathology test results.

After up to 26 weeks on study, enhanced cell proliferation was not evident in the pancreas or testes of male monkeys, whereas in the liver the findings were equivocal.

Test material-related and statistically significant increases were seen in mean absolute liver weights and mean liver-to-body weight percentages in animals in all dose groups at the terminal sacrifice. In addition, mean liver-to-brain weight significantly increased in animals in the 10 mg/kg/day group; this was also considered test material-related. However, no test material-related macroscopic or microscopic changes were seen in any organs at the terminal sacrifice, including liver, adrenal, spleen, pancreas, and testis.

At the recovery sacrifice, there were no test material-related effects on terminal body weights or on absolute or relative organ weights, indicating that the liver weight increases seen at the termination of dosing were reversible. There were no macroscopic or microscopic findings attributed to test material administration at the recovery sacrifice.

Two animals were sacrificed in a moribund condition during the course of the study, a male given 30/20 mg/kg/day (Day 29) and a male given 3 mg/kg/day (Day 137). The male given 30/20 mg/kg/day had esophageal and gastric lesions indicative of a dosing injury, and liver lesions presumed to be due to the test material. The cause of the moribund condition of the male given 3 mg/kg/day was unclear.

Based on the results of this study in which ammonium perfluorooctanoate (APFO) was administered orally by capsule to cynomolgus monkeys at doses of 0, 3, 10, or 30/20 mg/kg/day for 26 weeks, the no-observable-adverse-effect level (NOAEL) was

10 mg/kg/day. Effects seen in animals administered 10 mg/kg/day were not evident after 13 weeks of recovery.

PURPOSE

The purpose of this study was to assess the effect of the test material, ammonium perfluorooctanoate, on critical enzyme levels, hormones, and other selected biochemical parameters when administered daily by capsule to cynomolgus monkeys for at least 26 weeks.

REGULATORY COMPLIANCE

All aspects of this study were done in accordance with the Environmental Protection Agency Good Laboratory Practice Standards, 40 CFR 792, except that bile acid and palmitoyl CoA oxidase determinations done by the University of Dundee were not done in compliance with GLPs and will be reported separately by the University of Dundee.

TEST MATERIAL

Test Material

The test material, ammonium perfluorooctanoate (APFO), Lot No. 332 (expiration date: December 15, 2001), is a white powder and is 95.2% pure. It was received at Covance on June 10, and October 22, 1998. The test material was stored at room temperature.

Information on synthesis methods, composition, or other characteristics that define the test material is on file with the Sponsor. The Certificate of Analysis is in Appendix 1.

Reserve (Archive) Samples

A reserve sample (1 g) of the test material was taken before initiation of treatment and stored at room temperature. This sample was transferred to the Sponsor on May 2, 2001.

Disposition

The remaining test material was returned on May 2, 2001.

TEST ANIMALS AND HUSBANDRY

Animals

Young adult to adult cynomolgus monkeys were obtained from Covance Research Products Inc. (Denver, Pennsylvania) on August 25, 1998. The animals were approximately 3 to 7 years old and weighed 3.2 to 4.5 kg at initiation of treatment.

Identification

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

Justification

APFO 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.

Husbandry

Animal Rooms 253 and 227 were used for this study. Recovery animals were transferred to Animal Room 227 on April 15, 1999 (Day 15 of recovery). Environmental controls for the animal rooms 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 suspended, 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. During the study, animals in the high-dose group were offered Gatorade® as well as other supplements to rehydrate and to stimulate food consumption. The lot numbers of the Gatorade® are recorded in the data.

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.

Acclimation

Twenty-four males were received on August 25, 1998, and acclimated in Animal Room 253 for 35 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 test for parasites were performed on each animal.

PROCEDURES

This study was conducted in accordance with the Protocol dated September 23, 1998, and Protocol Amendment Nos. 1 and 2. The protocol, protocol amendments, and protocol deviations are in Appendix 1.

Group Designations and Dose Level

Selection of animals for the study was based on data collected during acclimation. 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)	No. of Males
1 (Control)	0[a]	6[b]
2 (Low)	3	4[c]
3 (Mid)	10	6[b]
4 (High)[d]	30/20	6

a The control group (Group 1) received empty gelatin capsules.
b Two animals in Groups 1 and 3 designated as recovery animals were treated for 26 weeks, then treatment was discontinued, and the animals were observed for reversibility, persistence, or delayed occurrence of toxic effects for 13 weeks posttreatment.
c Animal No. I05723 was replaced with Animal No. I05721. Dosing for Animal No. I05721 began on Day 17 (October 15, 1998).
d Dosing for Group 4 was suspended on Day 12 (October 10, 1998) and reinitiated at 20 mg/kg/day on Day 22 (October 20, 1998).

Dosing Procedures

Gelatin capsules (Torpac, Inc., Fairfield, New Jersey), Size No. 2, Lot No. 122932 were used for dose administration. Expiration dates for the empty gelatin capsules are maintained in the raw data.

The test material was dispensed into capsules at least weekly. The dose levels were based on the test material as supplied. For Groups 2 through 4, the specified amount of test material was weighed and transferred into the gelatin capsules. The top and bottom halves of each capsule were joined, and the capsules were placed into the appropriately labeled container. The prepared capsules were stored at room temperature.

Method of Administration. Gelatin capsules were administered orally to compare with previously conducted toxicology studies using the oral route.

The dose preparations were administered orally in gelatin capsules once daily, 7 days/week, for at least 26 weeks (183 days) except that Animal No. I05721 (Group 2 replacement animal) initiated dose administration on Day 17 and the animals in Group 4 were not dosed on Days 12 through 21; dose administration was also discontinued for Animal Nos. I05711, I05722, and I05703 (Group 4) on Days 43 (Week 7), 66 (Week 10), and 81 (Week 10), respectively (see Protocol Deviations for exceptions). Individual daily 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.

Dose Analyses
Because the test material was not mixed with a vehicle, dose analyses were not required.

Observation of Animals
Clinical Observations. The animals were observed twice daily (a.m. and p.m.) for mortality and moribundity. Animals were observed at least once daily (a.m.) for signs of poor health or abnormal behavior and food consumption was assessed qualitatively; only abnormal findings were recorded. Animals were observed once weekly; abnormal findings or an indication of normal was recorded (see Protocol Deviations for exceptions).

Ophthalmology. Ophthalmic examinations were done on each animal before initiation of treatment and during Weeks 27 and 40 (recovery). The pupils were dilated with 1% Mydriacyl® and the anterior portion of the eye, optic media, and ocular fundus were examined with an indirect ophthalmoscope.

Body Weights. Individual body weight data were recorded weekly before initiation of treatment, on the first day of treatment, and weekly thereafter. An additional body weight was recorded on Day -1 for the Day 1 dose calculations.

Blood Hormone Determination
Blood was collected from a femoral vein of each animal three times before initiation of treatment (Days -18, -8, and -4) and on Days 35, 66, 94, and 183 of treatment and on Days 220, 248, and 276 during recovery. Animals were not fasted before collections. Approximately 6 mL of blood for plasma samples was collected into tubes with potassium EDTA as the anticoagulant. Blood samples for plasma were maintained chilled until plasma was harvested (see Protocol Deviations for exceptions). Approximately 6 mL of blood for serum samples was collected without anticoagulant and allowed to clot. Blood samples for serum were maintained at room temperature until serum was harvested. Samples for serum were centrifuged within 1 hour after collection, and serum was harvested. Serum was 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 Ani Lytics Inc., for analyses. The serum samples were analyzed for estradiol (E2), estrone (E1), estriol (E3), thyroid stimulating hormone (TSH), total and free

triiodothyronine (T3 and FT3, respectively), total and free thyroxin (T4 and FT4, respectively). Results of these analyses provided by Ani Lytics Inc. are in Appendix 6.

Samples for plasma were centrifuged within 1 hour after collection. Plasma was harvested and stored in a freezer, set to maintain -60 to -80°C, until packed on dry ice and shipped to DuPont for analyses. The plasma samples were analyzed by DuPont for cholecystokinin. Results of these analyses provided by DuPont are in Appendix 7.

Because the decision to analyze blood for testosterone (TESTOS) was made after the terminal sacrifice, an aliquot of plasma from prestudy and Days 35, 66, 94, and 183 collection intervals was transferred from DuPont to Ani Lytics Inc. for analysis of testosterone. In addition, serum samples collected during recovery (Days 220, 248, and 276) were also analyzed for testosterone. Results of these analyses provided by Ani Lytics Inc. are in Appendix 6.

Serum APFO Level Determination

Approximately 2 mL of whole blood were collected from a femoral vein of each animal during Week 2 (after 7 days of treatment) and every 2 weeks thereafter during treatment and recovery. In addition, blood was collected from Animal No. I05724 (Group 4) that was sacrificed in moribund condition. Animals were not fasted before collections. All samples were collected without anticoagulant, maintained at room temperature, and allowed to clot. Samples were centrifuged within 1 hour after collection, serum was harvested and stored in a freezer, set to maintain -10 to -30°C, until packed on dry ice and shipped to 3M for analyses. The samples were analyzed for APFO. Results of the analyses will be reported separately by 3M.

Urine and Feces APFO Level Determination

Samples of urine (at least 2 mL) and feces (at least 5 grams, see Protocol Deviations for exceptions) were collected from each animal during Week 2 (after 7 days of treatment) and every 2 weeks thereafter during treatment and recovery (concurrent with serum APFO sample collection). Animals were not fasted before collections. Urine (collected on wet ice) and feces were collected overnight. Urine and fecal samples were stored in a freezer, set to maintain -10 to -30°C, until packed on dry ice and shipped to 3M for

analyses. The samples were analyzed for APFO. Results of the analyses will be reported separately by 3M.

Clinical Pathology

Blood and urine samples were collected from each animal before initiation of treatment; before the daily dose on Days 31, 63, 91, and 182; and on Days 217, 245, and 275 during recovery. Animals were fasted overnight, and urine was collected on wet ice overnight (approximately 16 hours) before blood sampling; water was provided *ad libitum*. Blood was collected from a femoral vein. Anticoagulants were sodium citrate for coagulation tests and potassium EDTA for hematology tests. Samples for clinical chemistry were collected without anticoagulant. Blood samples were collected from animals sacrificed at an unscheduled interval. Animals were bled in random order. 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

Coagulation

- prothrombin time
- activated partial thromboplastin time
- fibrinogen

Clinical Chemistry

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

Urinalysis

volume (approximately 16 hours)	bilirubin
specific gravity	blood
pH	urobilinogen
protein	microscopic examination of sediment
glucose	appearance
ketones	

Additional Blood Collection

Whole blood (approximately 19 mL) was collected from the vena cava of each animal at the time of exsanguination (scheduled and unscheduled sacrifices). Approximately equal sized samples of serum [approximately 7 mL (collected without anticoagulant)], whole blood (approximately 5 mL), and plasma (approximately 7 mL) using potassium EDTA as the anticoagulant were transferred into containers and stored in a freezer, set to maintain -60 to -80°C, until packed on dry ice and shipped to 3M for possible future analysis. In addition to the required blood samples, additional whole blood (approximately 40 to 80 mL/animal) was collected from the animals in the control group at the terminal sacrifice using sodium heparin as an anticoagulant. One-half of this sample was transferred into cryotubes and pooled. The remaining half of the sample was centrifuged and the plasma and red blood cells were transferred into cryotubes and pooled. The pooled samples were stored in a freezer, set to maintain -60 to -80°C, until packed on dry ice and shipped to 3M for possible future analysis.

Anatomic Pathology

Necropsy. A necropsy was done on each animal that was sacrificed at an unscheduled interval. After 26 weeks of treatment, four animals/group in Groups 1 through 3 and all surviving animals in Group 4 were fasted overnight, then anesthetized with ketamine and xylazine, weighed, exsanguinated, and necropsied (see Protocol Deviations for exceptions). After 26 weeks of treatment and 13 weeks without treatment, two animals/group in Groups 1 and 3 were fasted overnight, then anesthetized with ketamine and xylazine, weighed, exsanguinated, and necropsied. Animals were necropsied in random order.

The necropsy included a macroscopic examination of the external surface of the body; all orifices; 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.

Organ Weights. At each scheduled and unscheduled sacrifice, the following organs (when present) were weighed; paired organs were weighed separately.

adrenal (2)	liver
brain	pancreas
epididymis (2)	testis (2)
kidney (2)	thyroid (2) with parathyroid

Organ-to-body weight percentages and organ-to-brain weight ratios were calculated.

Palmitoyl CoA Oxidase Determinations

The right lateral lobe of liver was collected from each animal at the scheduled and unscheduled sacrifices. The sample was weighed, flash-frozen in liquid nitrogen, and stored in a freezer set to maintain -60 to -80°C these samples will be packed on dry ice and shipped to the University of Dundee for palmitoyl CoA oxidase activity analyses. Results of palmitoyl CoA oxidase activity analyses will be reported separately by the University of Dundee.

Cell Proliferation Evaluation

Representative samples of the left lateral lobe of the liver, left and right testes, and pancreas were collected from each animal at the scheduled and unscheduled sacrifices

and preserved in zinc formalin (unscheduled sacrifices and for animals sacrificed during Week 27) or formalin [animals sacrificed during Week 40 (see Protocol Deviations for exceptions)]. After fixation, samples for proliferation cell nuclear antigen (PCNA) evaluation were embedded in paraffin and maintained at ambient temperature (with slides stained with hematoxylin and eosin) until shipped to Pathology Associates, A Charles River Company for PCNA analyses. Results of the evaluation provided by Pathology Associates, A Charles River Company are in Appendix 8.

Bile Acid Determination

All available bile (up to 5 mL) was collected from each animal at the scheduled and unscheduled sacrifices, flash-frozen in liquid nitrogen, and stored in a freezer set to maintain -60 to -80°C; these samples were packed on dry ice and shipped to the University of Dundee for bile acid determination. Results of the bile acid determination will be reported separately by the University of Dundee.

Receptor Level Determination

Samples (approximately 2 g each) of the liver (left median lobe) and pancreas were collected from each animal at the scheduled and unscheduled sacrifices, flash-frozen in liquid nitrogen, and stored in a freezer, set to maintain -60 to -80°C until packed on dry ice and shipped to DuPont for possible analysis. Results of receptor level determination, if any, will be reported separately.

Liver APFO Determination

A section of liver (a non-formalin treated liver sample) was collected from each animal at the scheduled sacrifice and unscheduled sacrifices, 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 to 3M for APFO analyses. Results of the analyses will be reported separately by 3M.

Tissue Preservation. The following tissues (when present) or representative samples were collected and preserved in 10% neutral-buffered formalin, unless otherwise specified.

adrenal (2)
aorta
brain
cecum
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)
lesions
liver
lung
lymph node (mesenteric)
mammary gland
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
stomach
testis [(2) preserved in Bouin's solution]
thymus
thyroid (2) with parathyroid
trachea
urinary bladder

Three samples (approximately 5 g each) of the liver and all remaining pancreas and left and right testes tissue (divided into three approximately equal samples) were collected from each animal at the scheduled and unscheduled sacrifices, weighed, flash-frozen in liquid nitrogen, and stored in a freezer, set to maintain -60 to -80°C, for possible future analysis. In addition, after all other required samples were taken, remaining kidney tissue was collected from the control animals at the terminal sacrifice (Week 27). These tissues were weighed, flash-frozen in liquid nitrogen, and stored in a freezer set to maintain -60 to -80°C. Testes and kidney tissue samples collected from control animals were packed on dry ice and shipped to 3M for possible future analysis.

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

Histopathology. Tissues (as appropriate) were embedded in paraffin, sectioned, stained with hematoxylin and eosin, and examined microscopically from each animal including the Group 2 male that was replaced, Animal No. I05723 (see Protocol Deviations for exceptions). Pathology findings and histopathology tissue slides from specified animals

in the control, low-, and high-dose groups were transferred to Sierra Biomedical, Inc for a pathology peer review.

Statistical Analyses

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.

One-way analysis of variance [ANOVA (Winer, 1971a)] was used to analyze initial body weights, body weight changes, continuous clinical pathology values, and organ weight data.

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, covariate-adjusted means were used for control versus treated group comparisons.

Groups 2 through 4 were compared with Group 1 (Control). Group comparisons were evaluated at the 5.0%, two-tailed probability level. Only data collected on or after the first day of treatment were analyzed statistically. Data collected before the first day of treatment or during recovery (except for blood hormone analyses data) were not analyzed statistically.

Blood hormone levels, excluding estriol and cholecystokinin, were analyzed by repeated measures analysis of covariance (ANCOVA) procedure with average pretreatment measurements for the parameters as covariates. Treatment effects under ANOVA or ANCOVA procedures were evaluated at $p = 0.05$ level. All post hoc control-versus-treated-group mean comparisons (including values during recovery) were conducted using Dunnett's many-on-one t procedure. Analyses were carried out with SAS procedure PROC MIXED (SAS, 1996) or BMDP (BMDP, 1992), or both.

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 at least one 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, the protocol, study correspondence, and the 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 from the Sponsor's designees (Ani Lytics Inc., DuPont, 3M E.T. & S, and the University of Dundee) will be sent to the Sponsor (Paul Lieder, PhD, DABT, 3M). Pathology Associates, A Charles River Company (PAI) is responsible for the maintenance of any raw data or specimens produced by PAI.

RESULTS

Observation of Animals
Clinical Observations. Clinical observations are summarized in Tables 1 and 2; individual data are in Appendix 2. Individual animal fate data are also in Appendix 2.

One male (Animal No. I05724) given 30/20 mg/kg/day was sacrificed in moribund condition on Day 29 (Week 5). Test material-related observations noted for Animal No. I05724 included hypoactive behavior, entire body cold to the touch, few or no feces, and low or no food consumption; this animal lost 12.5% (0.5 kg) of its body weight from Week 1 to Week 5. One male given 3 mg/kg/day (Animal No. I05721) was sacrificed in moribund condition on Day 137. Clinical observations noted for Animal No. I05721 on Day 137 (Week 20) included limited use and paralysis of the hind limbs, ataxic and hypoactive behavior, few feces, and no food consumption; this animal lost 9.5% (0.4 kg) of its body weight from Week 19 to Week 20.

During Week 1, all males given 30 mg/kg/day had low food consumption and lost from 3.1 to 7.5% of their body weight; four of the six animals also had observations of few feces. Based on decreased food consumption and body weight loss, the dose level was lowered to 20 mg/kg/day beginning on Day 22. After the dose level was lowered, only two animals (Animal Nos. I05704 and I05713) tolerated the dose level for the remaining 23 weeks of dose administration. After Week 2, test material-related observations noted

for Animal No. I05713 included few feces and low food consumption. After Week 2, there were no clinical observations considered to be test material-related noted for Animal No. I05704.

During the study, dose administration was discontinued for three males given 30/20 mg/kg/day based on test material-related observations. Dose administration for Animal Nos. I05711, I05722, and I05703 was discontinued on Days 43 (Week 7), 66 (Week 10), and 81 (Week 12), respectively. Test material-related observations noted for Animal No. I05711 prior to the suspension of dosing included few or no feces and low or no food consumption; this animal lost 17.5% (0.7 kg) of its body weight from Week 1 to Week 7. Test material-related observations noted for Animal No. I05722 prior to the suspension of dosing included thin appearance, few or no feces, and low or no food consumption; this animal lost 23.1% (0.9 kg) of its body weight from Week 1 to Week 10. Test material-related observations noted for Animal No. I05703 prior to the suspension of dosing included thin appearance, few or no feces, and low or no food consumption; this animal lost 18.7% (0.6 kg) of its body weight from Week 1 to Week 12. These animals appeared to recover from the test material-related effects within 3 weeks after dose administration was discontinued.

During the study, several animals developed physical conditions that required examination by a laboratory animal veterinarian and administration of treatments. On Day 11 (Week 2), Animal No. I05724 (Group 4) had observations of no feces and no food consumption; this animal was treated with Lactated Ringers solution (Abbott Laboratories) on Days 11 through 13. During Weeks 5 and 6, Animal No. I05713 (Group 4) had observations of liquid feces and low food consumption; this animal was treated with erythromycin (Distal Products Co.) on Days 36 through 46. On Day 134 (Week 20), Animal No. I05721 (Group 2) had observations of few feces and low food consumption. Animal No. I05721 was treated with Ensure® (Abbott Laboratories) and Lactated Ringers solution (Abbott Laboratories) on Day 137; however, because the animal had observations of paralysis and limited use of the hind limbs, it was subsequently sacrificed. During Weeks 21 and 26, Animal No. I05719 (Group 3) had liquid feces; this animal was treated with erythromycin (Distal Products Co. or Barre) on Days 143 through 151 and on Days 179 through 183. The condition of these animals improved with treatment except for Animal No. I05721.

Ophthalmology. Ophthalmic observations are summarized in Tables 3 and 4; individual data are in Appendix 2. The Ophthalmology Report contains a discussion of the data.

There were no ophthalmic findings for any animal during the baseline or the Weeks 27 or 40 examinations.

Body Weights. Body weight data are summarized in Tables 5 and 6; individual data are in Appendix 3.

Covariate-adjusted mean body weights were notably lower throughout the study (statistically significant during Weeks 2 through 5 and Week 10) for males given 30/20 mg/kg/day. The lower body weights for the males given 30/20 mg/kg/day were considered test material-related.

All animals maintained body weights during recovery; there were no marked changes in body weight for each individual animal between the treatment and recovery phases. Differences in mean body weights between the mean body weights of the animals given 10 mg/kg/day and those of the controls during recovery can be attributed to biological variation.

Body Weight Changes. Body weight change data are summarized in Tables 7 and 8; individual data are in Appendix 3.

During the first 2 weeks of the study, mean body weight changes were notably lower (significantly lower during Week 2) for males initially given 30 mg/kg/day. After the dose level was lowered to 20 mg/kg/day, mean body weight changes were significantly lower than those of controls during Weeks 7, 9, and 24. Overall mean body weight changes (Weeks 1 through 27) were notably lower for the males given 30/20 mg/kg/day (14.3% of those of the control males).

Food Consumption. Food consumption data are summarized in Tables 1 and 2 (Summary of Clinical Observations); individual data are included in the individual clinical observations in Appendix 2.

There was an increased incidence of low or no food consumption for animals given 30/20 mg/kg/day. The decreased food consumption was considered to be test material-related.

Blood Hormone Determination

Summary and individual hormone analyses data provided by Ani Lytics Inc. or DuPont, are in Appendices 6 and 7 (cholecystokinin), respectively.

There were no effects on estrone, estradiol, estriol, thyroid stimulating hormone, or testosterone that were clearly dose-related or consistent in their effects over time. Total triiodothyronine was decreased beginning on Day 35 in animals administered 10 or 30/20 mg APFO/kg/day. While the low number of animals that remained on treatment in the group administered 30/20 mg/kg/day makes interpretation difficult, it appears that the level of triiodothyronine remained depressed through Day 183 in this group. Total thyroxin was decreased beginning on Day 35 in animals administered 10 or 30/20 mg/kg/day. While the low number of animals that remained on treatment in the group administered 30/20 mg/kg/day makes the interpretation difficult, it appears that the effect on thyroxin was most pronounced at Days 35 and 66 in animals administered 10 or 30/20 mg/kg/day, after which the effect began to diminish and there appeared to be recovery by the end of the study. Free triiodothyronine and free thyroxin were decreased beginning on Day 35 in animals administered 10 or 30/20 mg/kg/day. While the low number of animals that remained on treatment in the group administered 30/20 mg/kg/day makes the interpretation difficult, it appears that the level of triiodothyronine remained depressed through Day 183 in animals administered 10 or 30/20 mg/kg/day and that recovery occurred in animals administered 10 mg/kg during the recovery phase.

No alterations in cholecystokinin concentrations were observed at any of the time points.

Clinical Pathology

Hematology, coagulation, clinical chemistry, and urinalysis data are summarized in Tables 9 through 32; individual data are in Appendix 4. The Pathology Report contains a discussion of the data.

Administration of APFO at dose levels of 3 or 10 mg/kg/day had no apparent effects on hematology, coagulation, clinical chemistry, or urinalysis results. Of uncertain relationship to administration of APFO at 30/20 mg/kg/day were mildly increased triglyceride concentration and mildly to moderately decreased absolute neutrophil count, total protein concentration, and albumin concentration. In addition, two animals given APFO at 30/20 mg/kg/day exhibited moderately to markedly increased serum enzyme

activities (i.e., aspartate aminotransferase, alanine aminotransferase, sorbitol dehydrogenase, and creatine kinase) and mildly increased serum bile acid concentration prior to the unscheduled sacrifice of one of the animals and the cessation of treatment for the other animal because of poor health. These findings, although not observed for most of the animals given 30/20 mg/kg/day, may also have been caused by the test material.

During recovery, there was no evidence of persistent or delayed toxic effects on clinical pathology test results.

Cell Proliferation Evaluation

Results of cell proliferation evaluation provided by Pathology Associates, A Charles River Company are in Appendix 8.

After up to 26 weeks on study, enhanced cell proliferation was not evident in the pancreas or testes of male monkeys, whereas in the liver the findings were equivocal.

Anatomic Pathology

Terminal body weight and organ weight data are summarized in Tables 33 and 34; incidences of macroscopic and microscopic observations are summarized in Tables 35 through 38. Individual data are in Appendix 5. The Pathology Report contains a discussion of the data.

Test material-related and statistically significant increases were seen in mean absolute liver weights and mean liver-to-body weight percentages in animals in all dose groups at the terminal sacrifice. In addition, mean liver-to-brain weight significantly increased in animals in the 10 mg/kg/day group; this was also considered test material-related. However, no test material-related macroscopic or microscopic changes were seen in any organs at the terminal sacrifice, including liver, adrenal, spleen, pancreas, and testis.

At the recovery sacrifice, there were no test material-related effects on terminal body weights or on absolute or relative organ weights, indicating that the liver weight increases seen at the termination of dosing were reversible. There were no macroscopic or microscopic findings attributed to test material administration at the recovery sacrifice.

Two animals were sacrificed in a moribund condition during the course of the study, a male given 30/20 mg/kg/day (Day 29) and a male given 3 mg/kg/day (Day 137). The male given 30/20 mg/kg/day had esophageal and gastric lesions indicative of a dosing injury and liver lesions presumed to be due to the test material. The cause of the moribund condition of the male given 3 mg/kg/day was unclear.

DISCUSSION AND CONCLUSIONS

Based on the results of this study in which ammonium perfluorooctanoate (APFO) was administered orally by capsule to cynomolgus monkeys at doses of 0, 3, 10, or 30/20 mg/kg/day for 26 weeks, the no-observable-adverse-effect level (NOAEL) was 10 mg/kg/day. Effects seen in animals administered 10 mg/kg/day were not evident after 13 weeks of recovery.

SIGNATURES

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

18 Dec 2001
Date

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

18 Dec. 2001
Date

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OPHTHALMOLOGY REPORT

Ophthalmic examinations were done on each animal before initiation of treatment and during Weeks 27 and 40 (recovery). The pupils were dilated with 1% Mydriacyl®, and the anterior portion of the eye, optic media, and ocular fundus were examined with an indirect ophthalmoscope.

There were no ophthalmic findings for any animal during the baseline or the Weeks 27 or 40 examinations.

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Diplomate, ACLAM

17 DEC 01
Date

PATHOLOGY REPORT

SUMMARY

The purpose of the study was to assess the effect of the test material, ammonium perfluorooctanoate (APFO), on critical enzyme levels, hormones, and other selected biochemical parameters when administered daily by capsule to cynomolgus monkeys for at least 26 weeks. The test material was initially administered at dose levels of 3, 10, and 30 mg/kg/day. Administration of the highest dose was stopped on Day 12 because of signs of toxicity and then resumed on Day 22 at a lower dose level, 20 mg/kg/day.

Administration of APFO at dose levels of 3 or 10 mg/kg/day had no apparent effects on hematology, coagulation, clinical chemistry, or urinalysis results. Of uncertain relationship to administration of APFO at 30/20 mg/kg/day were mildly increased triglyceride concentration and mildly to moderately decreased absolute neutrophil count, total protein concentration, and albumin concentration. In addition, two animals given APFO at 30/20 mg/kg/day exhibited moderately to markedly increased serum enzyme activities (i.e., aspartate aminotransferase, alanine aminotransferase, sorbitol dehydrogenase, and creatine kinase) and mildly increased serum bile acid concentration prior to the unscheduled sacrifice of one of the animals and the cessation of treatment for the other animal because of poor health. These findings, although not observed for most of the animals given 30/20 mg/kg/day, may also have been caused by the test material.

During recovery, there was no evidence of persistent or delayed toxic effects on clinical pathology test results.

Test material-related and statistically significant increases were seen in mean absolute liver weights and mean liver-to-body weight percentages in animals in all dose groups at the terminal sacrifice. In addition, mean liver-to-brain weight significantly increased in animals in the 10 mg/kg/day group; this was also considered test material-related. However, no test material-related macroscopic or microscopic changes were seen in any organs at the terminal sacrifice, including liver, adrenal, spleen, pancreas, and testis.

At the recovery sacrifice, there were no test material-related effects on terminal body weights or on absolute or relative organ weights, indicating that the liver weight increases

seen at the termination of dosing were reversible. There were no macroscopic or microscopic findings attributed to test material administration at the recovery sacrifice.

Two animals were sacrificed in a moribund condition during the course of the study, a male given 30/20 mg/kg/day (Day 29) and a male given 3 mg/kg/day (Day 137). The male given 30/20 mg/kg/day had esophageal and gastric lesions indicative of a dosing injury, and liver lesions presumed to be due to the test material. The reason for the moribund condition of the male given 3 mg/kg/day was unclear.

METHODS

Four groups of male cynomolgus monkeys were administered the test material daily by capsule at a dose level of 0 (control group; received empty capsules), 3, 10, or 30 mg/kg of body weight/day (mg/kg/day). Treatment of the animals given the highest dose level was stopped on Day 12 because of signs of toxicity. The highest dose level was then reduced to 20 mg/kg/day, and treatment of these animals was resumed on Day 22. One animal given 30/20 mg/kg/day was sacrificed on Day 29 because of poor health, and dosing was permanently stopped for three additional animals given 30/20 mg/kg/day, one on each of Days 43, 66, and 81. At study initiation, there were six animals in the control group and the groups given 10 or 30 mg/kg/day; two animals in each of these groups were designated as recovery animals to be observed for approximately 13 weeks posttreatment. Because only two animals were given 30/20 mg/kg/day for the duration of the treatment period (approximately 26 weeks), there were no high-dose recovery animals. There were four animals in the group given 3 mg/kg/day; one of these animals was sacrificed on Day 137 because of poor health.

Blood and urine were collected for hematology, coagulation, clinical chemistry, and urinalysis tests once before initiation of treatment (Day -11), on Days 31, 63, 91, and 182, and on Days 217, 245, and 275 (recovery animals). Blood for hematology, coagulation, and clinical chemistry tests was also collected from animals prior to unscheduled sacrifices. The terminal and recovery sacrifices occurred on Days 184 and 277, respectively. All animals were necropsied; macroscopic observations were recorded, organ weights were obtained, and tissues were placed in fixative as specified by the protocol. The right lateral lobe of the liver was collected and frozen for analysis of palmitoyl CoA oxidase activity. Samples of pancreas, left and right testes, and the left lateral lobe of the liver were collected and preserved for cell proliferation evaluation

using proliferation cell nuclear antigen. Samples of bile were collected and frozen for bile acid determination. Samples of liver and pancreas were collected and frozen for receptor level determinations. A sample of liver was collected and frozen for APFO determination. Additional samples of the liver and all remaining pancreas and left and right testes tissue were collected and frozen for possible future analysis. Microscopic examinations were done on collected tissues from all animals, including the replaced animal.

Statistically significant differences cited in the Results and Discussion Section are based on comparisons between the control and treated groups.

RESULTS AND DISCUSSION

Mortality

One animal given 30/20 mg/kg/day (Animal No. I05724) was sacrificed on Day 29 because of poor health, and one animal given 3 mg/kg/day (Animal No. I05721) was sacrificed on Day 137 because of poor health. All other animals survived to the respective scheduled sacrifice.

Animal No. I05724, the male given 30/20 mg/kg/day that was sacrificed in a moribund condition on Day 29, had multiple significant microscopic findings. Edema and inflammation of the esophagus and erosions and ulcerations in both the esophagus and stomach suggested that a dosing injury was the immediate cause of the animal's death. However, lesions in the liver, including centrilobular and midzonal hepatocellular degeneration and necrosis, diffuse hepatocellular vacuolation, and hepatocyte basophilia in centrilobular areas (liver regeneration) probably contributed to the animal's moribund condition and were likely to be test material-related. Other important findings included involution of the thymus, a relatively common finding in stressed animals, and degeneration and necrosis in the heart, which were probably agonal changes.

The cause of death for Animal No. 105721, the male given 3 mg/kg/day that was sacrificed in a moribund condition on Day 137, was not apparent. The clinical history suggested that the blood supply to the animal's hind limbs was severely compromised, as the rear limbs were noticeably cold at the time of the final medical examination, and ketamine injected into the thigh muscles apparently failed to reach the systemic circulation (sedation did not occur). However, the macroscopic and microscopic findings

for this animal were minimal and incidental (i.e., evidence for spinal cord injury or impaired blood circulation was not uncovered in the post-life evaluations). Therefore, the role of test material-related toxicity in the animal's declining condition was unclear.

Clinical Pathology

Day -11. Results of clinical pathology tests indicated no obvious group or individual health abnormalities. Animal No. I05721 (Group 2) had a notably high hematocrit (49.7%) and albumin concentration (5.6 g/dL) that may have been an indication of mild dehydration. It also had the lowest absolute neutrophil count of all the animals (1,600/μL). Whether these findings were directly or indirectly related to the animal's illness requiring early sacrifice on Day 137 could not be determined.

Days 31, 63, 91, and 182. There were relatively few statistically significant or otherwise notable differences for clinical pathology test results between the control and treated animals, especially those animals given 3 or 10 mg/kg/day. None of the differences were consistent over time. Comparisons with the animals given 30/20 mg/kg/day were compromised by the unscheduled sacrifice of one animal in this group on Day 29 and the cessation of treatment for three others by Day 80. For the clinical pathology testing intervals on Days 91 and 182, there were only two animals in this group still receiving treatment.

Of uncertain relationship to administration of the test material were mildly increased triglyceride concentration and mildly to moderately decreased absolute neutrophil count, total protein concentration, and albumin concentration for animals given 30/20 mg/kg/day. The difference for triglyceride concentration was statistically significant on Days 31 and 91. The other differences were not statistically significant but were relatively consistent over time. Prior to stopping their treatment, absolute neutrophil count and albumin concentration were mildly decreased for each of the three animals given 30/20 mg/kg/day that had their treatment stopped prematurely because of poor health. All of these findings are generally nonspecific and can be associated with poor health for a variety of reasons. Specific mechanisms related to direct actions of the test material were not apparent.

Animal No. I05722, the animal in the high-dose group whose treatment was stopped on Day 66, had moderately high serum activities for aspartate aminotransferase, alanine aminotransferase, and creatine kinase and moderately high serum bile acid concentration

on Day 63. The relationship of these findings to administration of the test material is not known.

Statistically significant differences for other test results were considered incidental and unrelated to administration of the test material. These differences were inconsistent over time, and in some cases, were similar to differences that existed before the initiation of treatment.

Days 217, 245, and 275 (Recovery animals). There was no evidence of persistent or delayed toxic effects on clinical pathology test results.

Unscheduled Sacrifice Animals. Animal No. I05724, an animal in the high-dose group, was sacrificed on Day 29. Its most notable clinical pathology findings were a mild neutrophilia (13,700 neutrophils/µL); mild hypoglycemia (glucose = 53 mg/dL); mild azotemia (urea nitrogen = 29 mg/dL); moderate to marked hypoproteinemia (total protein = 5.6 g/dL; albumin = 2.9 g/dL; globulin = 2.7 g/dL); moderate hypocalcemia (calcium = 8.0 mg/dL; likely due to low albumin concentration); marked hypocholesterolemia (cholesterol = 14 mg/dL); marked serum enzyme activities (e.g., aspartate aminotransferase = 1,974 IU/L; alanine aminotransferase = 1,463 IU/L; sorbitol dehydrogenase = 59 IU/L; and creatine kinase = 68,850 IU/L); mild hyperbilirubinemia (total bilirubin = 1.8 mg/dL); mildly increased serum bile acid concentration (49 µmol/L); and moderate to marked hyponatremia (sodium = 133 mmol/L) and hypochloridemia (89 mmol/L). Although many of these findings are nonspecific and are commonly observed in animals that are very ill, the serum enzyme activities were indicative of substantial liver and muscle injury, and the hypocholesterolemia was unusually severe.

Animal No. I05721, an animal in the low-dose group, was sacrificed on Day 137. Its most notable clinical pathology findings were marked hyperfibrinogenemia (fibrinogen = 702 mg/dL); moderate lymphopenia (1,700 lymphocytes/µL); moderate hypoalbuminemia (albumin = 3.3 g/dL); and mild hypocholesterolemia (94 mg/dL). These findings were also nonspecific, and with the exception of low albumin concentration, were not typical of the findings observed in the animals in the high-dose group that had to be withdrawn from treatment. Although the findings for this animal in the low-dose group did not indicate a specific cause for its poor health, they were not considered to be directly related to administration of the test material.

Anatomic Pathology/Terminal Sacrifice (Week 27)

Terminal Body Weights and Organ Weights. Mean absolute liver weights and mean liver-to-body weight percentages were statistically significantly increased in animals that were dosed until Week 27 in the 3, 10, and 30/20 mg/kg/day dose groups. In addition, mean liver-to-brain weight ratio was statistically significantly increased in animals in the 10 mg/kg/day group only. Although no correlative macroscopic or microscopic changes were seen in livers in any of the animals from the terminal sacrifice, the increased liver weights in all dose groups may indicate a test material effect, given the nature of the test material and the liver lesions seen in the male in the high-dose group sacrificed on Day 29.

Absolute left kidney weight was statistically significantly increased in animals in the 30/20 mg/kg/day group, but this was considered an incidental finding because there were no test material-related macroscopic or microscopic findings in the kidney. There were no other statistically significant or toxicologically significant organ weight variations in treated animals.

Macroscopic Findings. There were no test material-related macroscopic findings. All macroscopic findings were of low incidence, were randomly distributed among treated and control animals, and were considered to be spontaneous or incidental changes that were of no toxicological significance.

Microscopic Findings. There were no test material-related microscopic findings in any of the tissues that were examined, including liver, adrenal, spleen, pancreas, and testis. All microscopic findings were considered to be spontaneous or incidental changes and typical of findings seen in monkeys on toxicity studies.

Anatomic Pathology/Recovery Sacrifice (Week 40)

Terminal Body Weights and Organ Weights. There were no test material-related effects on terminal body weights or on absolute or relative organ weights. Absolute organ weights and organ-to-brain weight ratios were consistently higher in the control males, but these elevations were attributed to higher terminal body weights in the control animals (one was even noted as being obese at necropsy). Mean organ-to-body weight percentages, including mean liver-to-body weight, showed only slight variations that were considered unremarkable. These findings indicated that the liver weight increases were reversible.

Macroscopic Findings. There were no test material-related macroscopic findings. In fact, no macroscopic lesions of any kind were seen in one control animal or in either of the 10 mg/kg/day animals. The remaining control male was considered to be obese and had liver adhesions, an incidental change.

Microscopic Findings. There were no test material-related microscopic findings at the recovery sacrifice. All microscopic findings were incidental, occurred randomly in control animals and in animals given 10 mg/kg/day, and were typical of findings seen in cynomolgus monkeys on toxicity studies.

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Date

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18 December 2001
Date

COMMENTS ON THE DATA

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

Some tabular data were compiled using Excel® Version 7.0 software.

The units for the dose levels on the data collection system (PTS) summary tables are mg/kg/day.

The number of animals listed in the heading of the summary of clinical observations table (Table 1) reflects the number of animals assigned to each group at the start of the study.

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 level of severity for observations of ataxic and hypoactive behavior was not specified at the time of the observation and is indicated as "UNSPECIFIED" on the summary and individual observations tables.

The specific details for comments in the individual clinical observations tables that are indicated with a "C" can be found at the end of each group for each sex.

The day of initiation of treatment is "Day 1, Week 1." Body weight data are entered at the start of a study week (e.g., a body weight recorded on Day 1 is considered a Week 1 body weight, a body weight recorded on Day 8 is considered a Week 2 body weight). Body weight change data are calculated from the first day of the study week to the first day of the following study week (e.g., Week 1 values are calculated from Day 1 through 7).

Differences in the population size (N) on the summary tables for clinical pathology are explained on the individual data tables.

COMMENTS ON THE DATA (Continued)

Results of clinical pathology samples collected for animals sacrificed at an unscheduled interval appear on the individual clinical pathology tables for the next scheduled interval. These results are not on the summary tables and are not included in the statistical analyses.

Dosing was discontinued for Animal Nos. I05711, I05722, and I05703 (Group 4) on Days 43 (Week 7), 66 (Week 10), and 81 (Week 12). Summary tables do not include data from these animals after dosing was discontinued and this data are not included in the statistical analyses.

Some animals were observed and treated by the laboratory animal veterinary staff, and the data were recorded on the day the examination was done. These data are referenced in the Request for Veterinary Services and are archived with the raw data but do not appear on the summary or individual clinical observations tables.

Data collected for Animal No. I05723 (Group 2) will be maintained in the raw data; this data will not be included in this report. Animal No. I05723 was sacrificed in moribund condition on Day 14; the cause of the moribund condition of this animal was determined to be a bacterial septicemia which was unrelated to the test material. Animal No. I05723 was replaced by Animal No. I05721 on Day 15.

CODES, ABBREVIATIONS, AND UNITS

General Codes and Abbreviations
Codes for Clinical Pathology
Abbreviations and Units for Clinical Hematology
Abbreviations and Units for Clinical Chemistry
Abbreviations and Units for Clinical Urinalysis
Codes for Anatomic 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 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
NVL	No visible lesions
C	Comment found at the end of each group for each sex
UNSCHED	Unscheduled
#	Number

Animal Death Codes:

T	Terminal sacrifice
M	Moribund
U	First postrecovery sacrifice

Codes for Clinical Pathology

GENERAL CODES

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

Codes for Clinical Pathology (Continued)

RESULTS NOT INCLUDED IN STATISTICAL ANALYSES

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

CODES FOR BLOOD CELL MORPHOLOGY

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

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

URINE APPEARANCE

Color			Clarity	Miscellaneous
A Pale	E Amber	I Black	J Clear	M Debris
B Straw	F Brown	P Blue/green	K Hazy	O Feces
C Yellow	G Red	Q Blue	L Cloudy	
D Dark yellow	H Green	R Orange		

Codes for Clinical Pathology (Continued)

URINE CHEMISTRY MULTISTIX® STRIP

Urine Glucose		Urine Ketone		Urine Blood	
-	Negative	-	Negative	-	Negative
+	100 mg/dL	+	5 mg/dL	+	Small
++	250 mg/dL	++	15 mg/dL	++	Moderate
+++	500 mg/dL	+++	40 mg/dL	+++	Large
++++	1,000 mg/dL	++++	80 mg/dL		
+++++	≥2,000 mg/dL	+++++	160 mg/dL		

Urine Urobilinogen		Urine Bilirubin	
-	0.2 mg/dL	-	Negative
+	1 mg/dL	+	Small
++	2 mg/dL	++	Moderate
+++	4 mg/dL	+++	Large
++++	8 mg/dL		

(1 mg = approximately 1 Ehrlich unit)

URINE SEDIMENT

Cells, Crystals, Casts, and Comments				Bacteria	
A	Amorphous urates	Q	Sperm	0	Not present
B	Amorphous phosphates	R	Fecal contamination	1	Few
C	Uric acid	S	Pinworm ova found	2	Moderate
D	Triple phosphates	T	Pinworm larvae found	3	Many
E	Calcium oxalate	U	Parasite ova found		
F	Calcium carbonate				
G	Granular casts				
H	Hyaline casts	0	Not present		
I	Cellular casts	1	1-5 per field		
J	Waxy casts	2	6-10 per field		
K	Unknown crystal	3	11-20 per field		
P	Mucous threads	4	>20 per field		

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 glutamyltransferase	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)
Pancreatic-specific Amylase	P AMYL (U/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)
Creatine kinase isoenzymes	
BB	CK-BB (U/L)
MB	CK-MB (U/L)
MM	CK-MM (U/L)

Abbreviations and Units for Clinical Urinalysis

Test	Abbreviation (Units)
Urine volume	U VOL (ML)
8 hour urine volume	8 HR VOL (ML)
Specific gravity	SP GR
Urine osmolality	U OSMO (MOSM/KG)
Quantitative urinary/cerebrospinal fluid protein	QUAN PRO (MG/DL)
Urine protein excretion	PRO EXC (MG)
Urine chemistry Multistix® strip	
Urine pH	U PH
Urine protein	U PRO (MG/DL)
Urine glucose	U GLU
Urine ketones	U KET
Urine bilirubin	U BILI
Urine blood	U BLOOD
Urine urobilinogen	UROBILI
Urine reducing substances	U RE SUB
Microscopic examination of urine sediment	
Red blood cells per high-power field	RBC (PER HPF)
White blood cells per high-power field	WBC (PER HPF)
Epithelial cells per high-power field	EPITH (PER HPF)
Bacteria per high-power field	BACT (PER HPF)
Casts per low-power field	CASTS (PER LPF)
Crystals per low-power field	CRYSTALS (PER LPF1 or PER LPF2)
Urine appearance	URINE APP1 or URINE APP2
Comments	COMMENTS

Miscellaneous Codes and Abbreviations for Clinical Pathology

Fecal occult blood	Not applicable
Fecal parasite detection	Not applicable
Hemolytic potential	Not applicable

Codes for Anatomic Pathology

Code	Definition

ANIMAL DEATH CODES

T	Terminal sacrifice
U	First postrecovery sacrifice
M	Moribund

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

TISSUE ABBREVIATIONS

Abbreviation	Definition
LF	Left
LN	Lymph node
LN, TRACHEOBRON	Tracheobronchial lymph node
RT	Right
STOMACH, GL	Glandular stomach
SALIV GL, MANDIB	Mandibular salivary gland
THYROID/PARA	Thyroid/parathyroid

Table 1

Summary of Clinical Observations

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) IN CYNOMOLGUS MONKEYS

DAYS 1-184

		NUMBER OF ANIMALS AFFECTED			
	SEX:	-------MALE-------			
	GROUP:	1	2	3	4[a]
CATEGORY	DOSE:	0	3	10	20
KEYWORD					
QUALIFIER	NUMBER:	6	4	6	6
*** TOP OF LIST ***					
APPEARANCE					
LIMITED USE					
LIMBS-HIND		0	1	0	0
PARALYSIS					
HIND QUARTERS		0	1	0	0
THIN		0	0	0	2
BEHAVIOR					
ATAXIC					
<UNSPECIFIED>		0	1	0	0
HYPOACTIVE					
<UNSPECIFIED>		0	1	0	1
DISCHARGE					
VOMITUS					
CONTAINING FOOD		4	2	3	2
EXCRETION					
DISCOLORED URINE					
BROWN IN COLOR		0	0	0	1
FEW FECES		5	1	0	6
LIQUID FECES		2	1	1	2
MUCOID FECES		1	1	0	0
NO FECES		0	0	0	4
NON-FORMED FECES		1	1	2	1

a Group 4 males were administered 30 mg/kg/day on Days 1 through 11. Animals were not dosed on Days 12 through 21. Beginning on Day 22 and continuing throughout the remainder of the study, Group 4 males were administered 20 mg/kg/day, except that dosing for Animal Nos. I05711, I05722, and I05703 was discontinued on Days 43 (Week 7), 66 (Week 10), and 81 (Week 12), respectively.

Table 1

Summary of Clinical Observations

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

DAYS 1-184

NUMBER OF ANIMALS AFFECTED

CATEGORY / KEYWORD / QUALIFIER	SEX:	-------MALE-------			
	GROUP:	1	2	3	4[a]
	DOSE:	0	3	10	20
	NUMBER:	6	4	6	6
SKIN & PELAGE					
ALOPECIA					
HEAD-CRANIAL		1	0	0	0
LIMB-FRONT-LEFT		1	0	0	0
LIMB-FRONT-RIGHT		1	0	0	0
LIMBS-FRONT		1	0	0	0
COLD TO TOUCH					
BODY-ENTIRE		0	0	0	1
SCAB(S)					
PERI-ORBITAL-LEFT		0	0	1	0
PERI-ORBITAL-RIGHT		0	0	1	0
SCAR					
LIP(S)		0	0	0	1
MASS					
FACE NEXT TO NOSE		0	0	1	0
QUALITATIVE FOOD CONSUMPTION					
LOW		5	3	3	6
NONE		0	1	0	4

*** END OF LIST ***

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Table 2

Summary of Clinical Observations
Recovery

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) IN CYNOMOLGUS MONKEYS

NUMBER OF ANIMALS AFFECTED

DAYS 185-277

	SEX:	--MALE--	
	GROUP:	1	3
CATEGORY	DOSE:	0	10
KEYWORD			
QUALIFIER	NUMBER:	2	2
*** TOP OF LIST ***			
DISCHARGE			
VOMITUS			
CONTAINING FOOD		2	1
EXCRETION			
NO FECES		0	1
QUALITATIVE FOOD CONSUMPTION			
LOW		1	2
*** END OF LIST ***			

Table 3

Summary of Ophthalmic Observations

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) IN CYNOMOLGUS MONKEYS

NUMBER OF ANIMALS AFFECTED

WEEK -1

	SEX:	-------MALE-------			
	GROUP:	1	2	3	4
CATEGORY	DOSE:	0	3	10	20
KEYWORD					
QUALIFIER	NUMBER:	6	4	6	6
*** TOP OF LIST ***					
NO VISIBLE LESIONS					
NO VISIBLE LESIONS					
EYES		6	4	6	6
*** END OF LIST ***					

Table 3

Summary of Ophthalmic Observations

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) IN CYNOMOLGUS MONKEYS

	NUMBER OF ANIMALS AFFECTED			
WEEK 27				
SEX:	-------MALE-------			
GROUP:	1	2	3	4
CATEGORY / DOSE:	0	3	10	20[a]
KEYWORD / QUALIFIER / NUMBER:	6	3	6	5
*** TOP OF LIST ***				
NO VISIBLE LESIONS				
NO VISIBLE LESIONS				
EYES	6	3	6	5
*** END OF LIST ***				

a Group 4 males were administered 30 mg/kg/day on Days 1 through 11. Animals were not dosed on Days 12 through 21. Beginning on Day 22 and continuing throughout the remainder of the study, Group 4 males were administered 20 mg/kg/day, except that dosing for Animal Nos. I05711, I05722, and I05703 was discontinued on Days 43 (Week 7), 66 (Week 10), and 81 (Week 12), respectively.

Table 4

Summary of Ophthalmic Observations
Recovery

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) IN CYNOMOLGUS MONKEYS

	NUMBER OF ANIMALS AFFECTED	
WEEK 40		
	SEX:	--MALE--
	GROUP:	1 3
CATEGORY	DOSE:	0 10
KEYWORD		
QUALIFIER	NUMBER:	2 2
*** TOP OF LIST ***		
NO VISIBLE LESIONS		
NO VISIBLE LESIONS		
EYES		2 2
*** END OF LIST ***		

Table 5

Summary of Body Weight Data (kg)

26-WEEK CAPSULE TCXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

	SEX:	MALE			
	GROUP:	1	2	3	4
	DOSE:	0	3	10	20[a]
WEEK	UNITS:	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY
-2	N	6	4	6	6
	MEAN	3.7	4.0	3.8	3.8
	S.D.	0.45	0.24	0.34	0.26
-1[b]	N	6	4	6	6
	MEAN	3.8	4.0	3.8	3.8
	S.D.	0.52	0.34	0.37	0.27
-1[c]	N	6	4	6	6
	MEAN	3.8	3.9	3.7	3.8
	S.D.	0.54	0.34	0.43	0.29
1	N	6	4	6	6
	MEAN	3.8	4.0	3.8	3.9
	S.D.	0.56	0.36	0.33	0.32
2	N	6	4	6	6
	CAM	3.8	3.9	3.8	3.7 *
	MEAN	3.8	4.0	3.7	3.7
	S.D.	0.59	0.29	0.42	0.29
3	N	6	4	6	6
	CAM	3.9	3.8	3.7	3.6 *
	MEAN	3.9	4.0	3.7	3.6
	S.D.	0.56	0.24	0.46	0.29

a Group 4 males were administered 30 mg/kg/day on Days 1 through 11. Animals were not dosed on Days 12 through 21. Beginning on Day 22 and continuing throughout the remainder of the study, Group 4 males were administered 20 mg/kg/day, except that dosing for Animal Nos. I05711, I05722, and I05703 was discontinued on Days 43 (Week 7), 66 (Week 10), and 81 (Week 12), respectively.
b Day -7.
c Day -1.

Table 5

Summary of Body Weight Data (kg)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) IN CYNOMOLGUS MONKEYS

	SEX:	MALE			
	GROUP:	1	2	3	4
	DOSE:	0	3	10	20[a]
WEEK	UNITS:	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY
4	N	6	4	6	6
	CAM	4.0	3.9	3.9	3.7 *
	MEAN	4.0	4.0	3.8	3.7
	S.D.	0.57	0.22	0.44	0.27
5	N	6	4	6	6
	CAM	4.0	3.8	3.8	3.7 *
	MEAN	4.0	3.9	3.8	3.7
	S.D.	0.63	0.24	0.45	0.30
6	N	6	4	6	5
	CAM	4.0	4.0	3.9	3.7
	MEAN	4.0	4.1	3.9	3.7
	S.D.	0.53	0.21	0.53	0.30
7	N	6	4	6	5
	CAM	4.1	3.9	4.0	3.7
	MEAN	4.1	4.1	3.9	3.7
	S.D.	0.62	0.13	0.57	0.42
8	N	6	4	6	4
	CAM	4.0	4.0	4.0	3.6
	MEAN	4.0	4.1	3.9	3.6
	S.D.	0.51	0.14	0.52	0.42
9	N	6	4	6	4
	CAM	4.0	4.0	4.0	3.6
	MEAN	4.0	4.2	4.0	3.6
	S.D.	0.55	0.05	0.60	0.44

a Group 4 males were administered 30 mg/kg/day on Days 1 through 11. Animals were not dosed on Days 12 through 21. Beginning on Day 22 and continuing throughout the remainder of the study, Group 4 males were administered 20 mg/kg/day, except that dosing for Animal Nos. I05711, I05722, and I05703 was discontinued on Days 43 (Week 7), 66 (Week 10), and 81 (Week 12), respectively.

Table 5

Summary of Body Weight Data (kg)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

	SEX:	MALE			
	GROUP:	1	2	3	4
	DOSE:	0	3	10	20[a]
WEEK	UNITS:	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY
10	N	6	4	6	4
	CAM	4.0	4.0	4.0	3.5 *
	MEAN	4.0	4.1	4.0	3.4
	S.D.	0.54	0.10	0.58	0.56
11	N	6	4	6	3
	CAM	4.1	4.0	4.1	3.6
	MEAN	4.1	4.2	4.0	3.5
	S.D.	0.58	0.05	0.59	0.60
12	N	6	4	6	3
	CAM	4.1	4.0	4.0	3.5
	MEAN	4.1	4.2	4.0	3.4
	S.D.	0.53	0.06	0.60	0.76
13	N	6	4	6	2
	CAM	4.1	4.1	4.2	3.8
	MEAN	4.1	4.2	4.1	3.9
	S.D.	0.53	0.10	0.58	0.35
14	N	6	4	6	2
	CAM	4.1	4.1	4.1	3.7
	MEAN	4.1	4.2	4.0	3.9
	S.D.	0.55	0.05	0.59	0.35
15	N	6	4	6	2
	CAM	4.2	4.2	4.1	3.7
	MEAN	4.2	4.3	4.1	3.8
	S.D.	0.53	0.06	0.59	0.49

a Group 4 males were administered 30 mg/kg/day on Days 1 through 11. Animals were not dosed on Days 12 through 21. Beginning on Day 22 and continuing throughout the remainder of the study, Group 4 males were administered 20 mg/kg/day, except that dosing for Animal Nos. I05711, I05722, and I05703 was discontinued on Days 43 (Week 7), 66 (Week 10), and 81 (Week 12), respectively.

Table 5

Summary of Body Weight Data (kg)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

	SEX:	MALE			
	GROUP:	1	2	3	4
	DOSE:	0	3	10	20[a]
WEEK	UNITS:	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY
16	N	6	4	6	2
	CAM	4.2	4.1	4.2	3.7
	MEAN	4.2	4.2	4.1	3.8
	S.D.	0.53	0.05	0.56	0.49
17	N	6	4	6	2
	CAM	4.2	4.2	4.2	3.8
	MEAN	4.2	4.3	4.1	3.9
	S.D.	0.53	0.08	0.56	0.42
18	N	6	4	6	2
	CAM	4.3	4.3	4.3	3.9
	MEAN	4.2	4.4	4.2	4.0
	S.D.	0.57	0.10	0.58	0.42
19	N	6	4	6	2
	CAM	4.3	4.3	4.3	3.8
	MEAN	4.2	4.4	4.2	4.0
	S.D.	0.58	0.13	0.60	0.49
20	N	6	4	6	2
	CAM	4.3	4.2	4.3	3.7
	MEAN	4.3	4.3	4.2	3.9
	S.D.	0.56	0.32	0.58	0.64
21	N	6	3	6	2
	CAM	4.3	4.3	4.3	3.7
	MEAN	4.3	4.5	4.2	3.9
	S.D.	0.59	0.06	0.58	0.64

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Table 5

Summary of Body Weight Data (kg)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

	SEX:	MALE			
	GROUP:	1	2	3	4
	DOSE:	0	3	10	20[a]
WEEK	UNITS:	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY
22	N	6	3	6	2
	CAM	4.3	4.3	4.3	3.7
	MEAN	4.3	4.5	4.3	3.9
	S.D.	0.59	0.06	0.58	0.64
23	N	6	3	6	2
	CAM	4.4	4.4	4.4	3.9
	MEAN	4.3	4.5	4.3	4.0
	S.D.	0.60	0.06	0.56	0.57
24	N	6	3	6	2
	CAM	4.4	4.4	4.4	4.0
	MEAN	4.3	4.6	4.4	4.1
	S.D.	0.59	0.00	0.58	0.57
25	N	6	3	6	2
	CAM	4.4	4.5	4.4	3.9
	MEAN	4.4	4.6	4.3	3.9
	S.D.	0.59	0.06	0.60	0.64
26	N	6	3	6	2
	CAM	4.5	4.6	4.5	3.9
	MEAN	4.4	4.7	4.4	4.0
	S.D.	0.60	0.06	0.62	0.71
27	N	6	3	6	2
	CAM	4.5	4.6	4.5	4.0
	MEAN	4.5	4.8	4.4	4.1
	S.D.	0.64	0.06	0.60	0.71

a Group 4 males were administered 30 mg/kg/day on Days 1 through 11. Animals were not dosed on Days 12 through 21. Beginning on Day 22 and continuing throughout the remainder of the study, Group 4 males were administered 20 mg/kg/day, except that dosing for Animal Nos. I05711, I05722, and I05703 was discontinued on Days 43 (Week 7), 66 (Week 10), and 81 (Week 12), respectively.

Table 6

Summary of Body Weight Data (kg)
Recovery

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) IN CYNOMOLGUS MONKEYS

	SEX:	---------MALE---------	
	GROUP:	1	3
	DOSE:	0	10
WEEK	UNITS:	MG/KG/DAY	MG/KG/DAY
28	N	2	2
	MEAN	5.1	3.8
	S.D.	0.28	0.07
29	N	2	2
	MEAN	5.2	3.8
	S.D.	0.28	0.00
30	N	2	2
	MEAN	5.2	3.7
	S.D.	0.21	0.07
31	N	2	2
	MEAN	5.2	3.7
	S.D.	0.21	0.14
32	N	2	2
	MEAN	5.3	3.8
	S.D.	0.28	0.07
33	N	2	2
	MEAN	5.3	3.8
	S.D.	0.42	0.14
34	N	2	2
	MEAN	5.5	3.8
	S.D.	0.28	0.14

Table 6

Summary of Body Weight Data (kg)
Recovery

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) IN CYNOMOLGUS MONKEYS

	SEX:	---------MALE---------	
	GROUP:	1	3
	DOSE:	0	10
WEEK	UNITS:	MG/KG/DAY	MG/KG/DAY
35	N	2	2
	MEAN	5.5	3.8
	S.D.	0.28	0.14
36	N	2	2
	MEAN	5.6	3.8
	S.D.	0.35	0.14
37	N	2	2
	MEAN	5.6	3.8
	S.D.	0.28	0.14
38	N	2	2
	MEAN	5.6	3.8
	S.D.	0.28	0.14
39	N	2	2
	MEAN	5.7	3.8
	S.D.	0.28	0.21
40	N	2	2
	MEAN	5.7	3.8
	S.D.	0.28	0.21

Table 7

Summary of Body Weight Change Data (kg)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

	SEX:	MALE			
	GROUP:	1	2	3	4
	DOSE:	0	3	10	20[a]
WEEKS	UNITS:	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY
1-2	N	6	4	6	6
	MEAN	-0.1	0.0	-0.1	-0.2
	S.D.	0.05	0.08	0.12	0.08
2-3	N	6	4	6	6
	MEAN	0.1	0.0	0.0	-0.1 *
	S.D.	0.06	0.05	0.05	0.17
3-4	N	6	4	6	6
	MEAN	0.1	0.0	0.1	0.2
	S.D.	0.04	0.06	0.05	0.08
4-5	N	6	4	6	6
	MEAN	0.0	-0.1	-0.1	-0.1
	S.D.	0.10	0.08	0.05	0.08
5-6	N	6	4	6	5
	MEAN	0.0	0.2	0.1	0.0
	S.D.	0.10	0.05	0.10	0.07
6-7	N	6	4	6	5
	MEAN	0.1	0.0	0.0	0.0
	S.D.	0.10	0.08	0.10	0.15
7-8	N	6	4	6	4
	MEAN	-0.1	0.0	0.0	-0.3 *
	S.D.	0.12	0.10	0.09	0.10

a Group 4 males were administered 30 mg/kg/day on Days 1 through 11. Animals were not dosed on Days 12 through 21. Beginning on Day 22 and continuing throughout the remainder of the study, Group 4 males were administered 20 mg/kg/day, except that dosing for Animal Nos. I05711, I05722, and I05703 was discontinued on Days 43 (Week 7), 66 (Week 10), and 81 (Week 12), respectively.

Table 7

Summary of Body Weight Change Data (kg)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

	SEX:	MALE			
	GROUP:	1	2	3	4
	DOSE:	0	3	10	20[a]
WEEKS	UNITS:	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY
8-9	N	6	4	6	4
	MEAN	0.0	0.1	0.1	0.0
	S.D.	0.13	0.13	0.08	0.08
9-10	N	6	4	6	4
	MEAN	0.0	0.0	0.0	-0.1 *
	S.D.	0.05	0.06	0.08	0.13
10-11	N	6	4	6	3
	MEAN	0.0	0.0	0.1	0.0
	S.D.	0.05	0.06	0.10	0.00
11-12	N	6	4	6	3
	MEAN	0.0	0.0	0.0	-0.1
	S.D.	0.06	0.05	0.05	0.17
12-13	N	6	4	6	2
	MEAN	0.0	0.1	0.1	0.1
	S.D.	0.05	0.05	0.06	0.00
13-14	N	6	4	6	2
	MEAN	0.0	-0.1	-0.1	-0.1
	S.D.	0.04	0.10	0.05	0.00
14-15	N	6	4	6	2
	MEAN	0.1	0.1	0.1	0.0
	S.D.	0.05	0.05	0.08	0.14

a Group 4 males were administered 30 mg/kg/day on Days 1 through 11. Animals were not dosed on Days 12 through 21. Beginning on Day 22 and continuing throughout the remainder of the study, Group 4 males were administered 20 mg/kg/day, except that dosing for Animal Nos. I05711, I05722, and I05703 was discontinued on Days 43 (Week 7), 66 (Week 10), and 81 (Week 12), respectively.

Table 7

Summary of Body Weight Change Data (kg)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

	SEX:	MALE			
	GROUP:	1	2	3	4
	DOSE:	0	3	10	20[a]
WEEKS	UNITS:	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY
15-16	N	6	4	6	2
	MEAN	0.0	0.0	0.0	0.0
	S.D.	0.06	0.05	0.05	0.00
16-17	N	6	4	6	2
	MEAN	0.0	0.1	0.0	0.0
	S.D.	0.00	0.05	0.05	0.07
17-18	N	6	4	6	2
	MEAN	0.1	0.1	0.0	0.1
	S.D.	0.05	0.13	0.05	0.00
18-19	N	6	4	6	2
	MEAN	0.0	0.0	0.0	0.0
	S.D.	0.06	0.10	0.08	0.07
19-20	N	6	4	6	2
	MEAN	0.0	-0.1	0.0	-0.1
	S.D.	0.05	0.20	0.04	0.14
20-21	N	6	3	6	2
	MEAN	0.0	0.0	0.0	0.0
	S.D.	0.04	0.06	0.00	0.00
21-22	N	6	3	6	2
	MEAN	0.0	0.0	0.0	0.0
	S.D.	0.00	0.00	0.04	0.00

a Group 4 males were administered 30 mg/kg/day on Days 1 through 11. Animals were not dosed on Days 12 through 21. Beginning on Day 22 and continuing throughout the remainder of the study, Group 4 males were administered 20 mg/kg/day, except that dosing for Animal Nos. I05711, I05722, and I05703 was discontinued on Days 43 (Week 7), 66 (Week 10), and 81 (Week 12), respectively.

Table 7

Summary of Body Weight Change Data (kg)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

	SEX:	MALE			
	GROUP:	1	2	3	4
	DOSE:	0	3	10	20[a]
WEEKS	UNITS:	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY	MG/KG/DAY
22-23	N	6	3	6	2
	MEAN	0.1	0.1	0.0	0.1
	S.D.	0.05	0.06	0.05	0.07
23-24	N	6	3	6	2
	MEAN	0.0	0.1	0.1	0.1
	S.D.	0.06	0.06	0.05	0.00
24-25	N	6	3	6	2
	MEAN	0.0	0.0	0.0	-0.2 *
	S.D.	0.05	0.06	0.05	0.07
25-26	N	6	3	6	2
	MEAN	0.1	0.1	0.1	0.1
	S.D.	0.04	0.00	0.04	0.07
26-27	N	6	3	6	2
	MEAN	0.0	0.0	0.0	0.1
	S.D.	0.05	0.06	0.06	0.00
1-27	N	6	3	6	2
	MEAN	0.7	0.7	0.6	0.1
	S.D.	0.33	0.35	0.34	0.71

a Group 4 males were administered 30 mg/kg/day on Days 1 through 11. Animals were not dosed on Days 12 through 21. Beginning on Day 22 and continuing throughout the remainder of the study, Group 4 males were administered 20 mg/kg/day, except that dosing for Animal Nos. I05711, I05722, and I05703 was discontinued on Days 43 (Week 7), 66 (Week 10), and 81 (Week 12), respectively.

Table 8

Summary of Body Weight Change Data (kg)
Recovery

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) IN CYNOMOLGUS MONKEYS

SEX:		---------MALE---------	
GROUP:		1	3
DOSE:		0	10
WEEKS	UNITS:	MG/KG/DAY	MG/KG/DAY
27-28	N	2	2
	MEAN	-0.1	-0.1
	S.D.	0.07	0.07
28-29	N	2	2
	MEAN	0.1	0.1
	S.D.	0.00	0.07
29-30	N	2	2
	MEAN	0.0	-0.2
	S.D.	0.07	0.07
30-31	N	2	2
	MEAN	0.0	0.1
	S.D.	0.00	0.07
31-32	N	2	2
	MEAN	0.2	0.0
	S.D.	0.07	0.07
32-33	N	2	2
	MEAN	0.0	0.0
	S.D.	0.14	0.07
33-34	N	2	2
	MEAN	0.2	0.0
	S.D.	0.14	0.00

Table 8

Summary of Body Weight Change Data (kg)
Recovery

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) IN CYNOMOLGUS MONKEYS

	SEX:	---------MALE---------	
	GROUP:	1	3
	DOSE:	0	10
WEEKS	UNITS:	MG/KG/DAY	MG/KG/DAY
34-35	N	2	2
	MEAN	0.0	0.0
	S.D.	0.00	0.00
35-36	N	2	2
	MEAN	0.1	0.0
	S.D.	0.07	0.00
36-37	N	2	2
	MEAN	0.0	0.0
	S.D.	0.07	0.00
37-38	N	2	2
	MEAN	0.0	0.0
	S.D.	0.00	0.00
38-39	N	2	2
	MEAN	0.1	0.0
	S.D.	0.00	0.07
39-40	N	2	2
	MEAN	0.0	0.0
	S.D.	0.00	0.00
27-40	N	2	2
	MEAN	0.5	0.0
	S.D.	0.07	0.21

Table 9

Summary of Clinical Hematology Data

Males Day -11

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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 $X10^3/\mu L$	PT SEC	PTT SEC	FBR MG/DL
0	MEAN	6.60	12.4	42.1	63.9	18.9	29.5	513	.7	45	9.7	18.2	286
	S.D.	.405	.26	.85	3.05	1.21	1.03	155.0	.36	26.3	.32	1.23	32.2
	N	6	6	6	6	6	6	6	6	6	6	6	6
3	MEAN	6.88	12.9	43.9	63.8	18.8	29.4	562	.7	48	9.6	20.5	345
	S.D.	.433	1.23	4.51	3.80	.95	.22	109.5	.42	29.9	.10	5.03	52.3
	N	4	4	4	4	4	4	4	4	4	4	4	4
10	MEAN	6.70	12.1	40.4	60.4	18.1	30.0	515	.6	43	9.6	18.3	315
	S.D.	.268	.56	1.92	3.78	1.02	.48	98.3	.38	24.7	.18	1.59	22.2
	N	6	6	6	6	6	6	6	6	6	6	6	6
30/20	MEAN	6.84	12.2	41.2	60.2	17.8	29.6	547	.7	49	9.8	20.0	304
	S.D.	.302	.83	2.68	2.63	.89	.58	90.6	.22	16.9	.36	3.76	44.9
	N	6	6	6	6	6	6	6	6	6	6	6	6

Table 9

Summary of Clinical Hematology Data

Males Day -11

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUCROOCTANOATE (APFO)
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	12.7	6.0	5.5	1.0	.2	.0	47	43	8	2	0
	S.D.	4.36	2.21	2.06	.46	.12	.05	5.5	6.3	1.9	.5	.4
	N	6	6	6	6	6	6	6	6	6	6	6
3												
	MEAN	10.7	4.6	5.2	.8	.1	.0	40	51	8	1	0
	S.D.	3.62	2.84	1.00	.39	.15	.05	14.0	11.2	5.5	1.0	.6
	N	4	4	4	4	4	4	4	4	4	4	4
10												
	MEAN	11.4	5.7	4.6	.9	.2	.0	48	42	8	2	0
	S.D.	3.03	2.66	1.07	.32	.13	.05	14.4	11.2	2.8	2.0	.4
	N	6	6	6	6	6	6	6	6	6	6	6
30/20												
	MEAN	13.3	7.3	4.8	1.0	.2	.0	54	36	7	2	0
	S.D.	2.25	1.57	1.17	.60	.14	.08	5.0	7.1	4.6	.8	.4
	N	6	6	6	6	6	6	6	6	6	6	6

Table 10

Summary of Clinical Hematology Data

Males Day 31

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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 $X10^3/\mu L$	PT SEC	PTT SEC	FBR MG/DL
0	MEAN	6.81	12.9	44.0	64.7	19.0	29.3	428	.3	21	10.0	19.8	369
	S.D.	.415	.80	1.88	3.01	1.12	1.23	87.8	.11	8.4	.26	1.26	187.4
	N	6	6	6	6	6	6	6	6	6	6	6	6
3	MEAN	6.47	12.4	41.3	64.0	19.2	30.0	499	.2	13	9.8	21.9	334
	S.D.	.378	.57	1.76	3.43	1.06	.45	98.7	.14	10.4	.29	4.98	24.0
	N	4	4	4	4	4	4	4	4	4	4	4	4
10	MEAN	6.73	12.3	41.8	62.2	18.4	29.6	446	.2	11	10.1	20.0	291
	S.D.	.387	.51	2.11	3.73	1.09	.46	107.9	.08	5.2	.34	2.02	38.8
	N	6	6	6	6	6	6	6	6	6	6	6	6
30/20	MEAN	6.63	12.1	40.9	61.6	18.2	29.6	516	.3	23	10.0	24.0	475
	S.D.	.396	.99	3.06	3.23	.54	1.56	159.7	.26	19.1	.47	4.22	250.9
	N	5	5	5	5	5	5	5	5	5	5	5	5

Table 10

Summary of Clinical Hematology Data

Males Day 31

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	12.8	7.3	4.6	.8	.1	.0	54	40	6	1	0
	S.D.	4.48	4.05	.83	.54	.08	.00	14.1	15.0	3.1	.8	.0
	N	6	6	6	6	6	6	6	6	6	6	6
3												
	MEAN	7.8	2.8	4.2	.6	.2	.0	34	56	8	2	0
	S.D.	2.34	1.76	1.01	.36	.30	.05	15.3	11.1	3.5	3.4	.5
	N	4	4	4	4	4	4	4	4	4	4	4
10												
	MEAN	10.7	6.0	3.9	.6	.2	.0	53	38	6	2	0
	S.D.	3.51	3.45	.88	.23	.10	.04	13.6	11.9	2.4	1.2	.0
	N	6	6	6	6	6	6	6	6	6	6	6
30/20												
	MEAN	9.2	4.0	3.8	1.2	.1	.0	44	42	13 *	1	0
	S.D.	1.84	.98	.62	.88	.08	.00	5.0	7.1	6.6	.9	.4
	N	5	5	5	5	5	5	5	5	5	5	5

Table 11

Summary of Clinical Hematology Data

Males Day 63

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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 $X10^3/\mu L$	PT SEC	PTT SEC	FBR MG/DL
0	MEAN	6.66	12.5	42.1	63.3	18.8	29.7	458	.3	18	10.1	19.2	343
	S.D.	.641	1.10	3.75	3.24	1.03	.97	187.7	.05	4.4	.41	1.59	100.1
	N	6	6	6	6	6	6	6	6	6	6	6	6
3	MEAN	6.75	13.0	43.0	63.9	19.2	30.0	467	.4	28	10.0	21.7	318
	S.D.	.485	.90	2.45	4.66	1.27	.83	104.0	.17	10.4	.30	3.83	33.9
	N	4	4	4	4	4	4	4	4	4	4	4	4
10	MEAN	6.78	12.4	41.2	60.9	18.3	30.1	436	.2	13	10.2	20.0	257
	S.D.	.323	.37	1.17	2.86	1.05	.53	87.3	.11	6.6	.27	2.47	46.5
	N	6	6	6	6	6	6	6	6	6	6	6	6
30/20	MEAN	6.77	12.0	40.6	60.0	17.8	29.6	433	.2	12	10.8	24.7 *	194 *
	S.D.	.600	1.28	4.58	2.31	.54	.59	131.4	.10	5.6	.95	2.15	85.7
	N	4	4	4	4	4	4	4	4	4	4	4	4

Table 11

Summary of Clinical Hematology Data

Males Day 63

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	5.8	4.4	.7	.1	.0	51	41	6	1	0
	S.D.	1.78	1.83	1.04	.41	.05	.05	10.4	9.8	3.5	.5	.4
	N	6	6	6	6	6	6	6	6	6	6	6
3	MEAN	10.5	5.5	4.1	.6	.2	.0	50	42	6	2	0
	S.D.	3.52	2.91	.76	.17	.35	.06	13.5	12.3	1.0	2.9	.0
	N	4	4	4	4	4	4	4	4	4	4	4
10	MEAN	10.1	5.6	3.6	.7	.2	.0	54	37	7	2	0
	S.D.	1.60	1.93	.86	.22	.10	.05	12.6	10.9	2.0	.9	.5
	N	6	6	6	6	6	6	6	6	6	6	6
30/20	MEAN	7.7	2.7	4.2	.6	.2	.0	34	54	9	2	0
	S.D.	1.96	1.44	.95	.13	.17	.00	11.4	7.0	3.2	2.2	.6
	N	4	4	4	4	4	4	4	4	4	4	4

Table 12

Summary of Clinical Hematology Data

Males Day 91

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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 $X10^3/\mu L$	PT SEC	PTT SEC	FBR MG/DL
0	MEAN	6.87	12.9	44.2	64.4	18.8	29.1	435	.3	21	10.2	18.1	278
	S.D.	.372	.84	2.83	3.88	1.35	1.18	145.1	.11	8.2	.19	1.31	15.2
	N	6	6	6	6	6	6	6	6	6	6	6	6
3	MEAN	6.61	12.6	42.1	63.8	19.1	30.0	504	.3	22	10.3	19.6	311
	S.D.	.455	.91	3.30	4.08	.98	.81	129.5	.29	19.4	.22	2.73	49.0
	N	4	4	4	4	4	4	4	4	4	4	4	4
10	MEAN	6.82	12.5	41.6	61.1	18.4	30.1	421	.3	20	10.4	19.2	262
	S.D.	.374	.32	1.12	3.41	1.10	.75	42.1	.23	14.3	.34	1.64	36.2
	N	6	6	6	6	6	6	6	6	6	6	6	6
30/20	MEAN	6.46	11.1	37.2 *	57.6	17.2	29.8	406	.2	10	10.4	22.5	244
	S.D.	.559	.57	2.97	.42	.64	.92	70.7	.07	3.5	.49	2.05	57.3
	N	2	2	2	2	2	2	2	2	2	2	2	2

Table 12

Summary of Clinical Hematology Data

Males Day 91

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	10.8	4.4	5.5	.7	.2	.0	40	52	6	2	0
	S.D.	1.68	1.76	.57	.39	.14	.04	9.4	9.4	3.3	.8	.4
	N	6	6	6	6	6	6	6	6	6	6	6
3	MEAN	10.2	4.3	4.6	.6	.6	.0	42	46	6	5	0
	S.D.	2.73	1.91	1.45	.21	.82	.05	15.4	10.1	1.9	6.1	.5
	N	4	4	4	4	4	4	4	4	4	4	4
10	MEAN	10.4	5.4	4.0 *	.7	.2	.0	50	40	8	2	0
	S.D.	2.58	2.42	.88	.33	.18	.05	14.0	10.4	3.1	1.5	.4
	N	6	6	6	6	6	6	6	6	6	6	6
30/20	MEAN	7.7	3.4	3.6 *	.6	.1	.0	40	49	8	2	0
	S.D.	2.97	2.69	.35	.14	.00	.00	19.8	14.1	4.9	.7	.7
	N	2	2	2	2	2	2	2	2	2	2	2

Table 13

Summary of Clinical Hematology Data

Males Day 182

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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 $X10^3/\mu L$	PT SEC	PTT SEC	FBR MG/DL
0													
	MEAN	6.69	12.6	40.6	60.8	19.0	31.1	408	.6	42	10.2	17.9	272
	S.D.	.263	.55	.82	3.33	1.17	.98	133.8	.41	27.0	.43	1.53	30.2
	N	6	6	6	6	6	6	6	6	6	6	6	6
3													
	MEAN	6.91	12.7	40.9	59.4	18.5	31.2	516	.9	60	10.1	20.6	294
	S.D.	.928	1.04	4.41	2.56	1.01	1.21	132.3	.06	11.7	.45	4.98	7.5
	N	3	3	3	3	3	3	3	3	3	3	3	3
10													
	MEAN	6.76	12.3	39.1	58.1	18.3	31.5	416	.5	35	10.3	19.6	278
	S.D.	.470	.57	2.19	4.19	1.14	.67	103.5	.41	25.5	.23	1.74	66.9
	N	6	6	6	6	6	6	6	6	6	6	6	6
30/20													
	MEAN	6.18	10.6 *	33.9	55.0	17.2	31.4	378	.2	8	10.3	25.5	224
	S.D.	.841	1.13	4.45	.21	.49	.85	180.3	.21	12.0	.07	7.00	69.3
	N	2	2	2	2	2	2	2	2	2	2	2	2

Table 13

Summary of Clinical Hematology Data

Males Day 182

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	10.9	5.0	4.8	.8	.2	.0	45	45	7	2	0
	S.D.	3.43	2.08	1.40	.48	.13	.05	7.3	9.9	3.6	.5	.5
	N	6	6	6	6	6	6	6	6	6	6	6
3												
	MEAN	12.5	4.3	6.3	1.3	.5	.1	37	49	10	4	1
	S.D.	1.75	2.06	2.35	.85	.64	.06	20.7	11.4	5.0	4.6	.6
	N	3	3	3	3	3	3	3	3	3	3	3
10												
	MEAN	9.7	4.4	4.1	.8	.3	.1	45	43	9	3	1
	S.D.	2.93	1.84	1.53	.23	.19	.04	12.5	11.2	1.8	1.6	.4
	N	6	6	6	6	6	6	6	6	6	6	6
30/20												
	MEAN	7.8	2.5	4.1	.9	.2	.1	30	54	11	2	2
	S.D.	2.19	1.56	.28	.28	.21	.00	10.6	12.7	.0	2.1	.7
	N	2	2	2	2	2	2	2	2	2	2	2

Table 14

Summary of Clinical Hematology Data

Males Day 217 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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 $X10^3/\mu L$	PT SEC	PTT SEC	FBR MG/DL
0	MEAN	7.00	13.7	44.8	64.0	19.6	30.6	492	.6	46	9.8	17.9	305
	S.D.	.191	.14	.00	1.84	.28	.42	247.5	.07	6.4	.35	.92	53.7
	N	2	2	2	2	2	2	2	2	2	2	2	2
10	MEAN	7.04	12.3	39.8	56.5	17.5	31.0	390	.3	20	10.2	20.2	214
	S.D.	.389	.64	.99	1.70	.07	.71	78.5	.28	19.1	.21	1.34	14.8
	N	2	2	2	2	2	2	2	2	2	2	2	2

Table 14

Summary of Clinical Hematology Data

Males Day 217 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	18.7	7.4	8.8	1.7	.5	.2	36	49	10	3	1
	S.D.	8.56	5.87	2.62	.00	.00	.07	14.8	8.5	4.9	1.4	.0
	N	2	2	2	2	2	2	2	2	2	2	2
10												
	MEAN	11.1	4.6	4.9	1.1	.4	.1	42	43	10	4	0
	S.D.	1.13	1.48	1.56	.57	.42	.14	17.7	9.9	3.5	3.5	.7
	N	2	2	2	2	2	2	2	2	2	2	2

Table 15

Summary of Clinical Hematology Data

Males Day 245 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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 $X10^3/\mu L$	PT SEC	PTT SEC	FBR MG/DL
0	MEAN	6.92	13.6	44.4	64.1	19.6	30.5	529	.4	24	9.8	18.0	323
	S.D.	.028	.21	.85	1.56	.49	.00	190.9	.07	4.9	.35	1.77	4.2
	N	2	2	2	2	2	2	2	2	2	2	2	2
10	MEAN	7.25	12.7	40.8	56.3	17.5	31.2	421	.2	10	10.2	19.2	227
	S.D.	.410	.85	.85	1.98	.14	1.34	97.6	.21	14.8	.07	.21	14.1
	N	2	2	2	2	2	2	2	2	2	2	2	2

Table 15

Summary of Clinical Hematology Data

Males Day 245 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	15.8	5.7	8.2	1.4	.5	.2	35	52	8	4	1
	S.D.	2.90	2.83	.49	.21	.28	.07	11.3	5.7	3.5	2.1	.0
	N	2	2	2	2	2	2	2	2	2	2	2
10												
	MEAN	10.7	4.4	4.9	1.0	.3	.0	44	44	10	2	0
	S.D.	5.09	1.34	3.11	.35	.28	.07	8.5	7.8	.7	1.4	.7
	N	2	2	2	2	2	2	2	2	2	2	2

Table 16

Summary of Clinical Hematology Data

Males Day 275 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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 $X10^3/\mu L$	PT SEC	PTT SEC	FBR MG/DL
0													
	MEAN	6.96	13.8	43.6	62.5	19.8	31.6	584	.2	10	9.8	17.6	530
	S.D.	.714	1.20	3.89	.85	.35	.14	244.0	.07	4.2	.57	.49	173.2
	N	2	2	2	2	2	2	2	2	2	2	2	2
10													
	MEAN	7.20	12.8	41.1	57.2	17.7	31.0	446	.4	24	10.2	18.3	300
	S.D.	.325	.49	.64	1.63	.14	.64	53.7	.49	34.6	.21	.71	26.2
	N	2	2	2	2	2	2	2	2	2	2	2	2

Table 16

Summary of Clinical Hematology Data

Males Day 275 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	15.0	7.4	5.6	1.6	.2	.1	49	38	12	2	1
	S.D.	4.31	2.55	1.77	.07	.00	.00	2.8	.7	2.8	.7	.0
	N	2	2	2	2	2	2	2	2	2	2	2
10												
	MEAN	16.2	9.1	5.6	1.3	.1	.0	54	38	8	0	0
	S.D.	4.17	5.94	1.77	.00	.00	.00	23.3	20.5	2.1	.7	.0
	N	2	2	2	2	2	2	2	2	2	2	2

Table 17

Summary of Clinical Chemistry Data

Males Day -11

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	92	16	1.2	9.4	4.8	4.6	.0	9	147	39
	S.D.	15.3	2.6	.15	.58	.40	.56	.05	2.0	44.3	11.3
	N	6	6	6	6	6	6	6	6	6	6
3											
	MEAN	88	14	1.1	9.4	5.2	4.2	.1	10	174	50
	S.D.	11.7	4.6	.15	.87	.29	.63	.15	4.6	53.7	10.2
	N	4	4	4	4	4	4	4	4	4	4
10											
	MEAN	92	16	1.2	9.1	4.8	4.3	.2	9	145	61
	S.D.	21.5	1.6	.05	.68	.21	.63	.23	1.7	22.0	18.0
	N	6	6	6	6	6	6	6	6	6	6
30/20											
	MEAN	81	15	1.1	9.1	4.8	4.4	.2	8	140	56
	S.D.	4.6	2.0	.21	.77	.20	.70	.15	4.7	26.3	13.2
	N	6	6	6	6	6	6	6	6	6	6

Table 17

Summary of Clinical Chemistry Data

Males Day -11

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	35	58	455	126	3	145	516	25	237
	S.D.	9.6	28.8	202.2	32.4	.8	77.2	214.2	9.1	79.8
	N	6	6	6	6	6	6	6	6	6
3	MEAN	40	42	556	135	5	142	377	38	183
	S.D.	3.9	8.1	180.3	24.3	2.7	19.1	41.6	27.3	30.4
	N	4	4	4	4	4	4	4	4	4
10	MEAN	40	77	604	120	5	128	369	14	195
	S.D.	7.3	52.6	173.8	38.0	2.1	45.0	98.5	8.7	70.6
	N	6	6	6	6	6	6	6	6	6
30/20	MEAN	39	66	521	117	3	142	380	37	187
	S.D.	8.3	41.8	231.6	49.1	1.4	56.6	89.3	29.6	46.0
	N	6	6	6	6	6	5	6	6	6

Table 17

Summary of Clinical Chemistry Data

Males Day -11

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) 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	11.4	5.8	163	5.8	114
	S.D.	.45	.69	2.9	.50	1.6
	N	6	6	6	6	6
3						
	MEAN	11.4	6.7	162	5.9	110
	S.D.	.70	.53	5.7	.78	1.7
	N	4	4	4	4	4
10						
	MEAN	10.9	6.3	158	5.4	112
	S.D.	.45	1.37	2.4	.48	1.5
	N	6	6	6	6	6
30/20						
	MEAN	10.7	6.1	159	5.6	112
	S.D.	.57	.96	4.2	.56	2.2
	N	6	6	6	6	6

Table 18

Summary of Clinical Chemistry Data

Males Day 31

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	78	15	1.3	9.2	4.7	4.6	.2	8	146	44
	S.D.	22.9	2.4	.17	.58	.42	.56	.12	2.9	19.1	22.9
	N	6	6	6	6	6	6	6	6	6	6
3											
	MEAN	78	16	1.2	8.6	4.9	3.7	.1	7	151	51
	S.D.	9.3	4.4	.17	.37	.24	.45	.14	1.4	60.4	24.1
	N	4	4	4	4	4	4	4	4	4	4
10											
	MEAN	72	17	1.3	8.9	4.8	4.1	.2	10	142	76
	S.D.	8.5	1.5	.15	.75	.27	.55	.12	3.3	25.9	26.6
	N	6	6	6	6	6	6	6	6	6	6
30/20											
	MEAN	75	16	1.3	8.8	4.5	4.3	.1	8	158	108 *
	S.D.	9.3	2.4	.13	.49	.38	.37	.09	1.9	20.8	57.3
	N	5	5	5	5	5	5	5	5	5	5

Table 18

Summary of Clinical Chemistry Data

Males Day 31

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	34	48	577	121	4	115	551	39	255
	S.D.	6.7	16.7	232.0	29.3	1.6	51.3	177.3	20.2	87.1
	N	6	6	6	6	6	6	6	6	6
3										
	MEAN	39	29	629	107	3	157	396	46	181
	S.D.	10.9	6.4	193.9	24.5	2.6	88.3	58.3	21.0	33.5
	N	4	4	4	4	4	4	4	4	4
10										
	MEAN	36	55	704	107	2	144	372	19	197
	S.D.	7.0	22.6	165.2	29.6	1.4	36.4	109.2	10.6	85.8
	N	6	6	6	6	6	6	6	6	6
30/20										
	MEAN	33	36	571	98	1	128	434	34	205
	S.D.	6.6	13.5	313.5	34.1	1.3	66.4	109.7	28.5	49.0
	N	5	5	5	5	5	5	5	5	5

Table 18

Summary of Clinical Chemistry Data

Males Day 31

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) 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	5.9	158	5.8	113
	S.D.	.45	1.12	3.3	.37	2.8
	N	6	6	6	6	6
3	MEAN	10.1	5.8	152	5.3	111
	S.D.	.14	.88	2.5	.22	1.3
	N	4	4	4	4	4
10	MEAN	10.4	5.9	153	5.0	110
	S.D.	.34	.75	5.1	.55	2.1
	N	6	6	6	6	6
30/20	MEAN	10.7	4.9	157	5.8	112
	S.D.	.81	.63	6.2	.90	3.7
	N	5	5	5	5	5

Table 19

Summary of Clinical Chemistry Data

Males Day 63

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	78	17	1.2	9.0	4.6	4.4	.4	5	151	43
	S.D.	21.1	3.8	.19	.39	.42	.39	.18	3.7	36.9	13.5
	N	6	6	6	6	6	6	6	6	6	6
3											
	MEAN	68	18	1.1	8.9	5.0	3.8	.3	9	161	59
	S.D.	7.0	4.3	.10	.48	.25	.31	.08	5.1	61.3	20.4
	N	4	4	4	4	4	4	4	4	4	4
10											
	MEAN	71	17	1.2	8.6	4.6	4.0	.2	9	158	76
	S.D.	10.7	1.5	.16	.67	.35	.54	.10	3.2	46.2	27.4
	N	6	6	6	6	6	6	6	6	6	6
30/20											
	MEAN	76	20	1.2	8.1	3.9	4.2	.3	22	146	66
	S.D.	7.0	5.0	.13	1.20	.75	.67	.21	25.8	12.2	39.0
	N	4	4	4	4	4	4	4	4	4	4

Table 19

Summary of Clinical Chemistry Data

Males Day 63

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	36	62	582	123	4	139	481	28	262
	S.D.	8.0	23.9	193.3	31.2	2.9	78.9	147.1	16.2	81.8
	N	6	6	6	6	6	6	6	6	6
3										
	MEAN	35	45	612	121	2	131	396	86	220
	S.D.	10.4	26.7	169.9	15.9	1.0	16.2	58.5	81.3	45.4
	N	4	4	4	4	4	4	4	4	4
10										
	MEAN	36	53	668	114	3	143	347	13	211
	S.D.	6.9	19.4	190.3	29.7	1.5	65.6	106.2	12.2	83.4
	N	6	6	6	6	6	6	6	6	6
30/20										
	MEAN	141	192	484	110	9	379	352	8	204
	S.D.	187.4	269.7	159.5	55.7	8.6	496.0	71.3	13.6	49.5
	N	4	4	4	4	4	4	4	4	4

Table 19

Summary of Clinical Chemistry Data

Males Day 63

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) 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	10.6	5.9	156	5.1	111
	S.D.	.32	.44	3.4	.31	2.9
	N	6	6	6	6	6
3	MEAN	10.6	6.2	154	5.0	111
	S.D.	.33	1.07	3.9	.13	2.2
	N	4	4	4	4	4
10	MEAN	10.4	5.7	150 *	4.6	110
	S.D.	.38	.69	1.8	.45	2.6
	N	6	6	6	6	6
30/20	MEAN	9.8	4.9	152	5.8	111
	S.D.	.93	.48	3.9	.94	2.6
	N	4	4	4	4	4

Table 20

Summary of Clinical Chemistry Data

Males Day 91

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	79	19	1.3	9.5	4.9	4.6	.2	11	167	40
	S.D.	11.7	1.8	.23	.52	.33	.27	.17	4.5	45.3	8.5
	N	6	6	6	6	6	6	6	6	6	6
3											
	MEAN	78	18	1.2	8.9	4.9	4.0	.3	12	157	56
	S.D.	9.8	3.5	.14	.12	.19	.17	.10	4.0	51.3	25.2
	N	4	4	4	4	4	4	4	4	4	4
10											
	MEAN	77	20	1.3	9.1	4.7	4.3	.2	11	155	88 *
	S.D.	8.9	2.9	.12	.70	.33	.53	.12	5.2	30.6	36.8
	N	6	6	6	6	6	6	6	6	6	6
30/20											
	MEAN	84	17	1.0	9.0	4.4	4.6	.1	13	142	99 *
	S.D.	19.1	1.4	.21	1.13	.64	.49	.14	5.7	9.2	55.2
	N	2	2	2	2	2	2	2	2	2	2

Table 20

Summary of Clinical Chemistry Data

Males Day 91

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	38	63	529	128	10	143	515	20	270
	S.D.	7.8	22.7	240.3	31.4	3.7	55.8	148.7	17.4	66.1
	N	6	6	6	6	6	6	6	6	6
3										
	MEAN	40	47	585	118	10	126	378	50	207
	S.D.	6.7	25.2	177.6	22.5	1.0	35.3	63.6	32.0	47.2
	N	4	4	4	4	4	4	4	4	4
10										
	MEAN	40	53	656	113	11	133	367	9	219
	S.D.	6.8	15.5	208.6	30.8	2.9	34.4	100.7	12.6	77.0
	N	6	6	6	6	6	6	6	6	6
30/20										
	MEAN	38	48	432	120	10	156	318	11	184
	S.D.	7.1	17.7	306.2	88.4	.0	31.8	67.9	15.6	62.9
	N	2	2	2	2	2	2	2	2	2

Table 20

Summary of Clinical Chemistry Data

Males Day 91

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) 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	11.3	6.4	167	5.3	117
	S.D.	.20	.60	3.0	.38	2.7
	N	6	6	6	6	6
3	MEAN	10.8 *	6.3	162	5.1	118
	S.D.	.44	1.10	2.5	.46	1.7
	N	4	4	4	4	4
10	MEAN	10.8 *	6.1	160 *	4.8	117
	S.D.	.34	.80	3.7	.37	1.9
	N	6	6	6	6	6
30/20	MEAN	10.1 *	5.0	158 *	5.4	114
	S.D.	.71	.42	2.8	.85	3.5
	N	2	2	2	2	2

Table 21

Summary of Clinical Chemistry Data

Males Day 182

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	71	20	1.1	8.6	4.7	3.9	.3	18	156	44
	S.D.	14.5	3.1	.17	.50	.32	.41	.12	3.6	35.0	8.7
	N	6	6	6	6	6	6	6	6	6	6
3	MEAN	63	22	1.1	8.4	4.9	3.5	.2	17	142	51
	S.D.	8.1	5.8	.25	.51	.35	.35	.15	2.5	47.4	24.4
	N	3	3	3	3	3	3	3	3	3	3
10	MEAN	66	20	1.1	8.4	4.6	3.8	.2	16	154	72
	S.D.	19.7	2.4	.19	.71	.26	.62	.23	1.4	30.6	24.5
	N	6	6	6	6	6	6	6	6	6	6
30/20	MEAN	80	16	.9	8.3	4.2	4.2	.2	18	150	92
	S.D.	27.6	.7	.14	.14	.49	.35	.35	.7	15.6	40.3
	N	2	2	2	2	2	2	2	2	2	2

Table 21

Summary of Clinical Chemistry Data

Males Day 182

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	37	68	444	124	5	140	500	39	328
	S.D.	4.8	15.7	190.8	30.5	2.3	28.8	144.3	25.0	91.9
	N	6	6	6	6	6	6	6	6	6
3										
	MEAN	46	43	574	130	6	139	457	106	313
	S.D.	1.5	5.8	290.4	39.2	2.0	37.6	105.5	63.8	72.0
	N	3	3	3	3	3	3	3	3	3
10										
	MEAN	44	53	544	110	7	922	362	11 *	268
	S.D.	11.6	26.7	181.0	24.1	2.2	1902.1	114.7	9.1	107.9
	N	6	6	6	6	6	6	6	6	6
30/20										
	MEAN	40	48	384	122	2	169	305	8	215
	S.D.	3.5	7.8	260.9	95.5	.7	58.0	55.2	12.0	65.1
	N	2	2	2	2	2	2	2	2	2

Table 21

Summary of Clinical Chemistry Data

Males Day 182

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) 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	10.0	5.8	152	4.9	106
	S.D.	.23	.44	2.0	.33	1.3
	N	6	6	6	6	6
3	MEAN	10.3	6.0	154	4.9	109
	S.D.	1.29	2.12	10.4	.96	1.7
	N	3	3	3	3	3
10	MEAN	9.7	5.8	148	4.3	106
	S.D.	.52	1.16	3.9	.57	2.3
	N	6	6	6	6	6
30/20	MEAN	9.2	4.8	150	5.0	108
	S.D.	.21	.00	2.8	1.20	1.4
	N	2	2	2	2	2

Table 22

Summary of Clinical Chemistry Data

Males Day 217 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	101	17	1.4	9.2	4.8	4.4	.4	6	194	40
	S.D.	36.8	.0	.07	.28	.35	.07	.07	.0	48.8	.7
	N	2	2	2	2	2	2	2	2	2	2
10											
	MEAN	61	21	1.4	8.0	4.6	3.3	.2	7	159	80
	S.D.	9.9	1.4	.14	.21	.21	.42	.07	.0	39.6	43.8
	N	2	2	2	2	2	2	2	2	2	2

Table 22

Summary of Clinical Chemistry Data

Males Day 217 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	34	42	247	140	5	92	612	20	415
	S.D.	7.8	17.0	18.4	51.6	1.4	14.1	221.3	13.4	192.3
	N	2	2	2	2	2	2	2	2	2
10										
	MEAN	29	18	548	120	6	140	477	22	392
	S.D.	2.8	8.5	196.6	31.1	1.4	3.5	94.8	7.1	133.6
	N	2	2	2	2	2	2	2	2	2

Table 22

Summary of Clinical Chemistry Data

Males Day 217 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	10.9	6.3	156	5.8	108
	S.D.	.00	.28	4.2	.35	3.5
	N	2	2	2	2	2
10						
	MEAN	9.9	6.2	146	4.6	108
	S.D.	.00	1.41	1.4	.14	.7
	N	2	2	2	2	2

Table 23

Summary of Clinical Chemistry Data

Males Day 245 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	95	15	1.3	9.1	4.8	4.2	.2	4	203	49
	S.D.	1.4	.0	.14	.00	.35	.35	.07	.0	67.9	2.8
	N	2	2	2	2	2	2	2	2	2	2
10											
	MEAN	80	20	1.3	8.1	4.8	3.2	.2	5	164	92
	S.D.	2.1	2.8	.14	.14	.21	.35	.07	1.4	30.4	64.3
	N	2	2	2	2	2	2	2	2	2	2

Table 23

Summary of Clinical Chemistry Data

Males Day 245 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	35	44	245	134	4	508	604	46	420
	S.D.	7.1	1.4	58.0	65.8	.7	559.3	219.2	2.1	186.0
	N	2	2	2	2	2	2	2	2	2
10	MEAN	28	44	635	120	2	164	490	56	394
	S.D.	3.5	9.2	206.5	32.5	.7	53.0	70.0	13.4	112.4
	N	2	2	2	2	2	2	2	2	2

Table 23

Summary of Clinical Chemistry Data

Males Day 245 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	6.8	158	5.6	110
	S.D.	.00	.21	.0	1.27	.7
	N	2	2	2	2	2
10						
	MEAN	10.3	6.4	153	5.3	114
	S.D.	.00	1.06	2.8	.42	.7
	N	2	2	2	2	2

Table 24

Summary of Clinical Chemistry Data

Males Day 275 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	84	18	1.2	9.2	4.7	4.5	.3	10	194	38
	S.D.	12.0	2.1	.42	.57	.85	.28	.14	.7	88.4	12.0
	N	2	2	2	2	2	2	2	2	2	2
10											
	MEAN	90	21	1.3	8.2	4.9	3.3	.3	8	150	48
	S.D.	4.2	.0	.00	.00	.42	.42	.00	.7	39.6	36.8
	N	2	2	2	2	2	2	2	2	2	2

Table 24

Summary of Clinical Chemistry Data

Males Day 275 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
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	60	108	270	112	2	1024	826	164	574
	S.D.	6.4	63.6	75.7	21.2	2.1	533.9	224.2	61.5	168.3
	N	2	2	2	2	2	2	2	2	2
10										
	MEAN	50	76	603	116	2	1524	1074	357	903
	S.D.	4.9	7.8	210.7	31.1	1.4	563.6	813.2	422.8	787.7
	N	2	2	2	2	2	2	2	2	2

Table 24

Summary of Clinical Chemistry Data

Males Day 275 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) 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	10.9	4.9	154	6.0	107
	S.D.	.42	.99	.7	.78	4.2
	N	2	2	2	2	2
10						
	MEAN	10.2	5.2	150	4.4	103
	S.D.	.00	1.91	2.8	.00	.0
	N	2	2	2	2	2

Table 25

Summary of Clinical Urinalysis Data

Males Day -11

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		U VOL ML	SP GR	U PH
0	MEAN	136.8	1.016	8.2
	S.D.	131.02	.0073	.41
	N	6	6	6
3	MEAN	231.0	1.010	7.9
	S.D.	220.83	.0086	.25
	N	4	4	4
10	MEAN	141.0	1.014	8.2
	S.D.	157.36	.0060	.41
	N	6	6	6
30/20	MEAN	88.3	1.014	8.2
	S.D.	66.52	.0081	.42
	N	6	6	6

Table 26

Summary of Clinical Urinalysis Data

Males Day 31

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		U VOL ML	SP GR	U PH
0				
	MEAN	166.5	1.015	7.9
	S.D.	158.98	.0066	.38
	N	6	6	6
3				
	MEAN	241.8	1.010	7.8
	S.D.	141.01	.0092	.50
	N	4	4	4
10				
	MEAN	155.3	1.014	8.1
	S.D.	111.19	.0067	.20
	N	6	6	6
30/20				
	MEAN	223.2	1.007	7.5
	S.D.	99.35	.0056	.50
	N	5	5	5

Table 27

Summary of Clinical Urinalysis Data

Males Day 63

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		U VOL ML	SP GR	U PH
0				
	MEAN	189.0	1.013	8.1
	S.D.	191.82	.0078	.20
	N	6	6	6
3				
	MEAN	253.0	1.010	7.5 *
	S.D.	145.45	.0097	.41
	N	4	4	4
10				
	MEAN	190.0	1.012	8.2
	S.D.	188.04	.0057	.26
	N	6	6	6
30/20				
	MEAN	83.0	1.016	7.5
	S.D.	22.89	.0048	.58
	N	4	4	4

Table 28

Summary of Clinical Urinalysis Data

Males Day 91

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		U VOL ML	SP GR	U PH
0				
	MEAN	186.0	1.017	8.2
	S.D.	182.11	.0083	.27
	N	6	6	6
3				
	MEAN	272.0	1.012	7.8 *
	S.D.	218.99	.0088	.29
	N	4	4	4
10				
	MEAN	222.0	1.012	7.9
	S.D.	174.10	.0054	.20
	N	6	6	6
30/20				
	MEAN	71.0	1.020	8.2
	S.D.	9.90	.0000	.35
	N	2	2	2

Table 29

Summary of Clinical Urinalysis Data

Males Day 182

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		U VOL ML	SP GR	U PH
0				
	MEAN	159.5	1.015	7.7
	S.D.	67.63	.0063	.41
	N	6	6	6
3				
	MEAN	172.3	1.016	7.8
	S.D.	71.07	.0060	.29
	N	3	3	3
10				
	MEAN	208.5	1.013	7.2
	S.D.	159.04	.0067	.27
	N	6	6	6
30/20				
	MEAN	197.0	1.014	7.8
	S.D.	154.15	.0113	.35
	N	2	2	2

Table 30

Summary of Clinical Urinalysis Data

Males Day 217 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		U VOL ML	SP GR	U PH
0				
	MEAN	392.5	1.008	8.0
	S.D.	215.67	.0071	.00
	N	2	2	2
10				
	MEAN	290.0	1.006	7.8
	S.D.	233.35	.0035	.35
	N	2	2	2

Table 31

Summary of Clinical Urinalysis Data

Males Day 245 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		U VOL ML	SP GR	U PH
0				
	MEAN	196.0	1.013	8.0
	S.D.	166.88	.0099	.00
	N	2	2	2
10				
	MEAN	341.5	1.005	7.5
	S.D.	246.78	.0028	.00
	N	2	2	2

Table 32

Summary of Clinical Urinalysis Data

Males Day 275 (Recovery)

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO)
IN CYNOMOLGUS MONKEYS

DOSE mg/kg/day		U VOL ML	SP GR	U PH
0				
	MEAN	115.0	1.018	7.0
	S.D.	60.81	.0042	.00
	N	2	2	2
10				
	MEAN	135.5	1.012	8.0
	S.D.	61.52	.0028	.00
	N	2	2	2

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

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

LF ADRENAL

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	3947.5	0.3085	0.0078	0.0048
		STANDARD DEV:	591.1	0.0462	0.0003	0.0004
M	2					
		NUMBER IN GROUP:	3	3	3	3
		MEAN:	4486.7	0.3720	0.0083	0.0056
		STANDARD DEV:	30.6	0.0460	0.0010	0.0009
M	3					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	4447.5	0.3030	0.0069	0.0048
		STANDARD DEV:	498.5	0.0940	0.0024	0.0017
M	4					
		NUMBER IN GROUP:	5	2	2	2
		MEAN:	3925.0	0.3320	0.0087	0.0045
		STANDARD DEV:	583.0	0.0311	0.0006	0.0002

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

RT ADRENAL

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	3947.5	0.2513	0.0063	0.0039
		STANDARD DEV:	591.1	0.0503	0.0008	0.0006
M	2					
		NUMBER IN GROUP:	3	3	3	3
		MEAN:	4486.7	0.3573	0.0080	0.0054
		STANDARD DEV:	30.6	0.0492	0.0010	0.0009
M	3					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	4447.5	0.2328	0.0054	0.0036
		STANDARD DEV:	498.5	0.0512	0.0016	0.0009
M	4					
		NUMBER IN GROUP:	5	2	2	2
		MEAN:	3925.0	0.2620	0.0067	0.0035
		STANDARD DEV:	583.0	0.0891	0.0012	0.0010

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

BRAIN

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	3947.5	64.5708	1.6471	1.0000
		STANDARD DEV:	591.1	7.6823	0.1763	0.0000
M	2					
		NUMBER IN GROUP:	3	3	3	3
		MEAN:	4486.7	66.5134	1.4827	1.0000
		STANDARD DEV:	30.6	2.3695	0.0614	0.0000
M	3					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	4447.5	64.2743	1.4622	1.0000
		STANDARD DEV:	498.5	4.2590	0.2194	0.0000
M	4					
		NUMBER IN GROUP:	5	2	2	2
		MEAN:	3925.0	74.2460	1.9603	1.0000
		STANDARD DEV:	583.0	3.6416	0.2309	0.0000

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

LF EPIDIDYMIS

SEX	DOSE GROUP	TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1				
NUMBER IN GROUP:		4	4	4	4
MEAN:		3947.5	1.6380	0.0410	0.0256
STANDARD DEV:		591.1	0.5473	0.0112	0.0095
M	2				
NUMBER IN GROUP:		3	3	3	3
MEAN:		4486.7	2.3627	0.0526	0.0355
STANDARD DEV:		30.6	0.6805	0.0151	0.0100
M	3				
NUMBER IN GROUP:		4	4	4	4
MEAN:		4447.5	1.7010	0.0382	0.0268
STANDARD DEV:		498.5	0.5692	0.0127	0.0094
M	4				
NUMBER IN GROUP:		5	2	2	2
MEAN:		3925.0	1.8945	0.0510	0.0257
STANDARD DEV:		583.0	0.3345	0.0172	0.0058

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

RT EPIDIDYMIS

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	3947.5	1.7750	0.0449	0.0278
		STANDARD DEV:	591.1	0.4542	0.0100	0.0086
M	2					
		NUMBER IN GROUP:	3	3	3	3
		MEAN:	4486.7	2.3617	0.0526	0.0356
		STANDARD DEV:	30.6	0.5749	0.0127	0.0087
M	3					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	4447.5	1.6640	0.0375	0.0261
		STANDARD DEV:	498.5	0.5738	0.0133	0.0091
M	4					
		NUMBER IN GROUP:	5	2	2	2
		MEAN:	3925.0	1.7740	0.0476	0.0240
		STANDARD DEV:	583.0	0.2489	0.0144	0.0045

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

LF KIDNEY

SEX	DOSE GROUP	TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1				
NUMBER IN GROUP:		4	4	4	4
MEAN:		3947.5	6.5898	0.1674	0.1023
STANDARD DEV:		591.1	0.9070	0.0133	0.0110
M	2				
NUMBER IN GROUP:		3	3	3	3
MEAN:		4486.7	8.0123	0.1785	0.1209
STANDARD DEV:		30.6	1.1567	0.0245	0.0216
M	3				
NUMBER IN GROUP:		4	4	4	4
MEAN:		4447.5	8.0508	0.1818	0.1260
STANDARD DEV:		498.5	0.6366	0.0136	0.0168
M	4				
NUMBER IN GROUP:		5	2	2	2
MEAN:		3925.0	9.1090 *	0.2437	0.1232
STANDARD DEV:		583.0	1.0041	0.0668	0.0196

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

RT KIDNEY

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	3947.5	6.5520	0.1660	0.1014
		STANDARD DEV:	591.1	1.0155	0.0085	0.0092
M	2					
		NUMBER IN GROUP:	3	3	3	3
		MEAN:	4486.7	7.7810	0.1733	0.1175
		STANDARD DEV:	30.6	1.2850	0.0274	0.0237
M	3					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	4447.5	7.8853	0.1777	0.1235
		STANDARD DEV:	498.5	0.7930	0.0124	0.0191
M	4					
		NUMBER IN GROUP:	5	2	2	2
		MEAN:	3925.0	9.1500	0.2447	0.1237
		STANDARD DEV:	583.0	0.9772	0.0663	0.0192

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

LIVER

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	3947.5	60.1698	1.5303	0.9344
		STANDARD DEV:	591.1	6.9386	0.0769	0.0736
M	2					
		NUMBER IN GROUP:	3	3	3	3
		MEAN:	4486.7	81.7917 *	1.8228 *	1.2317
		STANDARD DEV:	30.6	2.8112	0.0502	0.0856
M	3					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	4447.5	83.1743 *	1.8700 *	1.3042 *
		STANDARD DEV:	498.5	9.6617	0.0616	0.2255
M	4					
		NUMBER IN GROUP:	5	2	2	2
		MEAN:	3925.0	90.3925 *	2.4057 *	1.2203
		STANDARD DEV:	583.0	4.2208	0.5106	0.1167

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

PANCREAS

SEX DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1				
NUMBER IN GROUP:		4	4	4	4
MEAN:		3947.5	5.6195	0.1427	0.0872
STANDARD DEV:		591.1	1.0600	0.0212	0.0136
M	2				
NUMBER IN GROUP:		3	3	3	3
MEAN:		4486.7	6.1023	0.1359	0.0922
STANDARD DEV:		30.6	1.2194	0.0262	0.0214
M	3				
NUMBER IN GROUP:		4	4	4	4
MEAN:		4447.5	5.2703	0.1194	0.0828
STANDARD DEV:		498.5	1.0885	0.0281	0.0206
M	4				
NUMBER IN GROUP:		5	2	2	2
MEAN:		3925.0	6.2610	0.1653	0.0843
STANDARD DEV:		583.0	0.3168	0.0192	0.0001

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

LF TESTIS

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	3947.5	9.9312	0.2516	0.1580
		STANDARD DEV:	591.1	3.9350	0.0984	0.0783
M	2					
		NUMBER IN GROUP:	3	3	3	3
		MEAN:	4486.7	15.1513	0.3375	0.2279
		STANDARD DEV:	30.6	3.7198	0.0822	0.0552
M	3					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	4447.5	12.1860	0.2728	0.1915
		STANDARD DEV:	498.5	4.6403	0.1022	0.0740
M	4					
		NUMBER IN GROUP:	5	2	2	2
		MEAN:	3925.0	10.2960	0.2777	0.1396
		STANDARD DEV:	583.0	2.1680	0.1029	0.0360

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

RT TESTIS

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1	NUMBER IN GROUP:	4	4	4	4
		MEAN:	3947.5	9.6432	0.2453	0.1540
		STANDARD DEV:	591.1	3.8907	0.1000	0.0788
M	2	NUMBER IN GROUP:	3	3	3	3
		MEAN:	4486.7	16.1067	0.3588	0.2425
		STANDARD DEV:	30.6	4.2181	0.0930	0.0641
M	3	NUMBER IN GROUP:	4	4	4	4
		MEAN:	4447.5	11.5203	0.2584	0.1810
		STANDARD DEV:	498.5	3.9126	0.0867	0.0633
M	4	NUMBER IN GROUP:	5	2	2	2
		MEAN:	3925.0	9.8880	0.2667	0.1340
		STANDARD DEV:	583.0	2.0633	0.0983	0.0344

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

LF THYROID/PARA

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	3947.5	0.2205	0.0058	0.0035
		STANDARD DEV:	591.1	0.0617	0.0023	0.0011
M	2					
		NUMBER IN GROUP:	3	3	3	3
		MEAN:	4486.7	0.1677	0.0037	0.0025
		STANDARD DEV:	30.6	0.0422	0.0009	0.0007
M	3					
		NUMBER IN GROUP:	4	4	4	4
		MEAN:	4447.5	0.3340	0.0074	0.0053
		STANDARD DEV:	498.5	0.1502	0.0028	0.0025
M	4					
		NUMBER IN GROUP:	5	2	2	2
		MEAN:	3925.0	0.2435	0.0063	0.0033
		STANDARD DEV:	583.0	0.0700	0.0008	0.0008

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

RT THYROID/PARA

SEX	DOSE GROUP	TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1				
NUMBER IN GROUP:		4	4	4	4
MEAN:		3947.5	0.2225	0.0058	0.0035
STANDARD DEV:		591.1	0.0654	0.0023	0.0011
M	2				
NUMBER IN GROUP:		3	3	3	3
MEAN:		4486.7	0.1850	0.0041	0.0028
STANDARD DEV:		30.6	0.0305	0.0007	0.0004
M	3				
NUMBER IN GROUP:		4	4	4	4
MEAN:		4447.5	0.3135	0.0070	0.0049
STANDARD DEV:		498.5	0.1146	0.0023	0.0019
M	4				
NUMBER IN GROUP:		5	2	2	2
MEAN:		3925.0	0.2150	0.0054	0.0029
STANDARD DEV:		583.0	0.1273	0.0024	0.0016

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

LF ADRENAL

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	5410.0	0.3990	0.0074	0.0061
		STANDARD DEV:	240.4	0.0438	0.0005	0.0000
M	3					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	3932.5	0.2770	0.0072	0.0041
		STANDARD DEV:	618.7	0.0509	0.0024	0.0004

TABLE 34

Summary of Organ Weight Data

Week 40 Recovery Sacrifice

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

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

RT ADRENAL

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	5410.0	0.2465	0.0045	0.0037
		STANDARD DEV:	240.4	0.0389	0.0005	0.0002
M	3					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	3932.5	0.1920	0.0050	0.0029
		STANDARD DEV:	618.7	0.0382	0.0018	0.0003

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

BRAIN

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	5410.0	65.7115	1.2128	1.0000
		STANDARD DEV:	240.4	7.2811	0.0807	0.0000
M	3					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	3932.5	66.8240	1.7330	1.0000
		STANDARD DEV:	618.7	6.1559	0.4292	0.0000

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

LF EPIDIDYMIS

SEX	DOSE GROUP	TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1				
NUMBER IN GROUP:		2	2	2	2
MEAN:		5410.0	2.6085	0.0481	0.0397
STANDARD DEV:		240.4	0.2963	0.0033	0.0001
M	3				
NUMBER IN GROUP:		2	2	2	2
MEAN:		3932.5	1.6595	0.0425	0.0250
STANDARD DEV:		618.7	0.0955	0.0043	0.0037

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

RT EPIDIDYMIS

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	5410.0	2.7290	0.0505	0.0418
		STANDARD DEV:	240.4	0.0382	0.0015	0.0040
M	3					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	3932.5	1.5995	0.0415	0.0239
		STANDARD DEV:	618.7	0.1605	0.0106	0.0002

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

LF KIDNEY

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	5410.0	9.0575	0.1680	0.1396
		STANDARD DEV:	240.4	1.0232	0.0264	0.0310
M	3					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	3932.5	5.8750	0.1493	0.0890
		STANDARD DEV:	618.7	0.9942	0.0018	0.0231

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

RT KIDNEY

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	5410.0	8.8620	0.1644	0.1365
		STANDARD DEV:	240.4	0.9730	0.0253	0.0299
M	3					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	3932.5	5.6370	0.1438	0.0852
		STANDARD DEV:	618.7	0.6449	0.0062	0.0175

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

LIVER

SEX	DOSE GROUP	TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1				
NUMBER IN GROUP:		2	2	2	2
MEAN:		5410.0	90.1885	1.6697	1.3831
STANDARD DEV:		240.4	2.4816	0.1201	0.1910
M	3				
NUMBER IN GROUP:		2	2	2	2
MEAN:		3932.5	66.0390	1.6898	0.9961
STANDARD DEV:		618.7	5.2212	0.1331	0.1699

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

PANCREAS

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	5410.0	8.4993	0.1570	0.1295
		STANDARD DEV:	240.4	0.7025	0.0060	0.0037
M	3					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	3932.5	5.4815	0.1409	0.0824
		STANDARD DEV:	618.7	0.0955	0.0197	0.0090

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

LF TESTIS

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	5410.0	16.0235	0.2975	0.2474
		STANDARD DEV:	240.4	2.4600	0.0587	0.0649
M	3					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	3932.5	10.0800	0.2598	0.1514
		STANDARD DEV:	618.7	0.1329	0.0443	0.0120

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

RT TESTIS

SEX	DOSE GROUP	TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1				
NUMBER IN GROUP:		2	2	2	2
MEAN:		5410.0	16.3235	0.3030	0.2519
STANDARD DEV:		240.4	2.3553	0.0570	0.0638
M	3				
NUMBER IN GROUP:		2	2	2	2
MEAN:		3932.5	10.2370	0.2627	0.1542
STANDARD DEV:		618.7	0.4454	0.0300	0.0209

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

LF THYROID/PARA

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	5410.0	0.2545	0.0047	0.0039
		STANDARD DEV:	240.4	0.0134	0.0005	0.0006
M	3					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	3932.5	0.3165	0.0085	0.0046
		STANDARD DEV:	618.7	0.1732	0.0057	0.0022

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

RT THYROID/PARA

SEX	DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	5410.0	0.2570	0.0048	0.0039
		STANDARD DEV:	240.4	0.0127	0.0004	0.0006
M	3					
		NUMBER IN GROUP:	2	2	2	2
		MEAN:	3932.5	0.3000	0.0081	0.0044
		STANDARD DEV:	618.7	0.1937	0.0062	0.0025

TABLE 35

Incidence of Macroscopic Observations

Week 27 Sacrifice

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

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

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---			
SEX:		-------MALE-------			
GROUP:		-1-	-2-	-3-	-4-
NUMBER:		4	3	4	5
** TOP OF LIST **					
GENERAL COMMENT (GC)	NUMBER EXAMINED :	4	3	4	5
BONE MARROW SMEAR TAKEN		4	3	4	5
EYES - DAVIDSONS		4	3	4	5
NO MACROSCOPIC LESIONS		3	0	1	4
ANIMAL OBESE		0	1	0	0
LIVER (LI)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	3	5
DIFFUSELY DARK		0	0	1	0
KIDNEY (KD)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	4
CYST(S)		0	0	0	1
LUNG (LU)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	2	3	5
MOTTLED		0	0	1	0
RED FOCUS(I)/AREA(S)		0	1	0	0

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

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

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---			
SEX:		-------MALE-------			
GROUP:		-1-	-2-	-3-	-4-
NUMBER:		4	3	4	5
PARATHYROID (PT)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	3	5
CYST(S)		0	0	1	0
CECUM (CE)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	3	2	4	5
RED FOCUS(I)/AREA(S)		1	1	0	0
SKIN (SK)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	3	5
CRUSTED AREA(S)		0	0	1	0
LN, TRACHEOBRON (TB)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	3	5
DIFFUSELY DARK		0	0	1	0
LN, MANDIBULAR (MN)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	4
LARGE		0	0	0	1

** END OF LIST

TABLE 36

Incidence of Macroscopic Observations

Week 40 Recovery Sacrifice

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

TABLE INCLUDES:
SEX=ALL;GROUP=1,3;WEEKS=ALL
DEATH=U;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---	
	SEX:	--MALE--	
	GROUP:	-1-	-3-
	NUMBER:	2	2
** TOP OF LIST **			
GENERAL COMMENT (GC)	NUMBER EXAMINED:	2	2
BONE MARROW SMEAR TAKEN		2	2
EYES - DAVIDSONS		2	2
NO MACROSCOPIC LESIONS		1	2
ANIMAL OBESE		1	0
LIVER (LI)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	1	2
ADHESION(S)		1	0
** END OF LIST			

TABLE 37

Incidence of Microscopic Observations

Week 27 Sacrifice

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) 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-------			
GROUP:		-1-	-2-	-3-	-4-
NUMBER:		4	3	4	5
** TOP CF LIST **					
ADRENAL, CORTEX (AC)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	3	1	2	3
--CORTICAL TISSUE, EXTRACAPSULAR		1	1	0	1
--ECTOPIC ZONA GLOMERULOSA-LIKE CELLS, ZONA FASCICULATA		0	0	0	1
--HYPERTROPHY, CORTICAL CELL		1	1	2	1
--MINERALIZATION		1	0	1	0
ADRENAL, MEDULLA (MA)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	5
LIVER (LI)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	1	1	0	0
--INFILTRATE, LYMPHOHISTIOCYTIC		3	2	4	5
--PIGMENT, HEPATOCELLULAR		0	1	0	0
--PIGMENT, KUPFFER CELL		0	1	0	2
SPLEEN (SP)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	5
PANCREAS (PA)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	3	5
--INFILTRATE, LYMPHOHISTIOCYTIC		0	0	1	0

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) 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-------			
GROUP:		-1-	-2-	-3-	-4-
NUMBER:		4	3	4	5
TESTIS (TE)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	4
--ATROPHY/DEGENERATION		0	0	0	1
BONE, FEMUR (FE)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	5
MARROW, FEMUR (FM)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	5
MARROW, STERNUM (SE)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	5
BONE, STERNUM (SB)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	5
EYE (EY)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	3	5
--INFILTRATE, LYMPHOHISTIOCYTIC, CONJUNCTIVAL		0	0	1	0

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) 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--------			
	GROUP:	-1-	-2-	-3-	-4-
	NUMBER:	4	3	4	5
BRAIN (BR)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	3
--INFILTRATE, LYMPHOHISTIOCYTIC		0	0	0	1
--MINERALIZATION		0	0	0	1
KIDNEY (KD)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	2	2	1	2
--CYST		0	0	0	1
--INFILTRATE, LYMPHOHISTIOCYTIC		1	1	0	1
--MINERALIZATION, TUBULAR		2	0	3	2
LUNG (LU)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	0	0	0	0
--CONGESTION		0	1	0	0
--INFILTRATE, EOSINOPHILIC		1	0	0	0
--INFILTRATE, MACROPHAGE, ALVEOLAR		0	0	3	1
--MINERALIZATION, ALVEOLAR		1	0	0	0
--PIGMENT		4	3	4	5
HEART (HT)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	2	2	4
--INFILTRATE, LYMPHOHISTIOCYTIC		0	1	2	1
--PIGMENT		0	1	0	0

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) 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-------			
GROUP:		-1-	-2-	-3-	-4-
NUMBER:		4	3	4	5
GALLBLADDER (GB)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	5
THYMUS (TH)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	2	2	5
--INVOLUTION		0	1	2	0
LN, MESENTERIC (MS)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	3	2	3	3
--INFILTRATE, EOSINOPHILIC		1	0	0	1
--INFLAMMATION, GRANULOMATOUS		1	0	0	0
--PARASITISM		1	0	0	0
--PIGMENT		1	1	1	1
TRACHEA (TR)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	5
ESOPHAGUS (ES)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	5

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

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---			
	SEX:	-------MALE-------			
	GROUP:	-1-	-2-	-3-	-4-
	NUMBER:	4	3	4	5
THYROID (TY)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	3	3	0	2
--ECTOPIC THYMUS		0	0	2	2
--INFILTRATE, LYMPHOHISTIOCYTIC		0	0	2	1
--ONE EXAMINED		1	0	0	0
--CYST, THYROGLOSSAL		0	0	1	0
PARATHYROID (PT)	NUMBER EXAMINED:	3	3	4	5
	NOT REMARKABLE:	3	2	3	5
--CYST, GLANDULAR		0	1	1	0
AORTA (AO)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	5
PITUITARY (PI)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	3	3	4	5
--CYST		1	0	0	0
SALIV GL, MANDIB (SG)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	2	2	3	4
--INFILTRATE, LYMPHOHISTIOCYTIC		2	1	1	1

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) IN CYNOMOLGUS MONKEYS

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

		--- NUMBER-OF-ANIMALS-AFFECTED ---			
	SEX:	-------MALE-------			
	GROUP:	-1-	-2-	-3-	-4-
ORGAN AND FINDING DESCRIPTION	NUMBER:	4	3	4	5
MUSCLE, SKELETAL (SM)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	3	5
--DEGENERATION/NECROSIS		0	0	1	0
--INFLAMMATION, ACUTE		0	0	1	0
SPINAL CORD (SC)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	5
NERVE, SCIATIC (SN)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	5
STOMACH, GL (ST)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	4
--INFLAMMATION, GRANULOMATOUS		0	0	0	1
--PARASITISM		0	0	0	1
DUODENUM (DU)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	3	5
--PARASITISM		0	0	1	0
JEJUNUM (JE)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	4	5

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

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---			
SEX:		-------MALE-------			
GROUP:		-1-	-2-	-3-	-4-
NUMBER:		4	3	4	5
ILEUM (IL)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	3	5
--INFILTRATE, EOSINOPHILIC		0	0	1	0
CECUM (CE)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	3	3	3	5
--INFLAMMATION, GRANULOMATOUS		1	0	1	0
--PARASITISM		1	0	0	0
COLON (CO)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	3	3	4	5
--INFLAMMATION, CHRONIC		1	0	0	0
RECTUM (RE)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	3	5
--INFLAMMATION, GRANULOMATOUS		0	0	1	0
SKIN (SK)	NUMBER EXAMINED:	3	3	4	5
	NOT REMARKABLE:	3	3	3	5
--ACANTHOSIS		0	0	1	0
--INFLAMMATION, CHRONIC		0	0	1	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-------			
	GROUP:	-1-	-2-	-3-	-4-
	NUMBER:	4	3	4	5
MAMMARY, MALE (MM)	NUMBER EXAMINED:	3	3	3	5
	NOT REMARKABLE:	3	3	3	5
URINARY BLADDER (UB)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	2	2	1	1
--INFILTRATE, EOSINOPHILIC		1	0	0	0
--INFILTRATE, LYMPHOHISTIOCYTIC		2	1	3	4
PROSTATE (PR)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	2	2	1	2
--INFILTRATE, LYMPHOHISTIOCYTIC		2	1	2	3
--INFLAMMATION, SUBACUTE		0	0	1	0
SEMINAL VESICLES (SV)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	4	3	2	5
--MINERALIZATION		0	0	2	0
EPIDIDYMIDES (EP)	NUMBER EXAMINED:	4	3	4	5
	NOT REMARKABLE:	3	3	4	4
--INFILTRATE, LYMPHOHISTIOCYTIC		1	0	0	1

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) 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-------			
	GROUP:	-1-	-2-	-3-	-4-
	NUMBER:	4	3	4	5
LN, MANDIBULAR (MN)	NUMBER EXAMINED:	0	0	0	1
	NOT REMARKABLE:	0	0	0	1
LN, TRACHEOBRON (TB)	NUMBER EXAMINED:	0	0	1	0
	NOT REMARKABLE:	0	0	0	0
--PIGMENT		0	0	1	0

** END OF LIST

TABLE 38

Incidence of Microscopic Observations

Week 40 Recovery Sacrifice

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

TABLE INCLUDES:
SEX=ALL;GROUP=1,3;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- N U M B E R - O F - A N I M A L S - A F F E C T E D ---	
	SEX:	--MALE--	
	GROUP:	-1-	-3-
	NUMBER:	2	2
** TOP OF LIST **			
ADRENAL, CORTEX (AC)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	1	0
--CORTICAL TISSUE, EXTRACAPSULAR		1	2
ADRENAL, MEDULLA (MA)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
LIVER (LI)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	0	1
--FIBROSIS, CAPSULAR/SUBCAPSULAR		1	0
--INFILTRATE, LYMPHOHISTIOCYTIC		2	1
--PIGMENT, HEPATOCELLULAR		1	0
SPLEEN (SP)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
PANCREAS (PA)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
TESTIS (TE)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2

TABLE INCLUDES:
SEX=ALL;GROUP=1,3;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---	
	SEX:	--MALE--	
	GROUP:	-1-	-3-
	NUMBER:	2	2
BONE, FEMUR (FE)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
MARROW, FEMUR (FM)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
MARROW, STERNUM (SE)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
BONE, STERNUM (SB)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
EYE (EY)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	0	2
--INFILTRATE, LYMPHOHISTIOCYTIC, CHOROIDAL		2	0
BRAIN (BR)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	0	1
--INFILTRATE, LYMPHOHISTIOCYTIC		2	1
MINERALIZATION		1	0

TABLE INCLUDES:
SEX=ALL;GROUP=1,3;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER OF ANIMALS AFFECTED ---	
SEX:		--MALE--	
GROUP:		-1-	-3-
NUMBER:		2	2
KIDNEY (KD)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	1	2
--INFILTRATE, LYMPHOHISTIOCYTIC		1	0
--INFLAMMATION, VASCULAR		1	0
--THICKENING, INTIMAL, VASCULAR		1	0
LUNG (LU)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	0	0
--PIGMENT		2	2
HEART (HT)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	1
--INFILTRATE, LYMPHOHISTIOCYTIC		0	1
GALLBLADDER (GB)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
THYMUS (TH)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	0	2
--INVOLUTION		2	0

TABLE INCLUDES:
SEX=ALL;GROUP=1,3;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED --- SEX: --MALE-- GROUP: -1-	-3-
	NUMBER:	2	2
LN, MESENTERIC (MS)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	0	2
--PIGMENT		2	0
TRACHEA (TR)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	1	2
--INFLAMMATION, ACUTE		1	0
ESOPHAGUS (ES)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
THYROID (TY)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	1
--CYST, GLANDULAR		0	1
PARATHYROID (PT)	NUMBER EXAMINED:	1	2
	NOT REMARKABLE:	1	1
--INFILTRATE, LYMPHOHISTIOCYTIC		0	1
AORTA (AO)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	1
--THICKENING, INTIMAL		0	1

TABLE 38

Incidence of Microscopic Observations

Week 40 Recovery Sacrifice

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) IN CYNOMOLGUS MONKEYS

TABLE INCLUDES:
SEX=ALL;GROUP=1,3;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---	
	SEX:	--MALE--	
	GROUP:	-1-	-3-
	NUMBER:	2	2
PITUITARY (PI)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
SALIV GL, MANDIB (SG)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	0	0
--INFILTRATE, LYMPHOHISTIOCYTIC		2	2
MUSCLE, SKELETAL (SM)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	1
--PARASITISM		0	1
SPINAL CORD (SC)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
NERVE, SCIATIC (SN)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	1	2
--FIBROSIS		1	0
--INFILTRATE, LYMPHOHISTIOCYTIC		1	0
STOMACH, GL (ST)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	1	1
--INFLAMMATION, CHRONIC		0	1

TABLE 38

Incidence of Microscopic Observations

Week 40 Recovery Sacrifice

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

TABLE INCLUDES:
SEX=ALL;GROUP=1,3;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- N U M B E R - O F - A N I M A L S - A F F E C T E D ---	
	SEX:	--MALE--	
	GROUP:	-1-	-3-
	NUMBER:	2	2
** FROM PREVIOUS PAGE **			
STOMACH, GL (ST)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	1	1
--PARASITISM		0	1
--THICKENING, INTIMAL, VASCULAR		1	0
DUODENUM (DU)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	1	2
--PARASITISM		1	0
JEJUNUM (JE)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
ILEUM (IL)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
CECUM (CE)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
COLON (CO)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	1	2
--INFLAMMATION, EOSINOPHILIC		1	0

TABLE 38

Incidence of Microscopic Observations

Week 40 Recovery Sacrifice

26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE (APFO) IN CYNOMOLGUS MONKEYS

TABLE INCLUDES:
SEX=ALL;GROUP=1,3;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---	
	SEX:	--MALE--	
	GROUP:	-1-	-3-
	NUMBER:	2	2
RECTUM (RE)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
SKIN (SK)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
MAMMARY, MALE (MM)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
URINARY BLADDER (UB)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	0	0
--INFILTRATE, LYMPHOHISTIOCYTIC		2	2
PROSTATE (PR)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	0	0
--INFILTRATE, LYMPHOHISTIOCYTIC		2	2
SEMINAL VESICLES (SV)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2
EPIDIDYMIDES (EP)	NUMBER EXAMINED:	2	2
	NOT REMARKABLE:	2	2

** END OF LIST

APPENDIX 1

Protocol Deviations
Protocol
Protocol Amendment No. 1
Protocol Amendment No. 2
Material Safety Data Sheet
Certificate of Analysis

Protocol Deviations

Protocol. Husbandry. Diet. "Certified primate diet (#8726C, Harlan Teklad) once or twice daily."

Actual Procedure. All animals were fasted beginning in the afternoon on November 15, 1998 (Day 48); animals were provided with food in the morning on November 16, 1998 (Day 49).

Protocol. Dosing Procedures. Method of Administration. "Orally by gelatin capsules, daily (7 days/week) for at least 26 weeks."

Actual Procedure. There were several occasions when the test material was not administered to animals due to the condition of the animal or at the recommendation of a laboratory animal veterinarian. Dose administration was discontinued for Animal No. I05724 (Group 4) on Day 28; this animal was subsequently sacrificed in moribund condition on Day 29. Dose administration was discontinued for Animal Nos. I05711, I05722, and I05703 (Group 4) on Days 43 (Week 7), 66 (Week 10), and 81 (Week 12), respectively. Dose administration was discontinued for Animal No. I05721 (Group 2) for Days 135 and 136; this animal was subsequently sacrificed in moribund condition on Day 137.

On Day 44, Animal No. I05703 (Group 4) did not receive its amount of dose preparation because the capsule broke during dose administration procedures.

Protocol. Observation of Animals. Clinical Observations. "Once weekly, each animal will be observed; abnormal findings, or an indication that the animal is normal will be recorded."

Protocol Deviations (Continued)

Actual Procedure. The following animals did not have a weekly observation recorded on the following days: Animal No. I05714 (Group 1) on Days 1 and 22; Animal No. I05725 (Group 1) on Day 1; Animal No. I05717 (Group 2) on Day 57; Animal No. I05719 (Group 3) on Days 1 and 29; Animal No. I05703 (Group 4) on Days 8 and 15; Animal No. I05704 (Group 4) on Day 15; Animal No. I05711 (Group 4) on Days 8 and 15; Animal No. I05713 (Group 4) on Days 15, 43, and 64; and Animal No. I05724 (Group 4) on Day 8.

Protocol. Blood Hormone Determination. Method of Collection. "Blood samples will be maintained chilled until plasma is harvested."

Actual Procedure. Blood samples collected for blood hormone determination on Days 35, 66, and 94 were stored at room temperature during harvesting.

Protocol. Urine and Feces APFO Level Determination. Sample Handling. "Samples of urine (at least 2 mL) and feces (at least 5 grams) will be stored in a freezer set to maintain -10 to -30°C."

Actual Procedure. Approximately 3 grams of feces were collected from Animal Nos. I05711 and I05724 (Group 4) during Week 2 for feces APFO level Determination.

Protocol. Termination. Scheduled Sacrifices. "After at least 26 weeks of treatment, four animals/sex/group will be fasted overnight, then anesthetized with ketamine and xylazine, weighed, exsanguinated, and necropsied."

Actual Procedure. Animal No. I05709 (Group 1) was weighed incorrectly at the terminal sacrifice (Week 27, Day 184). The body weight collected for this animal on Day 183 was entered into the computer system for organ-to-body weight weight percentage calculations.

Protocol Deviations (Continued)

Protocol. Termination. Postmortem Procedures. Cell Proliferation Evaluation. "Representative samples of the left lateral lobe of the liver, left and right testes, and pancreas will be collected from each animal at the scheduled and unscheduled sacrifices and preserved in formalin."

Actual Procedure. The fixative used for the tissue samples collected from the left lateral lobe of the liver, left and right testes, and pancreas of the recovery animals for cell proliferation evaluation was documented incorrectly.

Protocol. Experimental Design. Postmortem Procedures. Histopathology. "Tissues from each animal (including Animal No. I05723) will be embedded in paraffin, sectioned, stained with hematoxylin and eosin, and examined microscopically."

Actual Procedure. Some tissues, required by the protocol, were not available for histopathologic examination. Missing tissues or insufficient tissue samples are listed with appropriate comments in the pathology data sheets for individual animals. Summary tables do not include them as having been examined.

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