

AR226-1102

Final Summary Report

Study Title	Extended Recovery Study Following a 26-Week Capsule Toxicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295) in Cynomolgus Monkeys
Author	Peter J. Thomford, PhD
Sponsor	3M St. Paul, Minnesota
Test Facility	Covance Laboratories Inc. 3301 Kinsman Boulevard Madison, Wisconsin 53704-2595
Laboratory Study Identification	Covance 6329-268
Sponsor Study Identification	3M T-6295.22
Report Issued	04 December 2001
Page Number	1 of 23

RECEIVED
OPPT/NCIC
2002 JUL 29 AM 9:25

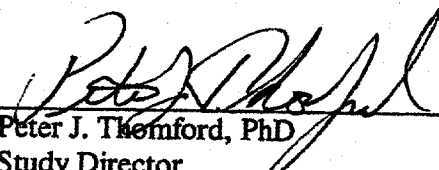
CONTAIN NO CBI

000032

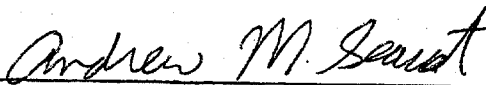
COMPLIANCE STATEMENT

Extended Recovery Study Following a 26-Week Capsule Toxicity Study
with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295)
in Cynomolgus Monkeys

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


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

04 Dec. 2001
Date


Andrew M. Seacat, PhD
3M
Toxicology Services

12/10/2001
Date

000033

QUALITY ASSURANCE STATEMENT

This report 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		Phase	Date Reported to Study Director and Study Director Management
From	To		
02 Mar 00	02 Mar 00	Protocol Review	02 Mar 00
03 Apr 00	03 Apr 00	Protocol Amendment Review	03 Apr 00
04 May 00	04 May 00	Analytical Laboratory Inspection	04 May 00
05 Jul 00	05 Jul 00	Body Weight	05 Jul 00
03 Jul 00	03 Jul 00	Data Review	06 Jul 00
20 Sep 00	20 Sep 00	Animal Observation	20 Sep 00
26 Sep 00	26 Sep 00	Data Review	28 Sep 00
27 Dec 00	28 Dec 00	Data Review	28 Dec 00
27 Feb 01	27 Feb 01	Protocol Amendment Review	27 Feb 01
09 Mar 01	09 Mar 01	Postlife	09 Mar 01
30 Mar 01	03 Apr 01	Data Review	03 Apr 01
24 Apr 01	24 Apr 01	Report Review	24 Apr 01
11 Jun 01	11 Jun 01	Protocol Amendment Review	11 Jun 01
15 Nov 01	16 Nov 01	Report Review	19 Nov 01

Alice Kubow
Representative
Quality Assurance Unit

04 December 01
Date

000034

KEY PERSONNEL

Extended Recovery Study Following a 26-Week Capsule Toxicity Study
with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295)
in Cynomolgus Monkeys

Study Monitor:	Andrew M. Seacat, PhD 3M
Study Director:	Peter J. Thomford, PhD
Study Toxicologist:	Dale Aldridge, BS
Study Coordinator:	Elizabeth A. Disch, BA
Supervisor, Large-Animal Toxicology:	Cynthia A. Weber, AS, LATG
Associate Director, Laboratory Animal Medicine:	Donna J. Clemons, DVM, MS Diplomate, ACLAM
Anatomic Pathologist:	Robert A. Leedle, DVM, PhD Diplomate, ACVP
Supervisor, Anatomic Pathology:	Laurie J. Schuller, BA, LAT
Principal Investigator:	Kris J. Hansen, PhD

000035

PURPOSE

The purpose of this study was to continue assessment of the toxicokinetics and distribution of the test material during an extended (approximately 1 year) recovery following daily administration by capsule to cynomolgus monkeys for at least 26 weeks and at least 52 weeks of recovery. The subject study was conducted at Covance Laboratories Inc., in Madison, Wisconsin, from 08 March 2000 through 09 March 2001. This document summarizes the major findings for the study. All aspects of this study were done in accordance with the Environmental Protection Agency Good Laboratory Practice Standards, 40 CFR 792.

PROCEDURES

The animals used for this study (male and female cynomolgus monkeys; two animals/sex) were previously assigned to the recovery phase of a completed study for this sponsor [3M T-6295.7, Covance 6329-223, "26-Week Capsule Toxicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295) in Cynomolgus Monkeys"]. During Covance 6329-223, the animals received 0.15 mg/kg/day of PFOS as a single daily capsule dose for at least 26 weeks followed by a 52-week recovery. At the end of the initial recovery, a partial hepatectomy was conducted on the animals, they were allowed to recover from the surgical procedure, then were transferred to the subject follow-up study (Covance 6329-268) for evaluation of extended recovery. Animals were not treated in the subject study.

Animals were obtained from Covance Research Products Inc. (Denver, Pennsylvania) on 30 June 1998. At study initiation, the animals were young adult to adult and weighed 2.8 to 4.1 kg. Each animal was identified with a collar tag. The animals were housed individually in stainless-steel cages (except when pair-housed for environmental enrichment), and certified primate diet [#8726C, Harlan Teklad (through 22 January 2001)] and Teklad Global Diet [#2055, Harlan Teklad (beginning 23 January 2001)] 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 and once daily for signs of poor health or abnormal behavior; findings were recorded as they were observed. In addition, animals were observed once weekly, and any findings or an indication that the animal was normal was recorded (see Protocol Deviations for exceptions). Individual body weight data were recorded monthly (see Protocol Deviations for exceptions). Blood samples for serum PFOS level determination were collected after 2, 4, 6, 8, 10, and 12 months following study initiation. Urine and fecal samples were collected for PFOS level determination after 4, 8, and 12 months following study initiation and within one day of the serum PFOS collections. During Week 53, animals that were fasted overnight were anesthetized with ketamine and xylazine, weighed, exsanguinated, and necropsied. At the scheduled sacrifice, macroscopic observations were recorded, and selected tissues were collected and preserved.

Please see Protocol Deviations on page 11 for a description of all deviations from the protocol.

Study Timetable:

Study Initiation Date:	28 February 2000
Inlife (Experimental) Start Date:	08 March 2000
Inlife Termination Date:	09 March 2001
Experimental Termination Date:	30 November 2001

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

The Sponsor is responsible for retention of all raw data, documentation, records, specimens, and final reports generated as a result of this study by the Sponsor.

RESULTS AND DISCUSSION

Observations of Animals

Clinical Observations

Clinical observations are presented in Table 1.

All animals survived to the end of the study and were sacrificed on Day 367. Clinical observations throughout the study were typical of cynomolgus monkeys in a recovery phase, with no evidence of test material effect.

Body Weights

Body weight data are summarized in Figure 1 and presented in Table 2.

Body weights for the animals remained normal throughout this extended recovery phase.

Individual Anatomic Pathology Data

Individual anatomic pathology data are presented in Table 3.

There were no macroscopic observations noted at necropsy.

Serum PFOS Level Determination

Reporting of the results is the responsibility of the sponsor.

000037

Urine and Feces PFOS Level Determination

Reporting of the results is the responsibility of the sponsor.

Liver Analysis

Reporting of the results is the responsibility of the sponsor.

Additional Tissue and Serum Analysis

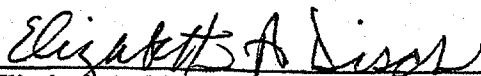
Reporting of the results is the responsibility of the sponsor.

CONCLUSIONS

After the completion of a previous study with 26 weeks of treatment and 52 weeks of recovery, two male and two female cynomolgus monkeys that underwent approximately 52 weeks of extended recovery had no clinical observations or macroscopic findings that indicated any residual test material effects.

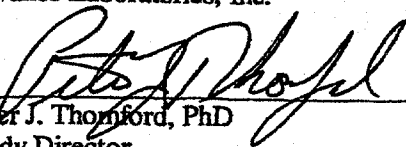
000038

SIGNATURES



Elizabeth A. Disch, BA
Study Coordinator
Covance Laboratories, Inc.

4 December 2001
Date



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

04 Dec 2001
Date

ANATOMIC PATHOLOGY REPORT

SUMMARY

Four cynomolgus monkeys, two males and two females, were used in an extended recovery study (52 weeks), following a 26-Week Capsule Toxicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295). On Day 367 of the extended recovery, the monkeys were fasted overnight, anesthetized with ketamine and xylazine, weighed, exsanguinated, and necropsied. All animals survived until the scheduled sacrifice. There were no macroscopic observations at necropsy. Samples of liver, lung, kidney, spleen, thyroid, brain, abdominal fat, heart, and bile and serum were collected, flash-frozen in liquid nitrogen, and shipped to the sponsor for analysis or storage.

METHODS

Four cynomolgus monkeys, two males and two females, were used in an extended recovery (52 weeks) study. The animals were previously assigned to the recovery phase of a completed study for this sponsor [3M T-6295.7, Covance 6329-223, "26-Week Capsule Toxicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295) in Cynomolgus Monkeys"]. During this study, the animals received 0.15 mg/kg/day of PFOS as a single daily capsule dose for at least 26 weeks followed by a 52-week recovery. At the end of the initial recovery, a partial hepatectomy was conducted on the animals, they were allowed to recover from the surgical procedure, and then they were transferred to the subject follow-up study (Covance 6329-268) for evaluation of extended recovery.

On Day 367 of the extended recovery, the monkeys were fasted overnight, anesthetized with ketamine and xylazine, weighed, exsanguinated, and necropsied. A sample liver (approximately 10 g) was flash-frozen in liquid nitrogen, stored in a freezer set to maintain -60 to -80°C, and shipped to the sponsor for analysis. Samples of lung, kidney, spleen, thyroid, brain, abdominal fat, heart, (approximately 3 g each, if possible), and bile and serum (each as much as possible) were collected and flash-frozen in liquid nitrogen and stored in a freezer, set to maintain -60 to -80°C, until shipped to the sponsor.

RESULTS AND DISCUSSION

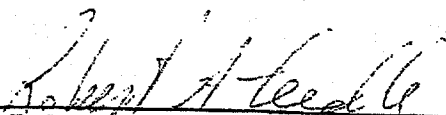
Mortality

All animals survived to the scheduled sacrifice at Day 367.

Macroscopic Observations

There were no macroscopic observations.

000040



Robert A. Leedle, DVM, PhD
Diplomate, ACVP

30 November 2001
Date

Protocol Deviations

Protocol

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

Actual Procedure

On Days 352 and 366 the light cycle was inadvertently interrupted.

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."

Actual Procedure

During Week 1, one male and each female had an observation of normal recorded more than once.

On Day 28 the weekly observations were made by exception, and an indication of normal was not recorded when appropriate.

During Week 29, the required observation of normal or abnormal was not recorded "weekly" for Animal No. I05552. The observation was recorded on Day 197, which immediately followed the previous week's scheduled normal observation day. The observation should have been recorded on Day 203.

Protocol

Observation of Animals. Body Weights. "Monthly"

Actual Procedure

The animals were weighed on Day 1 and again on Day 7, in order to accommodate the weighing schedule of the remainder of the stock colony.

Protocol

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

Actual Procedure

Samples collected on Day 114 were centrifuged several minutes after 1 hour had elapsed from the time of collection.

On Day 226, documentation was not made regarding the storage of serum samples prior to centrifugation and after harvest.

000042

Protocol

Urine and Feces PFOS Level Determination. Method of Collection. "Animals will not be fasted; urine (approximately 2 mL) and feces (approximately 5 grams) will be collected overnight."

Actual Procedure

The amount of urine collected on Day 113 cannot be verified.

The documentation for fecal collections on Day 113 indicates "at least" rather than "approximately" 5 grams were collected.

Protocol

Postmortem Procedures. Additional Tissue and Serum Samples. "Samples of lung, kidney, spleen, thyroid, brain, abdominal fat, heart, (approximately 3 g each, if possible), and bile and serum (each as much as possible) will be collected from animals at scheduled and unscheduled sacrifices."

Actual Procedure

Serum was not collected from three of the four monkeys at the necropsy.

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

000043

Figure 1

Covance 6329-268

Mean Body Weight Data (kg) - Males and Females

EXTENDED RECOVERY STUDY FOLLOWING A 26-WEEK CAPSULE TOXICITY
STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295)
IN CYNOMOLGUS MONKEYS

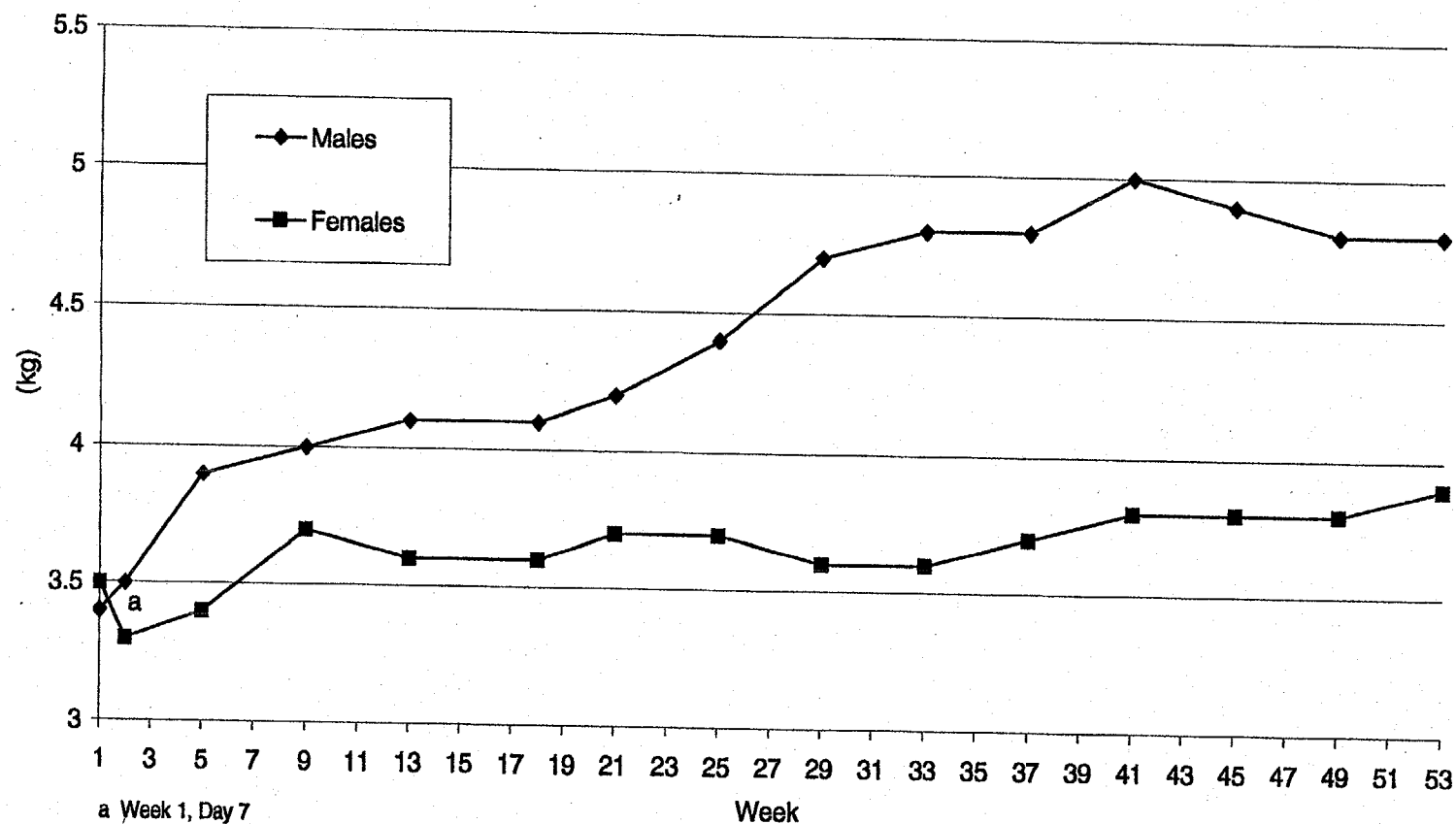


Table 1: Individual Clinical Observations

EXTENDED RECOVERY STUDY FOLLOWING A 26-WEEK CAPSULE TOXICITY
STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295)
IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M1	DAYS 1-367 - OBSERVED DURING THE DAYS LISTED BELOW; 'C' - COMMENTS LISTED AT END OF OBSERVATIONS
I05505	T	53	DISCHARGE VOMITUS CONTAINING FOOD		64, 116, 162
			SKIN & PELAGE ALOPECIA LIMB-FRONT-LEFT		154, 161
			NORMAL NO REMARKABLE OBSERVATIONS		1, 7, 14, 21, 35, 42, 49, 56, 63, 70, 77, 84, 91, 98, 105, 112, 120, 126, 133, 140, 147, 168, 175, 182, 189, 196, 203, 210, 217, 224, 231, 238, 245, 252, 259, 266, 273, 280, 287, 294, 301, 308, 315, 322, 329, 336, 343, 350, 357, 364, 367
			QUALITATIVE FOOD CONSUMPTION LOW NONE		227 312
I05523	T	53	APPEARANCE SWOLLEN HEAD-MAXILLARY-RIGHT NOSE		36-37 9
			DISCHARGE VOMITUS CONTAINING FOOD		64, 162
			EXCRETION FEW FECES NON-FORMED FECES		8 1, 4

Table 1
Individual Clinical Observations

EXTENDED RECOVERY STUDY FOLLOWING A 26-WEEK CAPSULE TOXICITY
STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295)
IN CYNOMOLGUS MONKEYS

PAGE: 2

ANIMAL	DEATH	WK OF	CATEGORY	GROUP: M1	DAYS 1-367 - OBSERVED DURING THE DAYS LISTED BELOW;
NUMBER	CODE	DEATH	KEYWORD		'C' - COMMENTS LISTED AT END OF OBSERVATIONS
			QUALIFIER		

(CONTINUED FROM PREVIOUS PAGE)					
I05523	T	53	SKIN & PELAGE		
			ALOPECIA		
			LIMB-FRONT-LEFT		154, 161
			SCAB(S)		
			HEAD-MAXILLARY-RIGHT		37
			NOSE		14
			NORMAL		
			NO REMARKABLE OBSERVATIONS		7, 21, 35, 42, 49, 56, 63, 70, 77, 84, 91, 98, 105, 112, 120 126, 133, 140, 147, 168, 175, 182, 189, 196, 203, 210, 217, 224 231, 238, 245, 252, 259, 266, 273, 280, 287, 294, 301, 308, 315 322, 329, 336, 343, 350, 357, 364, 367
			QUALITATIVE FOOD CONSUMPTION		
			LOW		9, 227, 254, 317
			NONE		8

000046

Table 1

Individual Clinical Observations

EXTENDED RECOVERY STUDY FOLLOWING A 26-WEEK CAPSULE TOXICITY
STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295)
IN CYNOMOLGUS MONKEYS

PAGE: 3

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F1	DAYS 1-367 - OBSERVED DURING THE DAYS LISTED BELOW; 'C' - COMMENTS LISTED AT END OF OBSERVATIONS
I05539	T	53	DISCHARGE VOMITUS CONTAINING FOOD APPEARS TO BE MENSTRUATING NORMAL NO REMARKABLE OBSERVATIONS QUALITATIVE FOOD CONSUMPTION LOW		64 164, 247, 276, 362 1, 5, 7, 14, 21, 35, 42, 49, 56, 63, 70, 77, 84, 91, 98, 105 112, 120, 126, 133, 140, 147, 154, 161, 168, 175, 182, 189, 196 203, 210, 217, 224, 231, 238, 245, 252, 266, 273, 280, 287, 294 301, 308, 315, 322, 329, 336, 343, 350, 357, 364, 367
I05552	T	53	DISCHARGE APPEARS TO BE MENSTRUATING EXCRETION LIQUID FECES NON-FORMED FECES SKIN & PELAGE ALOPECIA LIMBS-ALL LIMBS-FRONT SACRAL NORMAL NO REMARKABLE OBSERVATIONS		1, 5, 116-117, 227, 259, 317, 353 365 31, 37, 213-214, 223 35, 209 227, 230-231, 233, 238, 245, 252, 329 266, 273, 280, 287, 294, 301, 308, 312, 315, 317, 322 11, 14, 21, 31, 35, 37 1, 5, 7, 42, 49, 56, 63, 70, 77, 84, 91, 98, 105, 112, 120, 126 133, 140, 147, 154, 161, 168, 175, 182, 189, 196-197, 210, 217 224, 259, 336, 343, 350, 357, 364, 367

Covance 6329-268

Table 1

Individual Clinical Observations

EXTENDED RECOVERY STUDY FOLLOWING A 26-WEEK CAPSULE TOXICITY
STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295)
IN CYNOMOLGUS MONKEYS

PAGE: 4

ANIMAL DEATH WK OF	CATEGORY	GROUP: F1
NUMBER CODE DEATH	KEYWORD	
	QUALIFIER	
(CONTINUED FROM PREVIOUS PAGE)		
I05552 T 53	QUALITATIVE FOOD CONSUMPTION	
	LOW	

DAYS 1-367 - OBSERVED DURING THE DAYS LISTED BELOW;
'C' - COMMENTS LISTED AT END OF OBSERVATIONS

5, 163-164, 203, 214, 227, 312, 317, 322, 353

Table 2: Individual Body Weight Data (kg)

EXTENDED RECOVERY STUDY FOLLOWING A 26-WEEK CAPSULE TOXICITY
STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295)
IN CYNOMOLGUS MONKEYS

PAGE 1

ANIMAL NUMBER	WEEK 1 ^a	WEEK 1 ^b	WEEK 5	WEEK 9	WEEK 13	WEEK 18	WEEK 21	WEEK 25	WEEK 29	WEEK 33
GROUP: MALE 1										
I05505	3.5	3.8	3.8	4.0	4.1	3.9	3.9	4.3	4.7	4.8
I05523	3.3	3.2	3.9	4.0	4.0	4.2	4.5	4.5	4.7	4.8
GROUP: FEMALE 1										
I05539	4.1	4.0	4.1	4.3	4.2	4.2	4.3	4.3	4.3	4.4
I05552	2.8	2.7	2.7	3.0	3.0	3.0	3.1	3.0	2.8	2.8

a Week 1, Day 1
b Week 1, Day 7

000049

Covance 6329-268
3M T-6295.22

Covance 6329-268
3M T-6295.22

Table 2

Individual Body Weight Data (kg)

EXTENDED RECOVERY STUDY FOLLOWING A 26-WEEK CAPSULE TOXICITY
STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295)
IN CYNOMOLGUS MONKEYS

PAGE: 2

ANIMAL NUMBER	WEEK 37	WEEK 41	WEEK 45	WEEK 49	WEEK 53
GROUP: MALE 1					
I05505	4.9	5.1	4.9	4.9	4.9
I05523	4.7	4.9	4.8	4.6	4.7
GROUP: FEMALE 1					
I05539	4.5	4.5	4.5	4.6	4.7
I05552	2.9	3.0	3.0	3.0	3.1

Table 3: Individual Anatomic Pathology Data

EXTENDED RECOVERY STUDY FOLLOWING A 26-WEEK CAPSULE TOXICITY
STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS; T-6295)
IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05505 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 03/09/01 STUDY DAY OF DEATH: 357 STUDY WEEK OF DEATH: 53 TERMINAL BODY WEIGHT: 7.66 kg
DATE AND TIME OF NECROPSY: 03/09/01 7:37 PROSECTOR: JOHN S. HALFORD RECORDER: TROY CHRISTOPHERSON
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: AS ASSIGNED WEIGHER: TROY CHRISTOPHERSON

*** LAST IN LIFE OBSERVATIONS ***
CATEGORY KEYWORD QUALIFIER / FREE-TEXT COMMENT

NORMAL NO REMARKABLE OBSERVATIONS

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

GENERAL COMMENT (GC) -NO MACROSCOPIC LESIONS

Table 3

Individual Anatomic Pathology Data

PAGE: 2

EXTENDED RECOVERY STUDY FOLLOWING A 26-WEEK CAPSULE TOXICITY
STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295)
IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05523 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 03/09/01 STUDY DAY OF DEATH: 367 STUDY WEEK OF DEATH: 53 TERMINAL BODY WEIGHT: 4525.0 GRAMS
DATE AND TIME OF NECROPSY: 03/09/01 8:07 PROSECTOR: JOHN S. HALFORD RECORDER: TROY CHRISTOFFERSON
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: AS ASSIGNED WEIGHER: TROY CHRISTOFFERSON

*** LAST IN LIFE OBSERVATIONS ***	
CATEGORY	KEYWORD
NORMAL	NO REMARKABLE OBSERVATIONS
*** GROSS PATHOLOGY OBSERVATIONS ***	
ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE
GENERAL COMMENT (GC)	FREE-TEXT COMMENTS AND NOTES
	-NO MACROSCOPIC LESIONS

000052

Table 3

Individual Anatomic Pathology Data

PAGE: 3

EXTENDED RECOVERY STUDY FOLLOWING A 26-WEEK CAPSULE TOXICITY
STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295)
IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05539 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 03/09/01 STUDY DAY OF DEATH: 367 STUDY WEEK OF DEATH: 53 TERMINAL BODY WEIGHT: 4530.0 GRAMS
DATE AND TIME OF NECROPSY: 03/09/01 8:30 PROSECTOR: JOHN S. HALFORD RECORDER: TROY CHRISTOFFERSON
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: AS ASSIGNED WEIGHER: TROY CHRISTOFFERSON

*** LAST IN LIFE OBSERVATIONS ***	
CATEGORY	KEYWORD
NORMAL	NO REMARKABLE OBSERVATIONS
*** GROSS PATHOLOGY OBSERVATIONS ***	
ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE
GENERAL COMMENT (GC)	-NO MACROSCOPIC LESIONS

000053

Table 3

Individual Anatomic Pathology Data

PAGE: 4

EXTENDED RECOVERY STUDY FOLLOWING A 26-WEEK CAPSULE TOXICITY
STUDY WITH PERFLUOROOCTANE SULFONIC ACID POTASSIUM SALT (PFOS;T-6295)
IN CYNOMOLGUS MONKEYS

ANIMAL NUMBER: I05552 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 03/09/01 STUDY DAY OF DEATH: 367 STUDY WEEK OF DEATH: 53 TERMINAL BODY WEIGHT: 2985.0 GRAMS
DATE AND TIME OF NECROPSY: 03/09/01 8:48 PROSECTOR: JOHN S. HALFORD RECORDER: TROY CHRISTOFFERSON
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: AS ASSIGNED WEIGHER: TROY CHRISTOFFERSON

*** LAST IN LIFE OBSERVATIONS ***
CATEGORY KEYWORD QUALIFIER / FREE-TEXT COMMENT

NORMAL NO REMARKABLE OBSERVATIONS

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

GENERAL COMMENT (GC)
-NO MACROSCOPIC LESIONS