

Experiment Number: 20614 - 02
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Perfluorooctanoic Acid
CAS Number: 335-67-1

Date Report Requested: 06/07/2018
Time Report Requested: 17:36:32
First Dose M/F: 07/27/09 / NA
Lab: BAT

Custom Rpt (Litter-Based) -- 0-80, 300-80

NTP Study Number:	C20614B		
Lock Date:	01/10/2012		
Cage Range:	ALL		
Date Range:	ALL		
Reasons For Removal:	25021 TSAC	25020 NATD	25019 MSAC
Removal Date Range:	ALL		
Treatment Groups:	Include 007 0/80 ppm	Include 008 300/80 ppm	
Study Gender:	Male		
TDMSE Version:	2.5.0.0_sfh		
PWG Approval Date:	NONE		

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**FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES EXAMINED.
IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.**

Adrenal Cortex

Islets, Pancreatic

Liver

Pancreas

Pituitary Gland

Prostate

Thyroid Gland

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
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**Adrenal Cortex
Adenoma**

TUMOR RATES

OVERALL (a)	3/50 (6%)	1/50 (2%)
LITTERS (b)	3/25 (12%)	1/26 (4%)
POLY-3 RATE (c)	3/41.66	1/44.73
POLY-3 PERCENT (g)	7.2%	2.2%
TERMINAL (d)	3/37 (8%)	1/39 (3%)
FIRST INCIDENCE	743 (T)	743 (T)

STATISTICAL TESTS

POLY 3	P=0.280N
POLY 1.5	P=0.285N
POLY 6	P=0.280N
RAO-SCOTT	P=0.311N
LITTER C-A/FISHERS	P=0.290N

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TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
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**Islets, Pancreatic
Adenoma**

TUMOR RATES

OVERALL (a)	4/50 (8%)	5/50 (10%)
LITTERS (b)	4/25 (16%)	4/26 (15%)
POLY-3 RATE (c)	4/41.66	5/44.73
POLY-3 PERCENT (g)	9.6%	11.2%
TERMINAL (d)	4/37 (11%)	5/39 (13%)
FIRST INCIDENCE	743 (T)	743 (T)

STATISTICAL TESTS

POLY 3	P=0.545
POLY 1.5	P=0.536
POLY 6	P=0.545
RAO-SCOTT	P=0.549
LITTER C-A/FISHERS	P=0.626N

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
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Liver
Hepatocellular Adenoma

TUMOR RATES

OVERALL (a)	11/50 (22%)	10/50 (20%)
LITTERS (b)	8/25 (32%)	9/26 (35%)
POLY-3 RATE (c)	11/41.66	10/44.73
POLY-3 PERCENT (g)	26.4%	22.4%
TERMINAL (d)	11/37 (30%)	10/39 (26%)
FIRST INCIDENCE	743 (T)	743 (T)

STATISTICAL TESTS

POLY 3	P=0.426N
POLY 1.5	P=0.440N
POLY 6	P=0.425N
RAO-SCOTT	P=0.448N
LITTER C-A/FISHERS	P=0.540

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First Dose M/F: 07/27/09 / NA

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
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Liver
Hepatocellular Carcinoma

TUMOR RATES

OVERALL (a)	0/50 (0%)	4/50 (8%)
LITTERS (b)	0/25 (0%)	3/26 (12%)
POLY-3 RATE (c)	0/41.66	4/44.73
POLY-3 PERCENT (g)	0%	8.9%
TERMINAL (d)	0/37 (0%)	4/39 (10%)
FIRST INCIDENCE	---	743 (T)

STATISTICAL TESTS

POLY 3	P=0.070
POLY 1.5	P=0.068
POLY 6	P=0.070
RAO-SCOTT	P=0.201
LITTER C-A/FISHERS	P=0.125

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Test Type: CHRONIC

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Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

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First Dose M/F: 07/27/09 / NA

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
------	----------	------------

Liver

Hepatocellular Carcinoma or Hepatocellular Adenoma

TUMOR RATES

OVERALL (a)	11/50 (22%)	12/50 (24%)
LITTERS (b)	8/25 (32%)	10/26 (38%)
POLY-3 RATE (c)	11/41.66	12/44.73
POLY-3 PERCENT (g)	26.4%	26.8%
TERMINAL (d)	11/37 (30%)	12/39 (31%)
FIRST INCIDENCE	743 (T)	743 (T)

STATISTICAL TESTS

POLY 3	P=0.579
POLY 1.5	P=0.563
POLY 6	P=0.580
RAO-SCOTT	P=0.582
LITTER C-A/FISHERS	P=0.425

Experiment Number: 20614 - 02

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

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First Dose M/F: 07/27/09 / NA

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
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Liver
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

TUMOR RATES

OVERALL (a)	11/50 (22%)	12/50 (24%)
LITTERS (b)	8/25 (32%)	10/26 (38%)
POLY-3 RATE (c)	11/41.66	12/44.73
POLY-3 PERCENT (g)	26.4%	26.8%
TERMINAL (d)	11/37 (30%)	12/39 (31%)
FIRST INCIDENCE	743 (T)	743 (T)

STATISTICAL TESTS

POLY 3	P=0.579
POLY 1.5	P=0.563
POLY 6	P=0.580
RAO-SCOTT	P=0.582
LITTER C-A/FISHERS	P=0.425

Experiment Number: 20614 - 02

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

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First Dose M/F: 07/27/09 / NA

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
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Pancreas
Adenoma

TUMOR RATES

OVERALL (a)	32/50 (64%)	30/50 (60%)
LITTERS (b)	22/25 (88%)	21/26 (81%)
POLY-3 RATE (c)	32/41.81	30/44.75
POLY-3 PERCENT (g)	76.5%	67%
TERMINAL (d)	30/37 (81%)	29/39 (74%)
FIRST INCIDENCE	720	739

STATISTICAL TESTS

POLY 3	P=0.220N
POLY 1.5	P=0.259N
POLY 6	P=0.217N
RAO-SCOTT	P=0.223N
LITTER C-A/FISHERS	P=0.374N

Experiment Number: 20614 - 02

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

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First Dose M/F: 07/27/09 / NA

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
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Pancreas
Carcinoma

TUMOR RATES

OVERALL (a)	3/50 (6%)	3/50 (6%)
LITTERS (b)	3/25 (12%)	3/26 (12%)
POLY-3 RATE (c)	3/41.72	3/44.73
POLY-3 PERCENT (g)	7.2%	6.7%
TERMINAL (d)	2/37 (5%)	3/39 (8%)
FIRST INCIDENCE	726	743 (T)

STATISTICAL TESTS

POLY 3	P=0.630N
POLY 1.5	P=0.636N
POLY 6	P=0.631N
RAO-SCOTT	P=0.609N
LITTER C-A/FISHERS	P=0.647N

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Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

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First Dose M/F: 07/27/09 / NA

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
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Pancreas
Carcinoma or Adenoma

TUMOR RATES

OVERALL (a)	32/50 (64%)	30/50 (60%)
LITTERS (b)	22/25 (88%)	21/26 (81%)
POLY-3 RATE (c)	32/41.81	30/44.75
POLY-3 PERCENT (g)	76.5%	67%
TERMINAL (d)	30/37 (81%)	29/39 (74%)
FIRST INCIDENCE	720	739

STATISTICAL TESTS

POLY 3	P=0.220N
POLY 1.5	P=0.259N
POLY 6	P=0.217N
RAO-SCOTT	P=0.223N
LITTER C-A/FISHERS	P=0.374N

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Route: DOSED FEED

Species/Strain: RATS/HSD

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
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Pituitary Gland: Pars Distalis or Unspecified Site
Adenoma

TUMOR RATES

OVERALL (a)	2/50 (4%)	5/50 (10%)
LITTERS (b)	2/25 (8%)	4/26 (15%)
POLY-3 RATE (c)	2/42.11	5/44.75
POLY-3 PERCENT (g)	4.8%	11.2%
TERMINAL (d)	1/37 (3%)	4/39 (10%)
FIRST INCIDENCE	609	739

STATISTICAL TESTS

POLY 3	P=0.241
POLY 1.5	P=0.238
POLY 6	P=0.239
RAO-SCOTT	P=0.303
LITTER C-A/FISHERS	P=0.353

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Route: DOSED FEED

Species/Strain: RATS/HSD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

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First Dose M/F: 07/27/09 / NA

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
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Prostate
Adenoma

TUMOR RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)
LITTERS (b)	2/25 (8%)	0/26 (0%)
POLY-3 RATE (c)	2/41.66	0/44.73
POLY-3 PERCENT (g)	4.8%	0%
TERMINAL (d)	2/37 (5%)	0/39 (0%)
FIRST INCIDENCE	743 (T)	---

STATISTICAL TESTS

POLY 3	P=0.222N
POLY 1.5	P=0.225N
POLY 6	P=0.221N
RAO-SCOTT	P=0.331N
LITTER C-A/FISHERS	P=0.235N

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Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/HSD

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First Dose M/F: 07/27/09 / NA
Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE **0/80 ppm** **300/80 ppm**

Skin
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma

TUMOR RATES	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)
LITTERS (b)	2/25 (8%)	1/26 (4%)
POLY-3 RATE (c)	2/41.75	1/44.94
POLY-3 PERCENT (g)	4.8%	2.2%
TERMINAL (d)	1/37 (3%)	0/39 (0%)
FIRST INCIDENCE	720	689

STATISTICAL TESTS

POLY 3	P=0.474N
POLY 1.5	P=0.479N
POLY 6	P=0.473N
RAO-SCOTT	P=0.484N
LITTER C-A/FISHERS	P=0.485N

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Species/Strain: RATS/HSD

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
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Thyroid Gland: C-Cell
Adenoma

TUMOR RATES

OVERALL (a)	12/49 (24%)	12/50 (24%)
LITTERS (b)	11/25 (44%)	11/26 (42%)
POLY-3 RATE (c)	12/41.94	12/45.80
POLY-3 PERCENT (g)	28.6%	26.2%
TERMINAL (d)	10/37 (27%)	9/39 (23%)
FIRST INCIDENCE	609	550

STATISTICAL TESTS

POLY 3	P=0.495N
POLY 1.5	P=0.509N
POLY 6	P=0.492N
RAO-SCOTT	P=0.484N
LITTER C-A/FISHERS	P=0.564N

Experiment Number: 20614 - 02

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
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Thyroid Gland: C-Cell
Carcinoma

TUMOR RATES

OVERALL (a)	1/49 (2%)	2/50 (4%)
LITTERS (b)	1/25 (4%)	2/26 (8%)
POLY-3 RATE (c)	1/41.43	2/44.73
POLY-3 PERCENT (g)	2.4%	4.5%
TERMINAL (d)	1/37 (3%)	2/39 (5%)
FIRST INCIDENCE	743 (T)	743 (T)

STATISTICAL TESTS

POLY 3	P=0.527
POLY 1.5	P=0.524
POLY 6	P=0.526
RAO-SCOTT	P=0.520
LITTER C-A/FISHERS	P=0.515

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
------	----------	------------

Thyroid Gland: C-Cell
Carcinoma or Adenoma

TUMOR RATES

OVERALL (a)	13/49 (27%)	14/50 (28%)
LITTERS (b)	12/25 (48%)	12/26 (46%)
POLY-3 RATE (c)	13/41.94	14/45.80
POLY-3 PERCENT (g)	31%	30.6%
TERMINAL (d)	11/37 (30%)	11/39 (28%)
FIRST INCIDENCE	609	550

STATISTICAL TESTS

POLY 3	P=0.574N
POLY 1.5	P=0.589N
POLY 6	P=0.571N
RAO-SCOTT	P=0.565N
LITTER C-A/FISHERS	P=0.559N

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males

DOSE	0/80 ppm	300/80 ppm
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All Organs
Benign Tumors

TUMOR RATES	#	#
OVERALL (a)	38/50 (76%)	39/50 (78%)
LITTERS (b)	24/25 (96%)	23/26 (88%)
POLY-3 RATE (c)	38/42.26	39/45.81
POLY-3 PERCENT (g)	89.9%	85.1%
TERMINAL (d)	35/37 (95%)	35/39 (90%)
FIRST INCIDENCE	609	550

STATISTICAL TESTS

POLY 3	P=0.349N
POLY 1.5	P=0.445N
POLY 6	P=0.309N
RAO-SCOTT	P=0.347N
LITTER C-A/FISHERS	P=0.320N

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males		
DOSE	0/80 ppm	300/80 ppm
All Organs		
Malignant Tumors		
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TUMOR RATES	#	#
OVERALL (a)	8/50 (16%)	15/50 (30%)
LITTERS (b)	7/25 (28%)	14/26 (54%)
POLY-3 RATE (c)	8/44.09	15/46.74
POLY-3 PERCENT (g)	18.1%	32.1%
TERMINAL (d)	3/37 (8%)	10/39 (26%)
FIRST INCIDENCE	432	527
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STATISTICAL TESTS		
POLY 3		P=0.098
POLY 1.5		P=0.093
POLY 6		P=0.101
RAO-SCOTT		P=0.095
LITTER C-A/FISHERS		P=0.055

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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(HSD)
TERMINAL SACRIFICE AT 107 WEEKS**

Males		
DOSE	0/80 ppm	300/80 ppm
All Organs		
Malignant and Benign Tumors		
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TUMOR RATES	#	#
OVERALL (a)	41/50 (82%)	44/50 (88%)
LITTERS (b)	25/25 (100%)	25/26 (96%)
POLY-3 RATE (c)	41/44.54	44/46.96
POLY-3 PERCENT (g)	92.1%	93.7%
TERMINAL (d)	35/37 (95%)	37/39 (95%)
FIRST INCIDENCE	432	527
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STATISTICAL TESTS		
POLY 3		P=0.543
POLY 1.5		P=0.476
POLY 6		P=0.579
RAO-SCOTT		P=0.526
LITTER C-A/FISHERS		P=0.510N

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First Dose M/F: 07/27/09 / NA

Lab: BAT

LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
- (b) Number of litters with tumor-bearing animals/number of litters examined at site
- (c) Number of tumor-bearing animals/Poly-3 number
- (d) Observed incidence at terminal kill.
- (e) Value of statistic cannot be computed.
- (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
- (g) Poly-3 adjusted lifetime tumor incidence.
- (I) Interim sacrifice
- (T) Terminal sacrifice
- # Tumor rates based on numbers of animals necropsied.
- * To the right of any statistical result, indicates significance at ($P \leq 0.05$).
- ** To the right of any statistical result, indicates significance at ($P \leq 0.01$).
- N Indicates a negative trend for all tests
The Rao-Scott statistic performs the Poly-3 test with an adjustment for within-litter correlation.
The Litter C-A/Fishers statistic compares directly the litter incidence rates.

*** END OF REPORT ***