

**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:** 17:27:56  
**First Dose M/F:** 07/27/09 / NA  
**Lab:** BAT

Custom Rpt (Litter-Based) -- 0-40, 300-40

<b>NTP Study Number:</b>	C20614B		
<b>Lock Date:</b>	01/10/2012		
<b>Cage Range:</b>	ALL		
<b>Date Range:</b>	ALL		
<b>Reasons For Removal:</b>	25021 TSAC	25020 NATD	25019 MSAC
<b>Removal Date Range:</b>	ALL		
<b>Treatment Groups:</b>	Include 005 0/40 ppm	Include 006 300/40 ppm	
<b>Study Gender:</b>	Male		
<b>TDMSE Version:</b>	2.5.0.0_sfh		
<b>PWG Approval Date:</b>	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 Medulla

Islets, Pancreatic

Liver

Pancreas

Pituitary Gland

Testes

Thyroid Gland

**Experiment Number:** 20614 - 02

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**Lab:** BAT

**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF PERFLUOROOCCTANOIC ACID**

**MALE RATS**

**Organ**

Pituitary Gland: Pars Distalis or Unspecified Site

Thyroid Gland: C-Cell

All Organs

**Morphology**

Adenoma

Adenoma

Carcinoma or Adenoma

Benign Tumors

Malignant and Benign Tumors

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

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**Males**

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DOSE	0/40 ppm	300/40 ppm
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Adrenal Medulla  
Pheochromocytoma Benign

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**TUMOR RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)
LITTERS (b)	1/25 (4%)	2/25 (8%)
POLY-3 RATE (c)	1/42.02	3/46.07
POLY-3 PERCENT (g)	2.4%	6.5%
TERMINAL (d)	1/35 (3%)	2/38 (5%)
FIRST INCIDENCE	743 (T)	624

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**STATISTICAL TESTS**

POLY 3	P=0.339
POLY 1.5	P=0.329
POLY 6	P=0.346
RAO-SCOTT	P=0.449
LITTER C-A/FISHERS	P=0.500

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Experiment Number: 20614 - 02

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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	0/40 ppm	300/40 ppm
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Islets, Pancreatic  
Adenoma

---

**TUMOR RATES**

OVERALL (a)	8/50 (16%)	8/50 (16%)
LITTERS (b)	7/25 (28%)	7/25 (28%)
POLY-3 RATE (c)	8/42.02	8/45.68
POLY-3 PERCENT (g)	19%	17.5%
TERMINAL (d)	8/35 (23%)	7/38 (18%)
FIRST INCIDENCE	743 (T)	739

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**STATISTICAL TESTS**

POLY 3	P=0.536N
POLY 1.5	P=0.557N
POLY 6	P=0.524N
RAO-SCOTT	P=0.535N
LITTER C-A/FISHERS	P=0.623

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Lab: BAT

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

---

**Males**

---

DOSE	0/40 ppm	300/40 ppm
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Liver  
Hepatocellular Adenoma

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**TUMOR RATES**

OVERALL (a)	7/50 (14%)	5/50 (10%)
LITTERS (b)	6/25 (24%)	5/25 (20%)
POLY-3 RATE (c)	7/42.02	5/45.66
POLY-3 PERCENT (g)	16.7%	11%
TERMINAL (d)	7/35 (20%)	5/38 (13%)
FIRST INCIDENCE	743 (T)	743 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.322N
POLY 1.5	P=0.338N
POLY 6	P=0.311N
RAO-SCOTT	P=0.344N
LITTER C-A/FISHERS	P=0.500N

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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**

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DOSE	0/40 ppm	300/40 ppm
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**Mammary Gland  
Fibroadenoma**

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**TUMOR RATES**

	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)
LITTERS (b)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	2/42.65	1/45.66
POLY-3 PERCENT (g)	4.7%	2.2%
TERMINAL (d)	1/35 (3%)	1/38 (3%)
FIRST INCIDENCE	533	743 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.476N
POLY 1.5	P=0.482N
POLY 6	P=0.473N
RAO-SCOTT	P=0.486N
LITTER C-A/FISHERS	P=0.500N

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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**

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DOSE	0/40 ppm	300/40 ppm
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Pancreas  
Adenoma

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**TUMOR RATES**

OVERALL (a)	26/50 (52%)	30/50 (60%)
LITTERS (b)	20/25 (80%)	21/25 (84%)
POLY-3 RATE (c)	26/42.21	30/45.93
POLY-3 PERCENT (g)	61.6%	65.3%
TERMINAL (d)	24/35 (69%)	28/38 (74%)
FIRST INCIDENCE	700	701

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**STATISTICAL TESTS**

POLY 3	P=0.443
POLY 1.5	P=0.387
POLY 6	P=0.481
RAO-SCOTT	P=0.434
LITTER C-A/FISHERS	P=0.500

---



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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: 17:27:56

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	0/40 ppm	300/40 ppm
------	----------	------------

---

Pancreas  
Carcinoma or Adenoma

---

**TUMOR RATES**

OVERALL (a)	26/50 (52%)	30/50 (60%)
LITTERS (b)	20/25 (80%)	21/25 (84%)
POLY-3 RATE (c)	26/42.21	30/45.93
POLY-3 PERCENT (g)	61.6%	65.3%
TERMINAL (d)	24/35 (69%)	28/38 (74%)
FIRST INCIDENCE	700	701

---

**STATISTICAL TESTS**

POLY 3	P=0.443
POLY 1.5	P=0.387
POLY 6	P=0.481
RAO-SCOTT	P=0.434
LITTER C-A/FISHERS	P=0.500

---

Experiment Number: 20614 - 02

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

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Time Report Requested: 17:27:56

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

Lab: BAT

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

---

**Males**

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DOSE	0/40 ppm	300/40 ppm
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Pituitary Gland: Pars Distalis or Unspecified Site  
Adenoma

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**TUMOR RATES**

OVERALL (a)	2/50 (4%)	9/50 (18%)
LITTERS (b)	2/25 (8%)	9/25 (36%)
POLY-3 RATE (c)	2/42.41	9/46.89
POLY-3 PERCENT (g)	4.7%	19.2%
TERMINAL (d)	0/35 (0%)	4/38 (11%)
FIRST INCIDENCE	683	561

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**STATISTICAL TESTS**

POLY 3	P=0.038*
POLY 1.5	P=0.034*
POLY 6	P=0.041*
RAO-SCOTT	P=0.043*
LITTER C-A/FISHERS	P=0.019*

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Species/Strain: RATS/HSD

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Time Report Requested: 17:27:56

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

Lab: BAT

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

**Males**

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DOSE	0/40 ppm	300/40 ppm
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Skin  
Fibroma

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TUMOR RATES	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)
LITTERS (b)	1/25 (4%)	2/25 (8%)
POLY-3 RATE (c)	1/42.02	2/46.07
POLY-3 PERCENT (g)	2.4%	4.3%
TERMINAL (d)	1/35 (3%)	1/38 (3%)
FIRST INCIDENCE	743 (T)	624

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**STATISTICAL TESTS**

POLY 3	P=0.532
POLY 1.5	P=0.523
POLY 6	P=0.539
RAO-SCOTT	P=0.533
LITTER C-A/FISHERS	P=0.500

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Lab: BAT

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

---

**Males**

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DOSE	0/40 ppm	300/40 ppm
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Testes  
Adenoma

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**TUMOR RATES**

OVERALL (a)	3/50 (6%)	1/49 (2%)
LITTERS (b)	3/25 (12%)	1/25 (4%)
POLY-3 RATE (c)	3/42.09	1/44.80
POLY-3 PERCENT (g)	7.1%	2.2%
TERMINAL (d)	2/35 (6%)	1/38 (3%)
FIRST INCIDENCE	725	743 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.283N
POLY 1.5	P=0.291N
POLY 6	P=0.278N
RAO-SCOTT	P=0.320N
LITTER C-A/FISHERS	P=0.305N

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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**

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DOSE	0/40 ppm	300/40 ppm
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Thyroid Gland: C-Cell  
Adenoma

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**TUMOR RATES**

OVERALL (a)	4/50 (8%)	15/50 (30%)
LITTERS (b)	3/25 (12%)	13/25 (52%)
POLY-3 RATE (c)	4/42.02	15/46.22
POLY-3 PERCENT (g)	9.5%	32.5%
TERMINAL (d)	4/35 (11%)	13/38 (34%)
FIRST INCIDENCE	743 (T)	648

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**STATISTICAL TESTS**

POLY 3	P=0.008**
POLY 1.5	P=0.006**
POLY 6	P=0.009**
RAO-SCOTT	P=0.014*
LITTER C-A/FISHERS	P=0.003**

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Experiment Number: 20614 - 02

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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**

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DOSE	0/40 ppm	300/40 ppm
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Thyroid Gland: C-Cell  
Carcinoma

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**TUMOR RATES**

OVERALL (a)	2/50 (4%)	0/50 (0%)
LITTERS (b)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (c)	2/42.65	0/45.66
POLY-3 PERCENT (g)	4.7%	0%
TERMINAL (d)	1/35 (3%)	0/38 (0%)
FIRST INCIDENCE	533	---

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**STATISTICAL TESTS**

POLY 3	P=0.222N
POLY 1.5	P=0.226N
POLY 6	P=0.220N
RAO-SCOTT	P=0.329N
LITTER C-A/FISHERS	P=0.245N

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Lab: BAT

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

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**Males**

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DOSE	0/40 ppm	300/40 ppm
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Thyroid Gland: C-Cell  
Carcinoma or Adenoma

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**TUMOR RATES**

OVERALL (a)	6/50 (12%)	15/50 (30%)
LITTERS (b)	5/25 (20%)	13/25 (52%)
POLY-3 RATE (c)	6/42.65	15/46.22
POLY-3 PERCENT (g)	14.1%	32.5%
TERMINAL (d)	5/35 (14%)	13/38 (34%)
FIRST INCIDENCE	533	648

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**STATISTICAL TESTS**

POLY 3	P=0.035*
POLY 1.5	P=0.031*
POLY 6	P=0.038*
RAO-SCOTT	P=0.044*
LITTER C-A/FISHERS	P=0.019*

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Experiment Number: 20614 - 02

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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**

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DOSE	0/40 ppm	300/40 ppm
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**All Organs**

**Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type**

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**TUMOR RATES**

	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)
LITTERS (b)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (c)	2/42.39	1/46.01
POLY-3 PERCENT (g)	4.7%	2.2%
TERMINAL (d)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	659	645

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**STATISTICAL TESTS**

POLY 3	P=0.472N
POLY 1.5	P=0.479N
POLY 6	P=0.467N
RAO-SCOTT	P=0.481N
LITTER C-A/FISHERS	P=0.500N

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Lab: BAT

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

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Males		
DOSE	0/40 ppm	300/40 ppm
<hr/>		
All Organs		
Benign Tumors		
<hr/>		
<b>TUMOR RATES</b>	#	#
OVERALL (a)	31/50 (62%)	43/50 (86%)
LITTERS (b)	22/25 (88%)	24/25 (96%)
POLY-3 RATE (c)	31/43.14	43/47.70
POLY-3 PERCENT (g)	71.9%	90.2%
TERMINAL (d)	26/35 (74%)	34/38 (90%)
FIRST INCIDENCE	533	561
<hr/>		
<b>STATISTICAL TESTS</b>		
POLY 3		P=0.019*
POLY 1.5		P=0.010**
POLY 6		P=0.032*
RAO-SCOTT		P=0.031*
LITTER C-A/FISHERS		P=0.305

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Lab: BAT

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

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Males		
DOSE	0/40 ppm	300/40 ppm
<b>All Organs</b>		
<b>Malignant Tumors</b>		
<hr/>		
<b>TUMOR RATES</b>	#	#
OVERALL (a)	8/50 (16%)	5/50 (10%)
LITTERS (b)	6/25 (24%)	5/25 (20%)
POLY-3 RATE (c)	8/43.72	5/46.34
POLY-3 PERCENT (g)	18.3%	10.8%
TERMINAL (d)	4/35 (11%)	3/38 (8%)
FIRST INCIDENCE	502	645
<hr/>		
<b>STATISTICAL TESTS</b>		
POLY 3		P=0.238N
POLY 1.5		P=0.247N
POLY 6		P=0.234N
RAO-SCOTT		P=0.289N
LITTER C-A/FISHERS		P=0.500N

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

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Males		
DOSE	0/40 ppm	300/40 ppm
<b>All Organs</b>		
<b>Malignant and Benign Tumors</b>		
<hr/>		
<b>TUMOR RATES</b>	#	#
OVERALL (a)	35/50 (70%)	44/50 (88%)
LITTERS (b)	22/25 (88%)	24/25 (96%)
POLY-3 RATE (c)	35/44.76	44/48.05
POLY-3 PERCENT (g)	78.2%	91.6%
TERMINAL (d)	27/35 (77%)	34/38 (90%)
FIRST INCIDENCE	502	561
<hr/>		
<b>STATISTICAL TESTS</b>		
POLY 3		P=0.059
POLY 1.5		P=0.039*
POLY 6		P=0.082
RAO-SCOTT		P=0.094
LITTER C-A/FISHERS		P=0.305

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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 \*\*\*