

**Experiment Number:** 20614 - 01  
**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:** 09/16/2018  
**Time Report Requested:** 10:39:50  
**First Dose M/F:** 10/27/08 / 10/28/08  
**Lab:** BAT

Uterine section report with litter -- 0-0, 150-300, 300-1000

<b>NTP Study Number:</b>	C20614		
<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
	25016 Aborted		
<b>Removal Date Range:</b>	ALL		
<b>Treatment Groups:</b>	Include 002 0/0 ppm	Include 006 150/300 ppm	Include 010 300/1000 ppm
<b>Study Gender:</b>	Both		
<b>TDMSE Version:</b>	2.5.0.0_sfh		
<b>PWG Approval Date:</b>	07/25/2018		

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Lab: BAT

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

---

DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm

---

Uterus (Longitudinal Evaluation)  
Adenoma

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TUMOR RATES	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/32 (3%)	0/29 (0%)	0/30 (0%)
POLY-3 RATE (c)	1/36.81	0/41.44	0/37.22
POLY-3 PERCENT (g)	2.7%	0%	0%
TERMINAL (d)	1/23 (4%)	0/32 (0%)	0/23 (0%)
FIRST INCIDENCE	744 (T)	---	---

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**STATISTICAL TESTS**

POLY 3	P=0.439N	P=0.476N	P=0.498N
POLY 1.5	P=0.431N	P=0.487N	P=0.498N
POLY 6	P=0.450N	P=0.461N	P=0.499N
RAO-SCOTT	P=0.513N	P=0.576N	P=0.573N
LITTER C-A/FISHERS	P=0.429N	P=0.525N	P=0.516N

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

---

DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm

---

**Uterus (Standard or Longitudinal Evaluation)**  
**Adenoma**

---

TUMOR RATES	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/32 (3%)	0/29 (0%)	0/30 (0%)
POLY-3 RATE (c)	1/36.81	0/41.44	0/37.22
POLY-3 PERCENT (g)	2.7%	0%	0%
TERMINAL (d)	1/23 (4%)	0/32 (0%)	0/23 (0%)
FIRST INCIDENCE	744 (T)	---	---

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Lab: BAT

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

DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Uterus (Standard Evaluation)</b>			
<b>Carcinoma</b>			
<hr/>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	0/32 (0%)	2/29 (7%)	1/30 (3%)
POLY-3 RATE (c)	0/36.81	2/42.01	1/37.22
POLY-3 PERCENT (g)	0%	4.8%	2.7%
TERMINAL (d)	0/23 (0%)	1/32 (3%)	1/23 (4%)
FIRST INCIDENCE	---	564	744 (T)
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.536	P=0.267	P=0.502
POLY 1.5	P=0.534	P=0.254	P=0.502
POLY 6	P=0.535	P=0.288	P=0.501
RAO-SCOTT	P=0.512	P=0.285	P=0.477
LITTER C-A/FISHERS	P=0.514	P=0.222	P=0.484

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

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DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm

---

**Uterus (Longitudinal Evaluation)**  
**Carcinoma**

---

TUMOR RATES	#	#	#
OVERALL (a)	1/50 (2%)	3/50 (6%)	5/50 (10%)
LITTERS (b)	1/32 (3%)	3/29 (10%)	5/30 (17%)
POLY-3 RATE (c)	1/36.81	3/42.01	5/38.13
POLY-3 PERCENT (g)	2.7%	7.1%	13.1%
TERMINAL (d)	1/23 (4%)	2/32 (6%)	3/23 (13%)
FIRST INCIDENCE	744 (T)	564	574

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**STATISTICAL TESTS**

POLY 3	P=0.088	P=0.354	P=0.107
POLY 1.5	P=0.089	P=0.332	P=0.105
POLY 6	P=0.086	P=0.386	P=0.109
RAO-SCOTT	P=0.094	P=0.345	P=0.115
LITTER C-A/FISHERS	P=0.076	P=0.270	P=0.084

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DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Uterus (Standard or Longitudinal Evaluation)</b>			
<b>Carcinoma</b>			
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<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	1/50 (2%)	3/50 (6%)	5/50 (10%)
LITTERS (b)	1/32 (3%)	3/29 (10%)	5/30 (17%)
POLY-3 RATE (c)	1/36.81	3/42.01	5/38.13
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FIRST INCIDENCE	744 (T)	564	574
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DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Uterus (Standard Evaluation)</b>			
<b>Carcinoma or Adenoma</b>			
<hr/>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)
LITTERS (b)	0/32 (0%)	2/29 (7%)	1/30 (3%)
POLY-3 RATE (c)	0/36.81	2/42.01	1/37.22
POLY-3 PERCENT (g)	0%	4.8%	2.7%
TERMINAL (d)	0/23 (0%)	1/32 (3%)	1/23 (4%)
FIRST INCIDENCE	---	564	744 (T)
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<b>STATISTICAL TESTS</b>			
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POLY 6	P=0.535	P=0.288	P=0.501
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DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Uterus (Longitudinal Evaluation)</b>			
<b>Carcinoma or Adenoma</b>			
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<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	2/50 (4%)	3/50 (6%)	5/50 (10%)
LITTERS (b)	2/32 (6%)	3/29 (10%)	5/30 (17%)
POLY-3 RATE (c)	2/36.81	3/42.01	5/38.13
POLY-3 PERCENT (g)	5.4%	7.1%	13.1%
TERMINAL (d)	2/23 (9%)	2/32 (6%)	3/23 (13%)
FIRST INCIDENCE	744 (T)	564	574
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.171	P=0.560	P=0.228
POLY 1.5	P=0.172	P=0.533	P=0.224
POLY 6	P=0.165	P=0.597	P=0.232
RAO-SCOTT	P=0.169	P=0.535	P=0.220
LITTER C-A/FISHERS	P=0.151	P=0.452	P=0.186



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DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Uterus (Standard or Longitudinal Evaluation)</b>			
<b>Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	2/50 (4%)	3/50 (6%)	5/50 (10%)
LITTERS (b)	2/32 (6%)	3/29 (10%)	5/30 (17%)
POLY-3 RATE (c)	2/36.81	3/42.01	5/38.13
POLY-3 PERCENT (g)	5.4%	7.1%	13.1%
TERMINAL (d)	2/23 (9%)	2/32 (6%)	3/23 (13%)
FIRST INCIDENCE	744 (T)	564	574
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TERMINAL SACRIFICE AT 107 WEEKS**

DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Uterus (Standard Evaluation)</b>			
<b>Lymphoma</b>			
<hr/>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/32 (3%)	0/29 (0%)	0/30 (0%)
POLY-3 RATE (c)	1/37.44	0/41.44	0/37.22
POLY-3 PERCENT (g)	2.7%	0%	0%
TERMINAL (d)	0/23 (0%)	0/32 (0%)	0/23 (0%)
FIRST INCIDENCE	533	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.436N	P=0.480N	P=0.501N
POLY 1.5	P=0.429N	P=0.489N	P=0.500N
POLY 6	P=0.446N	P=0.466N	P=0.504N
RAO-SCOTT	P=0.523N	P=0.592N	P=0.589N
LITTER C-A/FISHERS	P=0.429N	P=0.525N	P=0.516N

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TERMINAL SACRIFICE AT 107 WEEKS**

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DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm

---

**Uterus (Longitudinal Evaluation)**  
**Lymphoma**

---

TUMOR RATES	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/32 (3%)	0/29 (0%)	0/30 (0%)
POLY-3 RATE (c)	1/37.44	0/41.44	0/37.22
POLY-3 PERCENT (g)	2.7%	0%	0%
TERMINAL (d)	0/23 (0%)	0/32 (0%)	0/23 (0%)
FIRST INCIDENCE	533	---	---

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**STATISTICAL TESTS**

POLY 3	P=0.436N	P=0.480N	P=0.501N
POLY 1.5	P=0.429N	P=0.489N	P=0.500N
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DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Uterus (Standard or Longitudinal Evaluation)</b>			
<b>Lymphoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/32 (3%)	0/29 (0%)	0/30 (0%)
POLY-3 RATE (c)	1/37.44	0/41.44	0/37.22
POLY-3 PERCENT (g)	2.7%	0%	0%
TERMINAL (d)	0/23 (0%)	0/32 (0%)	0/23 (0%)
FIRST INCIDENCE	533	---	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.436N	P=0.480N	P=0.501N
POLY 1.5	P=0.429N	P=0.489N	P=0.500N
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RAO-SCOTT	P=0.523N	P=0.592N	P=0.589N
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DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Uterus (Standard Evaluation)</b>			
<b>Polyp, Stromal</b>			
<hr/>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	6/50 (12%)	4/50 (8%)	3/50 (6%)
LITTERS (b)	5/32 (16%)	4/29 (14%)	3/30 (10%)
POLY-3 RATE (c)	6/37.44	4/41.81	3/37.63
POLY-3 PERCENT (g)	16%	9.6%	8%
TERMINAL (d)	4/23 (17%)	3/32 (9%)	2/23 (9%)
FIRST INCIDENCE	574	638	624
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.239N	P=0.300N	P=0.235N
POLY 1.5	P=0.232N	P=0.331N	P=0.237N
POLY 6	P=0.254N	P=0.259N	P=0.236N
RAO-SCOTT	P=0.255N	P=0.321N	P=0.257N
LITTER C-A/FISHERS	P=0.342N	P=0.565N	P=0.391N

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DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Uterus (Longitudinal Evaluation)</b>			
<b>Polyp, Stromal</b>			
<hr/>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	16/50 (32%)	13/50 (26%)	17/50 (34%)
LITTERS (b)	13/32 (41%)	11/29 (38%)	14/30 (47%)
POLY-3 RATE (c)	16/38.62	13/42.30	17/40.45
POLY-3 PERCENT (g)	41.4%	30.7%	42%
TERMINAL (d)	9/23 (39%)	9/32 (28%)	9/23 (39%)
FIRST INCIDENCE	574	634	491
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.417	P=0.218N	P=0.571
POLY 1.5	P=0.414	P=0.263N	P=0.544
POLY 6	P=0.406	P=0.166N	P=0.592
RAO-SCOTT	P=0.430	P=0.235N	P=0.558
LITTER C-A/FISHERS	P=0.345	P=0.519N	P=0.412

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DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Uterus (Standard or Longitudinal Evaluation)</b>			
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Lab: BAT

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

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DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm

---

**Uterus (Longitudinal Evaluation)**  
**Sarcoma Stromal**

---

TUMOR RATES	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/32 (3%)	0/29 (0%)	0/30 (0%)
POLY-3 RATE (c)	1/37.07	0/41.44	0/37.22
POLY-3 PERCENT (g)	2.7%	0%	0%
TERMINAL (d)	0/23 (0%)	0/32 (0%)	0/23 (0%)
FIRST INCIDENCE	673	---	---

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**STATISTICAL TESTS**

POLY 3	P=0.438N	P=0.478N	P=0.499N
POLY 1.5	P=0.430N	P=0.488N	P=0.499N
POLY 6	P=0.448N	P=0.464N	P=0.501N
RAO-SCOTT	P=0.512N	P=0.578N	P=0.575N
LITTER C-A/FISHERS	P=0.429N	P=0.525N	P=0.516N

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Experiment Number: 20614 - 01

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: 09/16/2018

Time Report Requested: 10:39:50

First Dose M/F: 10/27/08 / 10/28/08

Lab: BAT

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

DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Uterus (Standard or Longitudinal Evaluation)</b>			
<b>Sarcoma Stromal</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
LITTERS (b)	1/32 (3%)	0/29 (0%)	0/30 (0%)
POLY-3 RATE (c)	1/37.07	0/41.44	0/37.22
POLY-3 PERCENT (g)	2.7%	0%	0%
TERMINAL (d)	0/23 (0%)	0/32 (0%)	0/23 (0%)
FIRST INCIDENCE	673	---	---
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POLY 1.5	P=0.430N	P=0.488N	P=0.499N
POLY 6	P=0.448N	P=0.464N	P=0.501N
RAO-SCOTT	P=0.512N	P=0.578N	P=0.575N
LITTER C-A/FISHERS	P=0.429N	P=0.525N	P=0.516N

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

DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Uterus (Standard Evaluation)</b>			
<b>Sarcoma Stromal or Polyp Stromal</b>			
<hr/>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	6/50 (12%)	4/50 (8%)	3/50 (6%)
LITTERS (b)	5/32 (16%)	4/29 (14%)	3/30 (10%)
POLY-3 RATE (c)	6/37.44	4/41.81	3/37.63
POLY-3 PERCENT (g)	16%	9.6%	8%
TERMINAL (d)	4/23 (17%)	3/32 (9%)	2/23 (9%)
FIRST INCIDENCE	574	638	624
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.239N	P=0.300N	P=0.235N
POLY 1.5	P=0.232N	P=0.331N	P=0.237N
POLY 6	P=0.254N	P=0.259N	P=0.236N
RAO-SCOTT	P=0.255N	P=0.321N	P=0.257N
LITTER C-A/FISHERS	P=0.342N	P=0.565N	P=0.391N

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

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

---

DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm

---

**Uterus (Longitudinal Evaluation)**  
**Sarcoma Stromal or Polyp Stromal**

---

TUMOR RATES	#	#	#
OVERALL (a)	16/50 (32%)	13/50 (26%)	17/50 (34%)
LITTERS (b)	13/32 (41%)	11/29 (38%)	14/30 (47%)
POLY-3 RATE (c)	16/38.62	13/42.30	17/40.45
POLY-3 PERCENT (g)	41.4%	30.7%	42%
TERMINAL (d)	9/23 (39%)	9/32 (28%)	9/23 (39%)
FIRST INCIDENCE	574	634	491

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**STATISTICAL TESTS**

POLY 3	P=0.417	P=0.218N	P=0.571
POLY 1.5	P=0.414	P=0.263N	P=0.544
POLY 6	P=0.406	P=0.166N	P=0.592
RAO-SCOTT	P=0.430	P=0.235N	P=0.558
LITTER C-A/FISHERS	P=0.345	P=0.519N	P=0.412

---

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Perfluorooctanoic Acid

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

DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Uterus (Standard or Longitudinal Evaluation)</b>			
<b>Sarcoma Stromal or Polyp Stromal</b>			
<b>TUMOR RATES</b>			
	#	#	#
OVERALL (a)	16/50 (32%)	13/50 (26%)	17/50 (34%)
LITTERS (b)	13/32 (41%)	11/29 (38%)	14/30 (47%)
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FIRST INCIDENCE	574	634	491
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RAO-SCOTT	P=0.430	P=0.235N	P=0.558
LITTER C-A/FISHERS	P=0.345	P=0.519N	P=0.412

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

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Lab: BAT

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

DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Vagina (Longitudinal Evaluation)</b>			
<b>Granular Cell Tumor</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)
LITTERS (b)	2/32 (6%)	1/29 (3%)	0/30 (0%)
POLY-3 RATE (c)	2/36.96	1/41.54	0/37.22
POLY-3 PERCENT (g)	5.4%	2.4%	0%
TERMINAL (d)	1/23 (4%)	0/32 (0%)	0/23 (0%)
FIRST INCIDENCE	705	718	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.192N	P=0.459N	P=0.235N
POLY 1.5	P=0.187N	P=0.478N	P=0.235N
POLY 6	P=0.200N	P=0.433N	P=0.236N
RAO-SCOTT	P=0.227N	P=0.480N	P=0.275N
LITTER C-A/FISHERS	P=0.192N	P=0.537N	P=0.262N

Experiment Number: 20614 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

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DOSE	Females		
	0/0 ppm	150/300 ppm	300/1000 ppm
<b>Vagina (Standard or Longitudinal Evaluation)</b>			
<b>Granular Cell Tumor</b>			
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POLY-3 PERCENT (g)	5.4%	2.4%	0%
TERMINAL (d)	1/23 (4%)	0/32 (0%)	0/23 (0%)
FIRST INCIDENCE	705	718	---
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Experiment Number: 20614 - 01

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Route: DOSED FEED

Species/Strain: RATS/HSD

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**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 \*\*\*