



**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:** 03/13/2022

**Time Report Requested:** 11:25:00

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

**Lab:** BAT

**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

Adrenal Medulla

Pituitary Gland

Thyroid Gland

Uterus

Experiment Number: 20614 - 01

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

### FEMALE RATS

#### Organ

Mammary Gland

All Organs

#### Morphology

Fibroadenoma

Malignant and Benign Tumors

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

**Females**

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<b>DOSE</b>	<b>0/300 ppm</b>	<b>150/300 ppm</b>
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**Adrenal Cortex  
Adenoma**

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**TUMOR RATES**

<b>OVERALL (a)</b>	2/50 (4%)	1/50 (2%)
<b>LITTERS (b)</b>	2/29 (7%)	1/29 (3%)
<b>POLY-3 RATE (c)</b>	2/41.88	1/41.44
<b>POLY-3 PERCENT (g)</b>	4.8%	2.4%
<b>TERMINAL (d)</b>	2/28 (7%)	1/32 (3%)
<b>FIRST INCIDENCE</b>	744 (T)	744 (T)

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.504N
<b>POLY 1.5</b>	P=0.506N
<b>POLY 6</b>	P=0.494N
<b>RAO-SCOTT</b>	P=0.491N
<b>LITTER C-A/FISHERS</b>	P=0.500N

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Lab: BAT

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

**Females**

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<b>DOSE</b>	<b>0/300 ppm</b>	<b>150/300 ppm</b>
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**Adrenal Medulla  
Pheochromocytoma Benign**

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**TUMOR RATES**

<b>OVERALL (a)</b>	3/50 (6%)	4/50 (8%)
<b>LITTERS (b)</b>	3/29 (10%)	4/29 (14%)
<b>POLY-3 RATE (c)</b>	3/41.90	4/41.44
<b>POLY-3 PERCENT (g)</b>	7.2%	9.7%
<b>TERMINAL (d)</b>	2/28 (7%)	4/32 (13%)
<b>FIRST INCIDENCE</b>	737	744 (T)

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.494
<b>POLY 1.5</b>	P=0.491
<b>POLY 6</b>	P=0.508
<b>RAO-SCOTT</b>	P=0.472
<b>LITTER C-A/FISHERS</b>	P=0.500

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Species/Strain: RATS/HSD

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Lab: BAT

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

**Females**

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<b>DOSE</b>	<b>0/300 ppm</b>	<b>150/300 ppm</b>
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**Mammary Gland  
Carcinoma**

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**TUMOR RATES**

	<b>#</b>	<b>#</b>
<b>OVERALL (a)</b>	4/50 (8%)	5/50 (10%)
<b>LITTERS (b)</b>	4/29 (14%)	4/29 (14%)
<b>POLY-3 RATE (c)</b>	4/42.27	5/43.37
<b>POLY-3 PERCENT (g)</b>	9.5%	11.5%
<b>TERMINAL (d)</b>	1/28 (4%)	1/32 (3%)
<b>FIRST INCIDENCE</b>	695	351

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.516
<b>POLY 1.5</b>	P=0.505
<b>POLY 6</b>	P=0.538
<b>RAO-SCOTT</b>	P=0.523
<b>LITTER C-A/FISHERS</b>	P=0.647

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

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Females		
DOSE	0/300 ppm	150/300 ppm
<b>Mammary Gland Carcinoma or Adenoma</b>		
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<b>TUMOR RATES</b>	#	#
OVERALL (a)	5/50 (10%)	6/50 (12%)
LITTERS (b)	5/29 (17%)	5/29 (17%)
POLY-3 RATE (c)	5/42.27	6/43.37
POLY-3 PERCENT (g)	11.8%	13.8%
TERMINAL (d)	2/28 (7%)	2/32 (6%)
FIRST INCIDENCE	695	351
<hr/>		
<b>STATISTICAL TESTS</b>		
POLY 3		P=0.518
POLY 1.5		P=0.505
POLY 6		P=0.543
RAO-SCOTT		P=0.518
LITTER C-A/FISHERS		P=0.635

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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**

**Females**

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<b>DOSE</b>	<b>0/300 ppm</b>	<b>150/300 ppm</b>
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**Mammary Gland  
Fibroadenoma**

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**TUMOR RATES**

	<b>#</b>	<b>#</b>
<b>OVERALL (a)</b>	19/50 (38%)	27/50 (54%)
<b>LITTERS (b)</b>	14/29 (48%)	20/29 (69%)
<b>POLY-3 RATE (c)</b>	19/46.79	27/45.18
<b>POLY-3 PERCENT (g)</b>	40.6%	59.8%
<b>TERMINAL (d)</b>	8/28 (29%)	17/32 (53%)
<b>FIRST INCIDENCE</b>	470	322

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.048*
<b>POLY 1.5</b>	P=0.055
<b>POLY 6</b>	P=0.048*
<b>RAO-SCOTT</b>	P=0.074
<b>LITTER C-A/FISHERS</b>	P=0.091

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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: 10/27/08 / 10/28/08

Lab: BAT

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

**Females**

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DOSE	0/300 ppm	150/300 ppm
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**Mammary Gland**  
**Fibroma, Fibroadenoma or Adenoma**

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<b>TUMOR RATES</b>	#	#
OVERALL (a)	20/50 (40%)	27/50 (54%)
LITTERS (b)	15/29 (52%)	20/29 (69%)
POLY-3 RATE (c)	20/46.79	27/45.18
POLY-3 PERCENT (g)	42.7%	59.8%
TERMINAL (d)	9/28 (32%)	17/32 (53%)
FIRST INCIDENCE	470	322

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**STATISTICAL TESTS**

POLY 3	P=0.073
POLY 1.5	P=0.082
POLY 6	P=0.073
RAO-SCOTT	P=0.100
LITTER C-A/FISHERS	P=0.141

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Species/Strain: RATS/HSD

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Perfluorooctanoic Acid  
CAS Number: 335-67-1

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Lab: BAT

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

**Females**

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DOSE	0/300 ppm	150/300 ppm
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**Mammary Gland  
Fibroma, Fibroadenoma, Carcinoma, or Adenoma**

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<b>TUMOR RATES</b>	#	#
OVERALL (a)	23/50 (46%)	31/50 (62%)
LITTERS (b)	18/29 (62%)	22/29 (76%)
POLY-3 RATE (c)	23/47.01	31/47.08
POLY-3 PERCENT (g)	48.9%	65.8%
TERMINAL (d)	10/28 (36%)	18/32 (56%)
FIRST INCIDENCE	470	322

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**STATISTICAL TESTS**

POLY 3	P=0.070
POLY 1.5	P=0.069
POLY 6	P=0.078
RAO-SCOTT	P=0.085
LITTER C-A/FISHERS	P=0.197

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Lab: BAT

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

**Females**

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<b>DOSE</b>	<b>0/300 ppm</b>	<b>150/300 ppm</b>
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**Pituitary Gland: Pars Distalis or Unspecified Site  
Adenoma**

**TUMOR RATES**

<b>OVERALL (a)</b>	11/50 (22%)	13/50 (26%)
<b>LITTERS (b)</b>	9/29 (31%)	11/29 (38%)
<b>POLY-3 RATE (c)</b>	11/42.88	13/42.16
<b>POLY-3 PERCENT (g)</b>	25.7%	30.8%
<b>TERMINAL (d)</b>	6/28 (21%)	9/32 (28%)
<b>FIRST INCIDENCE</b>	676	622

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.386
<b>POLY 1.5</b>	P=0.384
<b>POLY 6</b>	P=0.405
<b>RAO-SCOTT</b>	P=0.389
<b>LITTER C-A/FISHERS</b>	P=0.391

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Species/Strain: RATS/HSD

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Lab: BAT

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

**Females**

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<b>DOSE</b>	<b>0/300 ppm</b>	<b>150/300 ppm</b>
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**Thyroid Gland: C-Cell  
Adenoma**

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**TUMOR RATES**

<b>OVERALL (a)</b>	11/50 (22%)	8/50 (16%)
<b>LITTERS (b)</b>	10/29 (34%)	8/29 (28%)
<b>POLY-3 RATE (c)</b>	11/42.99	8/41.46
<b>POLY-3 PERCENT (g)</b>	25.6%	19.3%
<b>TERMINAL (d)</b>	8/28 (29%)	7/32 (22%)
<b>FIRST INCIDENCE</b>	470	739

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.333N
<b>POLY 1.5</b>	P=0.331N
<b>POLY 6</b>	P=0.319N
<b>RAO-SCOTT</b>	P=0.326N
<b>LITTER C-A/FISHERS</b>	P=0.389N

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Experiment Number: 20614 - 01

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Species/Strain: RATS/HSD

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Lab: BAT

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

**Females**

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DOSE	0/300 ppm	150/300 ppm
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Thyroid Gland: C-Cell  
Carcinoma or Adenoma

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**TUMOR RATES**

OVERALL (a)	11/50 (22%)	9/50 (18%)
LITTERS (b)	10/29 (34%)	9/29 (31%)
POLY-3 RATE (c)	11/42.99	9/41.46
POLY-3 PERCENT (g)	25.6%	21.7%
TERMINAL (d)	8/28 (29%)	8/32 (25%)
FIRST INCIDENCE	470	739

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**STATISTICAL TESTS**

POLY 3	P=0.435N
POLY 1.5	P=0.432N
POLY 6	P=0.421N
RAO-SCOTT	P=0.423N
LITTER C-A/FISHERS	P=0.500N

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

**Females**

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DOSE	0/300 ppm	150/300 ppm
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Uterus  
Carcinoma

**TUMOR RATES**

OVERALL (a)	1/49 (2%)	2/50 (4%)
LITTERS (b)	1/29 (3%)	2/29 (7%)
POLY-3 RATE (c)	1/40.88	2/42.01
POLY-3 PERCENT (g)	2.5%	4.8%
TERMINAL (d)	1/27 (4%)	1/32 (3%)
FIRST INCIDENCE	744 (T)	564

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**STATISTICAL TESTS**

POLY 3	P=0.510
POLY 1.5	P=0.505
POLY 6	P=0.522
RAO-SCOTT	P=0.497
LITTER C-A/FISHERS	P=0.500

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

**Females**

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DOSE	0/300 ppm	150/300 ppm
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Uterus  
Polyp Stromal

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**TUMOR RATES**

OVERALL (a)	4/49 (8%)	4/50 (8%)
LITTERS (b)	4/29 (14%)	4/29 (14%)
POLY-3 RATE (c)	4/41.06	4/41.81
POLY-3 PERCENT (g)	9.7%	9.6%
TERMINAL (d)	3/27 (11%)	3/32 (9%)
FIRST INCIDENCE	695	638

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**STATISTICAL TESTS**

POLY 3	P=0.634N
POLY 1.5	P=0.639N
POLY 6	P=0.617N
RAO-SCOTT	P=0.612N
LITTER C-A/FISHERS	P=0.647

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

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Females		
DOSE	0/300 ppm	150/300 ppm
<hr/>		
All Organs		
Benign Tumors		
<hr/>		
<b>TUMOR RATES</b>	#	#
OVERALL (a)	35/50 (70%)	37/50 (74%)
LITTERS (b)	24/29 (83%)	26/29 (90%)
POLY-3 RATE (c)	35/48.42	37/45.69
POLY-3 PERCENT (g)	72.3%	81%
TERMINAL (d)	19/28 (68%)	25/32 (78%)
FIRST INCIDENCE	250	322
<hr/>		
<b>STATISTICAL TESTS</b>		
POLY 3		P=0.220
POLY 1.5		P=0.263
POLY 6		P=0.212
RAO-SCOTT		P=0.227
LITTER C-A/FISHERS		P=0.353

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

**Females**

---

<b>DOSE</b>	<b>0/300 ppm</b>	<b>150/300 ppm</b>
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All Organs  
Malignant Tumors

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<b>TUMOR RATES</b>	<b>#</b>	<b>#</b>
OVERALL (a)	10/50 (20%)	9/50 (18%)
LITTERS (b)	10/29 (34%)	8/29 (28%)
POLY-3 RATE (c)	10/42.99	9/44.05
POLY-3 PERCENT (g)	23.3%	20.4%
TERMINAL (d)	5/28 (18%)	3/32 (9%)
FIRST INCIDENCE	589	351

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**STATISTICAL TESTS**

POLY 3	P=0.476N
POLY 1.5	P=0.493N
POLY 6	P=0.444N
RAO-SCOTT	P=0.466N
LITTER C-A/FISHERS	P=0.389N

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

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Females		
DOSE	0/300 ppm	150/300 ppm
<b>All Organs</b>		
<b>Malignant and Benign Tumors</b>		
<hr/>		
<b>TUMOR RATES</b>	#	#
OVERALL (a)	38/50 (76%)	43/50 (86%)
LITTERS (b)	24/29 (83%)	29/29 (100%)
POLY-3 RATE (c)	38/49.14	43/48.17
POLY-3 PERCENT (g)	77.3%	89.3%
TERMINAL (d)	20/28 (71%)	27/32 (84%)
FIRST INCIDENCE	250	322
<hr/>		
<b>STATISTICAL TESTS</b>		
POLY 3		P=0.091
POLY 1.5		P=0.096
POLY 6		P=0.105
RAO-SCOTT		P=0.122
LITTER C-A/FISHERS		P=0.026*

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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 \*\*\*