

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
Perfluorooctanoic Acid  
**CAS Number:** 335-67-1

**Date Report Requested:** 06/14/2018  
**Time Report Requested:** 19:58:00  
**First Dose M/F:** 07/27/09 / NA  
**Lab:** BAT

SSAC Males 0-0, 0-20, 0-40, 0-80

<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>	25017 SSAC		
<b>Removal Date Range:</b>	ALL		
<b>Treatment Groups:</b>	Include 001 0/0 ppm Include 007 0/80 ppm	Include 003 0/20 ppm	Include 005 0/40 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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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF PERFLUOROOCCTANOIC ACID**

**MALE RATS**

**Organ**

Liver

Liver: Hepatocyte

**Morphology**

Necrosis

Pigment

Cytoplasmic Alteration

Hypertrophy

Single Cell Death

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LAST REMOVAL AT 16 WEEKS**

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DOSE	Males			
	0/0 ppm	0/20 ppm	0/40 ppm	0/80 ppm
<hr/>				
Liver				
Clear Cell Focus				
<hr/>				
<b>LESION RATES</b>				
OVERALL (a)	1/10 (10%)	1/10 (10%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	1/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	10%	10%	0%	10%
INT SACRIFICE 1	1/10 (10%)	1/10 (10%)	0/10 (0%)	1/10 (10%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	108 (I)	108 (I)	---	108 (I)
<hr/>				
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.615N	P=0.760	P=0.500N	P=0.760
POLY 1.5	P=0.615N	P=0.760	P=0.500N	P=0.760
POLY 6	P=0.615N	P=0.760	P=0.500N	P=0.760
COCH-ARM / FISHERS	P=0.620N	P=0.763N	P=0.500N	P=0.763N
MAX-ISO-POLY-3	P=0.541N	P=1.000	P=0.159N	P=1.000

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DOSE	Males			
	0/0 ppm	0/20 ppm	0/40 ppm	0/80 ppm
<b>Liver</b>				
<b>Hepatodiaphragmatic Nodule</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	108 (l)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.199	(e)	(e)	P=0.500
POLY 1.5	P=0.199	(e)	(e)	P=0.500
POLY 6	P=0.199	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.196	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.124	(e)	(e)	P=0.159

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LAST REMOVAL AT 16 WEEKS

DOSE	Males			
	0/0 ppm	0/20 ppm	0/40 ppm	0/80 ppm
<b>Liver</b>				
<b>Inflammation Focal</b>				
<b>LESION RATES</b>				
OVERALL (a)	9/10 (90%)	10/10 (100%)	10/10 (100%)	8/10 (80%)
POLY-3 RATE (b)	9/10.00	10/10.00	10/10.00	8/10.00
POLY-3 PERCENT (g)	90%	100%	100%	80%
INT SACRIFICE 1	9/10 (90%)	10/10 (100%)	10/10 (100%)	8/10 (80%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	108 (I)	108 (I)	108 (I)	108 (I)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.239N	P=0.500	P=0.500	P=0.500N
POLY 1.5	P=0.239N	P=0.500	P=0.500	P=0.500N
POLY 6	P=0.239N	P=0.500	P=0.500	P=0.500N
COCH-ARM / FISHERS	P=0.239N	P=0.500	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.124N	P=0.159	P=0.159	P=0.275N

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LAST REMOVAL AT 16 WEEKS**

---

DOSE	Males			
	0/0 ppm	0/20 ppm	0/40 ppm	0/80 ppm
<hr/>				
Liver Necrosis				
<hr/>				
<b>LESION RATES</b>				
OVERALL (a)	1/10 (10%)	1/10 (10%)	6/10 (60%)	4/10 (40%)
POLY-3 RATE (b)	1/10.00	1/10.00	6/10.00	4/10.00
POLY-3 PERCENT (g)	10%	10%	60%	40%
INT SACRIFICE 1	1/10 (10%)	1/10 (10%)	6/10 (60%)	4/10 (40%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	108 (I)	108 (I)	108 (I)	108 (I)
<hr/>				
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.040*	P=0.760	P=0.018*	P=0.148
POLY 1.5	P=0.040*	P=0.760	P=0.018*	P=0.148
POLY 6	P=0.040*	P=0.760	P=0.018*	P=0.148
COCH-ARM / FISHERS	P=0.051	P=0.763N	P=0.029*	P=0.152
MAX-ISO-POLY-3	P=0.028*	P=1.000	P=0.004**	P=0.058

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DOSE	Males			
	0/0 ppm	0/20 ppm	0/40 ppm	0/80 ppm
Liver Pigment				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	2/10 (20%)	8/10 (80%)	9/10 (90%)
POLY-3 RATE (b)	0/10.00	2/10.00	8/10.00	9/10.00
POLY-3 PERCENT (g)	0%	20%	80%	90%
INT SACRIFICE 1	0/10 (0%)	2/10 (20%)	8/10 (80%)	9/10 (90%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	108 (I)	108 (I)	108 (I)
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.227	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.227	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.227	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.237	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.067	P<0.001**	P<0.001**

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LAST REMOVAL AT 16 WEEKS**

---

DOSE	Males			
	0/0 ppm	0/20 ppm	0/40 ppm	0/80 ppm
<b>Liver: Hepatocyte Cytoplasmic Alteration</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	100%	100%	100%
INT SACRIFICE 1	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	108 (I)	108 (I)	108 (I)
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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---

DOSE	Males			
	0/0 ppm	0/20 ppm	0/40 ppm	0/80 ppm
<b>Liver: Hepatocyte Hypertrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	100%	100%	100%
INT SACRIFICE 1	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	108 (I)	108 (I)	108 (I)
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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LAST REMOVAL AT 16 WEEKS

DOSE	Males			
	0/0 ppm	0/20 ppm	0/40 ppm	0/80 ppm
Liver: Hepatocyte Single Cell Death				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	7/10 (70%)	9/10 (90%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	7/10.00	9/10.00	10/10.00
POLY-3 PERCENT (g)	0%	70%	90%	100%
INT SACRIFICE 1	0/10 (0%)	7/10 (70%)	9/10 (90%)	10/10 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	108 (l)	108 (l)	108 (l)
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.002**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	(e)

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**LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) 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.
  - (n) No statistics are calculated if all dose groups have fewer than two tumors.
  - (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 Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

\*\*\* END OF REPORT \*\*\*