

**Experiment Number:** 93027-24  
**Test Type:** 90-DAY  
**Route:** DOSED FEED  
**Species/Strain:** Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

**Test Compound:** Peroxisome project (Gemfibrozil)

**CAS Number:** 25812-30-0

**Date Report Requested:** 10/18/2014

**Time Report Requested:** 21:22:30

**First Dose M/F:** NA / NA

**Lab:** BAT

<b>C Number:</b>	C93027B
<b>Lock Date:</b>	06/12/1996
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Male
<b>PWG Approval Date</b>	NONE

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

**MALE MOUSE**

**Organ**

Liver

Preputial Gland

**Morphology**

Cytoplasmic Alteration

Inflammation Chronic

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	0 PPM	MALE				
		10 PPM	100 PPM	1000 PPM	4000 PPM	8000 PPM
<b>Kidney</b>						
<b>Nephropathy</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	2/10 (20%)	2/10 (20%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	1/10.00	2/10.00	2/10.00
POLY-3 PERCENT (g)	10%	0%	0%	10%	20%	20%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	2/10 (20%)	2/10 (20%)
FIRST INCIDENCE	92(T)	---	---	92(T)	92(T)	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.078	P=0.500N	P=0.500N	P=0.760	P=0.500	P=0.500
POLY 1.5	P=0.078	P=0.500N	P=0.500N	P=0.760	P=0.500	P=0.500
POLY 6	P=0.078	P=0.500N	P=0.500N	P=0.760	P=0.500	P=0.500
COCH-ARM / FISHERS	P=0.075	P=0.500N	P=0.500N	P=0.763N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.146	P=0.159N	P=0.159N	P=1.000	P=0.274	P=0.274
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	10 PPM	100 PPM	1000 PPM	4000 PPM	8000 PPM
<b>Liver</b>						
<b>Cytoplasmic Alteration</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	7/10 (70%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	7/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	70%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	7/10 (70%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	92(T)	92(T)	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	(e)	P=0.000**	P=NA	P=NA
POLY 1.5	P=0.000**	(e)	(e)	P=0.000**	P=NA	P=NA
POLY 6	P=0.000**	(e)	(e)	P=0.000**	P=NA	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	P=0.002**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	P=0.000**	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	10 PPM	100 PPM	1000 PPM	4000 PPM	8000 PPM
<b>Liver</b>						
<b>Infiltration Cellular Mixed Cell Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	10%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	92(T)	---	---	---	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.348	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.760
POLY 1.5	P=0.348	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.760
POLY 6	P=0.348	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.760
COCH-ARM / FISHERS	P=0.346	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.763N
MAX-ISO-POLY-3	P=0.307	P=0.159N	P=0.159N	P=0.159N	P=0.159N	P=1.000
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 93027-24  
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**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	10 PPM	100 PPM	1000 PPM	4000 PPM	8000 PPM
<b>Lung</b>						
<b>Hemorrhage</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	10 PPM	100 PPM	1000 PPM	4000 PPM	8000 PPM
<b>Preputial Gland</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	20%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	92(T)	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.010**	(e)	(e)	(e)	P=0.500	P=0.227
POLY 1.5	P=0.010**	(e)	(e)	(e)	P=0.500	P=0.227
POLY 6	P=0.010**	(e)	(e)	(e)	P=0.500	P=0.227
COCH-ARM / FISHERS	P=0.011*	(e)	(e)	(e)	P=0.500	P=0.237
MAX-ISO-POLY-3	P=0.018*	(e)	(e)	(e)	P=0.159	P=0.067
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	10 PPM	100 PPM	1000 PPM	4000 PPM	8000 PPM
<b>Testes</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	10%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	92(T)	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.489N	(e)	P=0.500	(e)	(e)	(e)
POLY 1.5	P=0.489N	(e)	P=0.500	(e)	(e)	(e)
POLY 6	P=0.489N	(e)	P=0.500	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.488N	(e)	P=0.500	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.517N	(e)	P=0.159	(e)	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



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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 \*\***