

TDMS No. 93027 - 27
Test Type: 90-DAY
Route: DOSED FEED
Species/Strain: HAMSTERS/SYRIAN

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Peroxisome project (Gemfibrozil)

CAS Number: 25812-30-0

Date Report Requested: 06/24/2009

Time Report Requested: 13:52:09

First Dose M/F: 10/21/94 / NA

Lab: BAT

F1_Rev1_H1

C Number: C93027B
Lock Date: 06/12/1996
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Male
TDMSE Version: 2.1.0

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

MALE HAMSTERS

Organ

Kidney

Liver

Pancreas

Prostate

Seminal Vesicle

Testes

Morphology

Mineralization

Nephropathy

Depletion Glycogen

Inflammation Chronic

Atrophy

Atrophy

Atrophy

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	100 PPM	1000 PPM	6000 PPM	12,000 PPM	24,000 PPM
Gallbladder						
Infiltration Cellular Mixed Cell						
LESION RATES						
OVERALL (a)	6/10 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	9/10 (90%)
POLY-3 RATE (b)	6/10.00	0/0.00	0/0.00	0/0.00	0/0.00	9/10.00
POLY-3 PERCENT (g)	60%	0%	0%	0%	0%	90%
TERMINAL (d)	6/10 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	9/10 (90%)
FIRST INCIDENCE	92 (T)	---	---	---	---	92 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.148
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.148
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.148
COCH-ARM / FISHERS	P=0.098	(e)	(e)	(e)	(e)	P=0.152
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.058

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	100 PPM	1000 PPM	6000 PPM	12,000 PPM	24,000 PPM
Kidney Mineralization						
LESION RATES						
OVERALL (a)	1/10 (10%)	1/9 (11%)	0/8 (0%)	1/10 (10%)	1/10 (10%)	8/10 (80%)
POLY-3 RATE (b)	1/10.00	1/9.00	0/8.00	1/10.00	1/10.00	8/10.00
POLY-3 PERCENT (g)	10%	11.1%	0%	10%	10%	80%
TERMINAL (d)	1/10 (10%)	1/9 (11%)	0/8 (0%)	1/10 (10%)	1/10 (10%)	8/10 (80%)
FIRST INCIDENCE	92 (T)	92 (T)	---	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P<0.001**	P=0.737	P=0.544N	P=0.760	P=0.760	P<0.001**
POLY 1.5	P<0.001**	P=0.737	P=0.544N	P=0.760	P=0.760	P<0.001**
POLY 6	P<0.001**	P=0.737	P=0.544N	P=0.760	P=0.760	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.737	P=0.556N	P=0.763N	P=0.763N	P=0.003**
MAX-ISO-POLY-3	P<0.001**	P=0.469	P=0.199N	P=1.000	P=1.000	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	100 PPM	1000 PPM	6000 PPM	12,000 PPM	24,000 PPM
Kidney						
Nephropathy						
LESION RATES						
OVERALL (a)	3/10 (30%)	1/9 (11%)	4/8 (50%)	6/10 (60%)	4/10 (40%)	10/10 (100%)
POLY-3 RATE (b)	3/10.00	1/9.00	4/8.00	6/10.00	4/10.00	10/10.00
POLY-3 PERCENT (g)	30%	11.1%	50%	60%	40%	100%
TERMINAL (d)	3/10 (30%)	1/9 (11%)	4/8 (50%)	6/10 (60%)	4/10 (40%)	10/10 (100%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P<0.001**	P=0.333N	P=0.358	P=0.186	P=0.500	P<0.001**
POLY 1.5	P<0.001**	P=0.333N	P=0.358	P=0.186	P=0.500	P<0.001**
POLY 6	P<0.001**	P=0.333N	P=0.358	P=0.186	P=0.500	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.333N	P=0.352	P=0.185	P=0.500	P=0.002**
MAX-ISO-POLY-3	P<0.001**	P=0.170N	P=0.214	P=0.089	P=0.325	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	100 PPM	1000 PPM	6000 PPM	12,000 PPM	24,000 PPM
Liver						
Depletion Glycogen						
LESION RATES						
OVERALL (a)	0/10 (0%)	5/9 (56%)	4/10 (40%)	8/10 (80%)	9/10 (90%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	5/9.00	4/10.00	8/10.00	9/10.00	10/10.00
POLY-3 PERCENT (g)	0%	55.6%	40%	80%	90%	100%
TERMINAL (d)	0/10 (0%)	5/9 (56%)	4/10 (40%)	8/10 (80%)	9/10 (90%)	10/10 (100%)
FIRST INCIDENCE	---	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P<0.001**	P=0.003**	P=0.033*	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.003**	P=0.033*	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.003**	P=0.033*	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.011*	P=0.043*	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P=0.007**	P<0.001**	P<0.001**	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	100 PPM	1000 PPM	6000 PPM	12,000 PPM	24,000 PPM
Liver						
Infiltration Cellular Mixed Cell						
LESION RATES						
OVERALL (a)	9/10 (90%)	9/9 (100%)	9/10 (90%)	9/10 (90%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	9/10.00	9/9.00	9/10.00	9/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	90%	100%	90%	90%	100%	100%
TERMINAL (d)	9/10 (90%)	9/9 (100%)	9/10 (90%)	9/10 (90%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P=0.276	P=0.521	P=0.760	P=0.760	P=0.500	P=0.500
POLY 1.5	P=0.276	P=0.521	P=0.760	P=0.760	P=0.500	P=0.500
POLY 6	P=0.276	P=0.521	P=0.760	P=0.760	P=0.500	P=0.500
COCH-ARM / FISHERS	P=0.271	P=0.526	P=0.763N	P=0.763N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.160	P=0.178	P=1.000	P=1.000	P=0.158	P=0.158

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	100 PPM	1000 PPM	6000 PPM	12,000 PPM	24,000 PPM
Lung Hemorrhage						
LESION RATES						
OVERALL (a)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
POLY-3 RATE (b)	5/10.00	0/0.00	0/0.00	0/0.00	0/0.00	4/10.00
POLY-3 PERCENT (g)	50%	0%	0%	0%	0%	40%
TERMINAL (d)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
FIRST INCIDENCE	92 (T)	---	---	---	---	92 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.411N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.332N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	100 PPM	1000 PPM	6000 PPM	12,000 PPM	24,000 PPM
Pancreas						
Inflammation Chronic						
LESION RATES						
OVERALL (a)	6/10 (60%)	6/10 (60%)	6/10 (60%)	7/10 (70%)	7/9 (78%)	10/10 (100%)
POLY-3 RATE (b)	6/10.00	6/10.00	6/10.00	7/10.00	7/9.00	10/10.00
POLY-3 PERCENT (g)	60%	60%	60%	70%	77.8%	100%
TERMINAL (d)	6/10 (60%)	6/10 (60%)	6/10 (60%)	7/10 (70%)	7/9 (78%)	10/10 (100%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P=0.012*	P=0.667	P=0.667	P=0.500	P=0.372	P=0.033*
POLY 1.5	P=0.012*	P=0.667	P=0.667	P=0.500	P=0.372	P=0.033*
POLY 6	P=0.012*	P=0.667	P=0.667	P=0.500	P=0.372	P=0.033*
COCH-ARM / FISHERS	P=0.012*	P=0.675N	P=0.675N	P=0.500	P=0.370	P=0.043*
MAX-ISO-POLY-3	P=0.012*	P=1.000	P=1.000	P=0.325	P=0.217	P=0.007**

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	100 PPM	1000 PPM	6000 PPM	12,000 PPM	24,000 PPM
Prostate Atrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	1/10 (10%)	3/10 (30%)	5/10 (50%)	2/9 (22%)	5/10 (50%)
POLY-3 RATE (b)	0/10.00	1/10.00	3/10.00	5/10.00	2/9.00	5/10.00
POLY-3 PERCENT (g)	0%	10%	30%	50%	22.2%	50%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	3/10 (30%)	5/10 (50%)	2/9 (22%)	5/10 (50%)
FIRST INCIDENCE	---	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P=0.021*	P=0.500	P=0.095	P=0.008**	P=0.201	P=0.008**
POLY 1.5	P=0.021*	P=0.500	P=0.095	P=0.008**	P=0.201	P=0.008**
POLY 6	P=0.021*	P=0.500	P=0.095	P=0.008**	P=0.201	P=0.008**
COCH-ARM / FISHERS	P=0.026*	P=0.500	P=0.105	P=0.016*	P=0.211	P=0.016*
MAX-ISO-POLY-3	P=0.004**	P=0.158	P=0.025*	P<0.001**	P=0.059	P<0.001**

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	100 PPM	1000 PPM	6000 PPM	12,000 PPM	24,000 PPM
Seminal Vesicle Atrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	1/10 (10%)	3/10 (30%)	5/10 (50%)	2/9 (22%)	5/10 (50%)
POLY-3 RATE (b)	0/10.00	1/10.00	3/10.00	5/10.00	2/9.00	5/10.00
POLY-3 PERCENT (g)	0%	10%	30%	50%	22.2%	50%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	3/10 (30%)	5/10 (50%)	2/9 (22%)	5/10 (50%)
FIRST INCIDENCE	---	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P=0.021*	P=0.500	P=0.095	P=0.008**	P=0.201	P=0.008**
POLY 1.5	P=0.021*	P=0.500	P=0.095	P=0.008**	P=0.201	P=0.008**
POLY 6	P=0.021*	P=0.500	P=0.095	P=0.008**	P=0.201	P=0.008**
COCH-ARM / FISHERS	P=0.026*	P=0.500	P=0.105	P=0.016*	P=0.211	P=0.016*
MAX-ISO-POLY-3	P=0.004**	P=0.158	P=0.025*	P<0.001**	P=0.059	P<0.001**

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	100 PPM	1000 PPM	6000 PPM	12,000 PPM	24,000 PPM
Testes						
Atrophy						
LESION RATES						
OVERALL (a)	1/10 (10%)	2/10 (20%)	3/10 (30%)	5/10 (50%)	4/10 (40%)	5/10 (50%)
POLY-3 RATE (b)	1/10.00	2/10.00	3/10.00	5/10.00	4/10.00	5/10.00
POLY-3 PERCENT (g)	10%	20%	30%	50%	40%	50%
TERMINAL (d)	1/10 (10%)	2/10 (20%)	3/10 (30%)	5/10 (50%)	4/10 (40%)	5/10 (50%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P=0.051	P=0.500	P=0.292	P=0.061	P=0.148	P=0.061
POLY 1.5	P=0.051	P=0.500	P=0.292	P=0.061	P=0.148	P=0.061
POLY 6	P=0.051	P=0.500	P=0.292	P=0.061	P=0.148	P=0.061
COCH-ARM / FISHERS	P=0.051	P=0.500	P=0.291	P=0.070	P=0.152	P=0.070
MAX-ISO-POLY-3	P=0.029*	P=0.274	P=0.136	P=0.020*	P=0.058	P=0.020*

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	100 PPM	1000 PPM	6000 PPM	12,000 PPM	24,000 PPM
Urinary Bladder Mineralization						
LESION RATES						
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	30%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	92 (T)	---	---	---	---	92 (T)
STATISTICAL TESTS						
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=0.398	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.310

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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.
 - (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 ***