

TDMS No. 93027 - 21
Test Type: 90-DAY
Route: DOSED FEED
Species/Strain: RATS/SD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Peroxisome project (Gemfibrozil)
CAS Number: 25812-30-0

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Time Report Requested: 13:51:32
First Dose M/F: 09/30/94 / NA
Lab: BAT

F1_Rev1_R8

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<=.05) RESULTS IN THE ANALYSIS OF PEROXISOME PROJECT (GEMFIBROZIL)

MALE RATS

Organ

Liver

Morphology

Cytoplasmic Alteration
Infiltration Cellular Mononuclear Cell
Inflammation Chronic
Necrosis

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 PPM	10 PPM	100 PPM	1000 PPM	8000 PPM	16,000 PPM
Kidney						
Nephropathy						
LESION RATES						
OVERALL (a)	8/10 (80%)	8/10 (80%)	9/10 (90%)	8/10 (80%)	9/10 (90%)	6/10 (60%)
POLY-3 RATE (b)	8/10.00	8/10.00	9/10.00	8/10.00	9/10.00	6/10.00
POLY-3 PERCENT (g)	80%	80%	90%	80%	90%	60%
TERMINAL (d)	8/10 (80%)	8/10 (80%)	9/10 (90%)	8/10 (80%)	9/10 (90%)	6/10 (60%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P=0.147N	P=0.702	P=0.500	P=0.702	P=0.500	P=0.318N
POLY 1.5	P=0.147N	P=0.702	P=0.500	P=0.702	P=0.500	P=0.318N
POLY 6	P=0.147N	P=0.702	P=0.500	P=0.702	P=0.500	P=0.318N
COCH-ARM / FISHERS	P=0.142N	P=0.709N	P=0.500	P=0.709N	P=0.500	P=0.314N
MAX-ISO-POLY-3	P=0.179N	P=1.000	P=0.274	P=1.000	P=0.274	P=0.171N

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TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 PPM	10 PPM	100 PPM	1000 PPM	8000 PPM	16,000 PPM
Liver						
Cytoplasmic Alteration						
LESION RATES						
OVERALL (a)	0/10 (0%)	7/10 (70%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	7/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	70%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	7/10 (70%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P=0.004**	P=0.002**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	(e)	(e)	(e)	(e)

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TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 PPM	10 PPM	100 PPM	1000 PPM	8000 PPM	16,000 PPM
Liver						
Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	3/10 (30%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	3/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	30%	0%	0%	0%	0%	0%
TERMINAL (d)	3/10 (30%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	P=0.175N	P=0.095N	P=0.095N	P=0.095N	P=0.095N	P=0.095N
POLY 1.5	P=0.175N	P=0.095N	P=0.095N	P=0.095N	P=0.095N	P=0.095N
POLY 6	P=0.175N	P=0.095N	P=0.095N	P=0.095N	P=0.095N	P=0.095N
COCH-ARM / FISHERS	P=0.199N	P=0.105N	P=0.105N	P=0.105N	P=0.105N	P=0.105N
MAX-ISO-POLY-3	P<0.001N**	P=0.024N*	P=0.024N*	P=0.024N*	P=0.024N*	P=0.024N*

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

DOSE	Males					
	0 PPM	10 PPM	100 PPM	1000 PPM	8000 PPM	16,000 PPM
Liver						
Inflammation Chronic						
LESION RATES						
OVERALL (a)	2/10 (20%)	2/10 (20%)	3/10 (30%)	2/10 (20%)	6/10 (60%)	4/10 (40%)
POLY-3 RATE (b)	2/10.00	2/10.00	3/10.00	2/10.00	6/10.00	4/10.00
POLY-3 PERCENT (g)	20%	20%	30%	20%	60%	40%
TERMINAL (d)	2/10 (20%)	2/10 (20%)	3/10 (30%)	2/10 (20%)	6/10 (60%)	4/10 (40%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P=0.077	P=0.702	P=0.500	P=0.702	P=0.077	P=0.318
POLY 1.5	P=0.077	P=0.702	P=0.500	P=0.702	P=0.077	P=0.318
POLY 6	P=0.077	P=0.702	P=0.500	P=0.702	P=0.077	P=0.318
COCH-ARM / FISHERS	P=0.077	P=0.709N	P=0.500	P=0.709N	P=0.085	P=0.314
MAX-ISO-POLY-3	P=0.141	P=1.000	P=0.310	P=1.000	P=0.029*	P=0.171

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TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 PPM	10 PPM	100 PPM	1000 PPM	8000 PPM	16,000 PPM
Liver						
Necrosis						
LESION RATES						
OVERALL (a)	2/10 (20%)	2/10 (20%)	2/10 (20%)	0/10 (0%)	4/10 (40%)	4/10 (40%)
POLY-3 RATE (b)	2/10.00	2/10.00	2/10.00	0/10.00	4/10.00	4/10.00
POLY-3 PERCENT (g)	20%	20%	20%	0%	40%	40%
TERMINAL (d)	2/10 (20%)	2/10 (20%)	2/10 (20%)	0/10 (0%)	4/10 (40%)	4/10 (40%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)	---	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P=0.043*	P=0.702	P=0.702	P=0.227N	P=0.318	P=0.318
POLY 1.5	P=0.043*	P=0.702	P=0.702	P=0.227N	P=0.318	P=0.318
POLY 6	P=0.043*	P=0.702	P=0.702	P=0.227N	P=0.318	P=0.318
COCH-ARM / FISHERS	P=0.044*	P=0.709N	P=0.709N	P=0.237N	P=0.314	P=0.314
MAX-ISO-POLY-3	P=0.081	P=1.000	P=1.000	P=0.067N	P=0.171	P=0.171

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TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 PPM	10 PPM	100 PPM	1000 PPM	8000 PPM	16,000 PPM
Lung Hemorrhage						
LESION RATES						
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227N
COCH-ARM / FISHERS	P=0.132N	(e)	(e)	(e)	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.067N

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TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 PPM	10 PPM	100 PPM	1000 PPM	8000 PPM	16,000 PPM
Preputial Gland Inflammation Chronic						
LESION RATES						
OVERALL (a)	8/9 (89%)	9/10 (90%)	10/10 (100%)	10/10 (100%)	9/10 (90%)	8/9 (89%)
POLY-3 RATE (b)	8/9.00	9/10.00	10/10.00	10/10.00	9/10.00	8/9.00
POLY-3 PERCENT (g)	88.9%	90%	100%	100%	90%	88.9%
TERMINAL (d)	8/9 (89%)	9/10 (90%)	10/10 (100%)	10/10 (100%)	9/10 (90%)	8/9 (89%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P=0.373N	P=0.737	P=0.479	P=0.479	P=0.737	P=0.760
POLY 1.5	P=0.373N	P=0.737	P=0.479	P=0.479	P=0.737	P=0.760
POLY 6	P=0.373N	P=0.737	P=0.479	P=0.479	P=0.737	P=0.760
COCH-ARM / FISHERS	P=0.369N	P=0.737	P=0.474	P=0.474	P=0.737	P=0.765N
MAX-ISO-POLY-3	P=0.574N	P=0.470	P=0.150	P=0.150	P=0.470	P=1.000

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TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 PPM	10 PPM	100 PPM	1000 PPM	8000 PPM	16,000 PPM
Stomach, Glandular Mineralization						
LESION RATES						
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	1/1.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	20%	0%	0%	100%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---	---	92 (T)	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	P=0.286	(e)	P=0.227N
POLY 1.5	(e)	(e)	(e)	P=0.286	(e)	P=0.227N
POLY 6	(e)	(e)	(e)	P=0.286	(e)	P=0.227N
COCH-ARM / FISHERS	P=0.079N	(e)	(e)	P=0.273	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.090	(e)	P=0.067N

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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 ***