

**TDMS No.** 93027 - 24  
**Test Type:** 90-DAY  
**Route:** DOSED FEED  
**Species/Strain:** MICE/B6C3F1

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

Peroxisome project (Gemfibrozil)

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

**Date Report Requested:** 06/24/2009

**Time Report Requested:** 13:51:51

**First Dose M/F:** 10/14/94 / NA

**Lab:** BAT

F1\_Rev1\_M3

**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

**TDMS No.** 93027 - 24  
**Test Type:** 90-DAY  
**Route:** DOSED FEED  
**Species/Strain:** MICE/B6C3F1

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

**Date Report Requested:** 06/24/2009  
**Time Report Requested:** 13:51:51  
**First Dose M/F:** 10/14/94 / NA  
**Lab:** BAT

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

**MALE MICE**

**Organ**

Liver  
Preputial Gland

**Morphology**

Cytoplasmic Alteration  
Inflammation Chronic

TDMS No. 93027 - 24  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 06/24/2009  
 Time Report Requested: 13:51:51  
 First Dose M/F: 10/14/94 / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)**  
**TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	10 PPM	100 PPM	1000 PPM	4000 PPM	8000 PPM
<b>Kidney</b>						
<b>Nephropathy</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	2/10 (20%)	2/10 (20%)
<b>POLY-3 RATE (b)</b>	1/10.00	0/10.00	0/10.00	1/10.00	2/10.00	2/10.00
<b>POLY-3 PERCENT (g)</b>	10%	0%	0%	10%	20%	20%
<b>TERMINAL (d)</b>	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	2/10 (20%)	2/10 (20%)
<b>FIRST INCIDENCE</b>	92 (T)	---	---	92 (T)	92 (T)	92 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.078	P=0.500N	P=0.500N	P=0.760	P=0.500	P=0.500
<b>POLY 1.5</b>	P=0.078	P=0.500N	P=0.500N	P=0.760	P=0.500	P=0.500
<b>POLY 6</b>	P=0.078	P=0.500N	P=0.500N	P=0.760	P=0.500	P=0.500
<b>COCH-ARM / FISHERS</b>	P=0.075	P=0.500N	P=0.500N	P=0.763N	P=0.500	P=0.500
<b>MAX-ISO-POLY-3</b>	P=0.146	P=0.158N	P=0.158N	P=1.000	P=0.274	P=0.274

TDMS No. 93027 - 24  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 06/24/2009  
 Time Report Requested: 13:51:51  
 First Dose M/F: 10/14/94 / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)**  
**TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	10 PPM	100 PPM	1000 PPM	4000 PPM	8000 PPM
<b>Liver</b>						
<b>Cytoplasmic Alteration</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/10 (0%)	0/10 (0%)	0/10 (0%)	7/10 (70%)	10/10 (100%)	10/10 (100%)
<b>POLY-3 RATE (b)</b>	0/10.00	0/10.00	0/10.00	7/10.00	10/10.00	10/10.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	0%	70%	100%	100%
<b>TERMINAL (d)</b>	0/10 (0%)	0/10 (0%)	0/10 (0%)	7/10 (70%)	10/10 (100%)	10/10 (100%)
<b>FIRST INCIDENCE</b>	---	---	---	92 (T)	92 (T)	92 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P<0.001**	(e)	(e)	P<0.001**	P<0.001**	P<0.001**
<b>POLY 1.5</b>	P<0.001**	(e)	(e)	P<0.001**	P<0.001**	P<0.001**
<b>POLY 6</b>	P<0.001**	(e)	(e)	P<0.001**	P<0.001**	P<0.001**
<b>COCH-ARM / FISHERS</b>	P<0.001**	(e)	(e)	P=0.002**	P<0.001**	P<0.001**
<b>MAX-ISO-POLY-3</b>	P<0.001**	(e)	(e)	P<0.001**	(e)	(e)

TDMS No. 93027 - 24  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 06/24/2009  
 Time Report Requested: 13:51:51  
 First Dose M/F: 10/14/94 / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	10 PPM	100 PPM	1000 PPM	4000 PPM	8000 PPM
<b>Preputial Gland 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=0.019*	(e)	(e)	(e)	P=0.158	P=0.067

TDMS No. 93027 - 24  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: MICE/B6C3F1

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

Date Report Requested: 06/24/2009  
Time Report Requested: 13:51:51  
First Dose M/F: 10/14/94 / NA  
Lab: BAT

## 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 \*\*\*