

**TDMS No.** 93027 - 14  
**Test Type:** 90-DAY  
**Route:** DOSED FEED  
**Species/Strain:** MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
Peroxisome project (Dibutyl phthalate)  
**CAS Number:** 84-74-2

**Date Report Requested:** 06/24/2009  
**Time Report Requested:** 13:50:21  
**First Dose M/F:** 09/22/94 / NA  
**Lab:** BAT

F1\_Rev1\_M3

**C Number:** C93027A  
**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 - 14  
**Test Type:** 90-DAY  
**Route:** DOSED FEED  
**Species/Strain:** MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
Peroxisome project (Dibutyl phthalate)  
**CAS Number:** 84-74-2

**Date Report Requested:** 06/24/2009  
**Time Report Requested:** 13:50:21  
**First Dose M/F:** 09/22/94 / NA  
**Lab:** BAT

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

**MALE MICE**

**Organ**

Liver

**Morphology**

Cytoplasmic Alteration

TDMS No. 93027 - 14  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Peroxisome project (Dibutyl phthalate)  
 CAS Number: 84-74-2

Date Report Requested: 06/24/2009  
 Time Report Requested: 13:50:21  
 First Dose M/F: 09/22/94 / NA  
 Lab: BAT

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

DOSE	Males					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
<b>Kidney</b>						
<b>Nephropathy</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	2/10 (20%)	1/10 (10%)	0/10 (0%)	2/10 (20%)	1/10 (10%)	1/10 (10%)
<b>POLY-3 RATE (b)</b>	2/10.00	1/10.00	0/10.00	2/10.00	1/10.00	1/10.00
<b>POLY-3 PERCENT (g)</b>	20%	10%	0%	20%	10%	10%
<b>TERMINAL (d)</b>	2/10 (20%)	1/10 (10%)	0/10 (0%)	2/10 (20%)	1/10 (10%)	1/10 (10%)
<b>FIRST INCIDENCE</b>	92 (T)	92 (T)	---	92 (T)	92 (T)	92 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.524N	P=0.500N	P=0.227N	P=0.702	P=0.500N	P=0.500N
<b>POLY 1.5</b>	P=0.524N	P=0.500N	P=0.227N	P=0.702	P=0.500N	P=0.500N
<b>POLY 6</b>	P=0.524N	P=0.500N	P=0.227N	P=0.702	P=0.500N	P=0.500N
<b>COCH-ARM / FISHERS</b>	P=0.525N	P=0.500N	P=0.237N	P=0.709N	P=0.500N	P=0.500N
<b>MAX-ISO-POLY-3</b>	P=0.458N	P=0.274N	P=0.067N	P=1.000	P=0.274N	P=0.274N

TDMS No. 93027 - 14  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Peroxisome project (Dibutyl phthalate)  
 CAS Number: 84-74-2

Date Report Requested: 06/24/2009  
 Time Report Requested: 13:50:21  
 First Dose M/F: 09/22/94 / NA  
 Lab: BAT

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

DOSE	Males					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 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%)	0/10 (0%)	2/10 (20%)	10/10 (100%)
<b>POLY-3 RATE (b)</b>	0/10.00	0/10.00	0/10.00	0/10.00	2/10.00	10/10.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	0%	0%	20%	100%
<b>TERMINAL (d)</b>	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	10/10 (100%)
<b>FIRST INCIDENCE</b>	---	---	---	---	92 (T)	92 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P<0.001**	(e)	(e)	(e)	P=0.227	P<0.001**
<b>POLY 1.5</b>	P<0.001**	(e)	(e)	(e)	P=0.227	P<0.001**
<b>POLY 6</b>	P<0.001**	(e)	(e)	(e)	P=0.227	P<0.001**
<b>COCH-ARM / FISHERS</b>	P<0.001**	(e)	(e)	(e)	P=0.237	P<0.001**
<b>MAX-ISO-POLY-3</b>	P<0.001**	(e)	(e)	(e)	P=0.067	(e)

TDMS No. 93027 - 14  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Peroxisome project (Dibutyl phthalate)  
 CAS Number: 84-74-2

Date Report Requested: 06/24/2009  
 Time Report Requested: 13:50:21  
 First Dose M/F: 09/22/94 / NA  
 Lab: BAT

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

DOSE	Males					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
<b>Liver</b>						
<b>Infiltration Cellular Mixed Cell</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	2/10 (20%)	1/10 (10%)	2/10 (20%)	1/10 (10%)	3/10 (30%)	4/10 (40%)
<b>POLY-3 RATE (b)</b>	2/10.00	1/10.00	2/10.00	1/10.00	3/10.00	4/10.00
<b>POLY-3 PERCENT (g)</b>	20%	10%	20%	10%	30%	40%
<b>TERMINAL (d)</b>	2/10 (20%)	1/10 (10%)	2/10 (20%)	1/10 (10%)	3/10 (30%)	4/10 (40%)
<b>FIRST INCIDENCE</b>	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.073	P=0.500N	P=0.702	P=0.500N	P=0.500	P=0.318
<b>POLY 1.5</b>	P=0.073	P=0.500N	P=0.702	P=0.500N	P=0.500	P=0.318
<b>POLY 6</b>	P=0.073	P=0.500N	P=0.702	P=0.500N	P=0.500	P=0.318
<b>COCH-ARM / FISHERS</b>	P=0.069	P=0.500N	P=0.709N	P=0.500N	P=0.500	P=0.314
<b>MAX-ISO-POLY-3</b>	P=0.132	P=0.274N	P=1.000	P=0.274N	P=0.310	P=0.171

TDMS No. 93027 - 14  
Test Type: 90-DAY  
Route: DOSED FEED  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Peroxisome project (Dibutyl phthalate)  
CAS Number: 84-74-2

Date Report Requested: 06/24/2009  
Time Report Requested: 13:50:21  
First Dose M/F: 09/22/94 / 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 \*\*\*