

**Experiment Number:** 93027-17  
**Test Type:** 90-DAY  
**Route:** DOSED FEED  
**Species/Strain:** HAMSTERS/SYRIAN

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

**Test Compound:** Peroxisome project (Dibutyl phthalate)

**CAS Number:** 84-74-2

**Date Report Requested:** 10/22/2014

**Time Report Requested:** 03:51:44

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

**Lab:** BAT

**C Number:** C93027A  
**Lock Date:** 06/12/1996  
**Cage Range:** All  
**Date Range:** All  
**Reasons For Removal:** All  
**Removal Date Range:** All  
**Treatment Groups:** All  
**Study Gender:** Male  
**PWG Approval Date:** NONE

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

**MALE HAMSTERS**

**Organ**

Pancreas

Testes

**Morphology**

Inflammation Chronic

Atrophy

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

DOSE	MALE					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
<b>Epididymis Degeneration</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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 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
<b>Gallbladder</b>						
<b>Infiltration Cellular Mixed Cell</b>						
<b>LESION RATES</b>						
OVERALL(a)	8/10 (80%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	8/10 (80%)
POLY-3 RATE (b)	8/10.00	0/0.00	0/0.00	0/0.00	0/0.00	8/10.00
POLY-3 PERCENT (g)	80%	0%	0%	0%	0%	80%
TERMINAL (d)	8/10 (80%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	8/10 (80%)
FIRST INCIDENCE	92(T)	---	---	---	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.702
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.702
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.702
COCH-ARM / FISHERS	P=0.610	(e)	(e)	(e)	(e)	P=0.709N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=1.000
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 HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
<b>Kidney Mineralization</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	10%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	92(T)	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.476N	P=0.500	(e)	(e)	(e)	(e)
POLY 1.5	P=0.476N	P=0.500	(e)	(e)	(e)	(e)
POLY 6	P=0.476N	P=0.500	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.476N	P=0.500	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.356N	P=0.159	(e)	(e)	(e)	(e)
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**

Test Compound: Peroxisome project (Dibutyl phthalate)

CAS Number: 84-74-2

Date Report Requested: 10/22/2014

Time Report Requested: 03:51:44

First Dose M/F: NA / NA

Lab: BAT

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

DOSE	MALE					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
<b>Kidney</b>						
<b>Nephropathy</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	2/10 (20%)	0/10 (0%)	4/10 (40%)	2/10 (20%)	2/10 (20%)
POLY-3 RATE (b)	1/10.00	2/10.00	0/10.00	4/10.00	2/10.00	2/10.00
POLY-3 PERCENT (g)	10%	20%	0%	40%	20%	20%
TERMINAL (d)	1/10 (10%)	2/10 (20%)	0/10 (0%)	4/10 (40%)	2/10 (20%)	2/10 (20%)
FIRST INCIDENCE	92(T)	92(T)	---	92(T)	92(T)	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.378	P=0.500	P=0.500N	P=0.148	P=0.500	P=0.500
POLY 1.5	P=0.378	P=0.500	P=0.500N	P=0.148	P=0.500	P=0.500
POLY 6	P=0.378	P=0.500	P=0.500N	P=0.148	P=0.500	P=0.500
COCH-ARM / FISHERS	P=0.378	P=0.500	P=0.500N	P=0.152	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.308	P=0.274	P=0.159N	P=0.059	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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First Dose M/F: NA / NA

Lab: BAT

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

DOSE	MALE					
	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>						
OVERALL(a)	9/10 (90%)	8/10 (80%)	9/10 (90%)	9/10 (90%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	9/10.00	8/10.00	9/10.00	9/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	90%	80%	90%	90%	100%	100%
TERMINAL (d)	9/10 (90%)	8/10 (80%)	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)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.122	P=0.500N	P=0.760	P=0.760	P=0.500	P=0.500
POLY 1.5	P=0.122	P=0.500N	P=0.760	P=0.760	P=0.500	P=0.500
POLY 6	P=0.122	P=0.500N	P=0.760	P=0.760	P=0.500	P=0.500
COCH-ARM / FISHERS	P=0.117	P=0.500N	P=0.763N	P=0.763N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.215	P=0.274N	P=1.000	P=1.000	P=0.159	P=0.159
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 HAMSTERS(SYRIAN)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
<b>Lung Hemorrhage</b>						
<b>LESION RATES</b>						
OVERALL(a)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
POLY-3 RATE (b)	4/10.00	0/0.00	0/0.00	0/0.00	0/0.00	4/10.00
POLY-3 PERCENT (g)	40%	0%	0%	0%	0%	40%
TERMINAL (d)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
FIRST INCIDENCE	92(T)	---	---	---	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.667
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.667
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.667
COCH-ARM / FISHERS	P=0.590	(e)	(e)	(e)	(e)	P=0.675N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=1.000
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



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First Dose M/F: NA / NA

Lab: BAT

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

DOSE	MALE					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
<b>Pancreas</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	5/10 (50%)	5/10 (50%)	5/10 (50%)	8/10 (80%)	7/10 (70%)	10/10 (100%)
POLY-3 RATE (b)	5/10.00	5/10.00	5/10.00	8/10.00	7/10.00	10/10.00
POLY-3 PERCENT (g)	50%	50%	50%	80%	70%	100%
TERMINAL (d)	5/10 (50%)	5/10 (50%)	5/10 (50%)	8/10 (80%)	7/10 (70%)	10/10 (100%)
FIRST INCIDENCE	92(T)	92(T)	92(T)	92(T)	92(T)	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.003**	P=0.664	P=0.664	P=0.174	P=0.329	P=0.008**
POLY 1.5	P=0.003**	P=0.664	P=0.664	P=0.174	P=0.329	P=0.008**
POLY 6	P=0.003**	P=0.664	P=0.664	P=0.174	P=0.329	P=0.008**
COCH-ARM / FISHERS	P=0.004**	P=0.672N	P=0.672N	P=0.175	P=0.325	P=0.016*
MAX-ISO-POLY-3	P=0.006**	P=1.000	P=1.000	P=0.080	P=0.189	P<0.001**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
<b>Testes</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	3/10 (30%)	3/10 (30%)	1/10 (10%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	3/10.00	3/10.00	1/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	30%	30%	10%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	3/10 (30%)	3/10 (30%)	1/10 (10%)	1/10 (10%)
FIRST INCIDENCE	---	---	92(T)	92(T)	92(T)	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.585	(e)	P=0.095	P=0.095	P=0.500	P=0.500
POLY 1.5	P=0.585	(e)	P=0.095	P=0.095	P=0.500	P=0.500
POLY 6	P=0.585	(e)	P=0.095	P=0.095	P=0.500	P=0.500
COCH-ARM / FISHERS	P=0.584	(e)	P=0.105	P=0.105	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.164	(e)	P=0.025*	P=0.025*	P=0.159	P=0.159
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 \*\***