

TDMS No. 93027 - 17
Test Type: 90-DAY
Route: DOSED FEED
Species/Strain: HAMSTERS/SYRIAN

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: 13:50:49
First Dose M/F: 09/08/94 / NA
Lab: BAT

F1_Rev1_H1

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

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

MALE HAMSTERS

Organ

Pancreas

Testes

Morphology

Inflammation Chronic

Atrophy

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

DOSE	Males					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
Gallbladder						
Infiltration Cellular Mixed Cell						
LESION RATES						
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)
STATISTICAL TESTS						
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

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
Kidney						
Nephropathy						
LESION RATES						
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)
STATISTICAL TESTS						
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=0.158N	P=0.059	P=0.274	P=0.274

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

DOSE	Males					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
Liver						
Infiltration Cellular Mixed Cell						
LESION RATES						
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)
STATISTICAL TESTS						
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=0.214	P=0.274N	P=1.000	P=1.000	P=0.158	P=0.158

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
Lung Hemorrhage						
LESION RATES						
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)
STATISTICAL TESTS						
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

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
Pancreas						
Inflammation Chronic						
LESION RATES						
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)
STATISTICAL TESTS						
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=0.079	P=0.187	P=0.002**

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DOSE	Males					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
Testes						
Atrophy						
LESION RATES						
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)
STATISTICAL TESTS						
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=0.024*	P=0.024*	P=0.158	P=0.158

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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 ***