

TDMS No. 93027 - 11
Test Type: 90-DAY
Route: DOSED FEED
Species/Strain: RATS/SD

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: 13:49:06
First Dose M/F: 09/15/94 / NA
Lab: BAT

F1_Rev1_R8

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 RATS

Organ

Kidney
Liver
Preputial Gland
Testes

Morphology

Nephropathy
Cytoplasmic Alteration
Inflammation Chronic
Atrophy

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)
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)	9/10 (90%)	7/10 (70%)	9/10 (90%)	5/10 (50%)	6/10 (60%)	7/10 (70%)
POLY-3 RATE (b)	9/10.00	7/10.00	9/10.00	5/10.00	6/10.00	7/10.00
POLY-3 PERCENT (g)	90%	70%	90%	50%	60%	70%
TERMINAL (d)	9/10 (90%)	7/10 (70%)	9/10 (90%)	5/10 (50%)	6/10 (60%)	7/10 (70%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P=0.247N	P=0.292N	P=0.760	P=0.061N	P=0.148N	P=0.292N
POLY 1.5	P=0.247N	P=0.292N	P=0.760	P=0.061N	P=0.148N	P=0.292N
POLY 6	P=0.247N	P=0.292N	P=0.760	P=0.061N	P=0.148N	P=0.292N
COCH-ARM / FISHERS	P=0.248N	P=0.291N	P=0.763N	P=0.070N	P=0.152N	P=0.291N
MAX-ISO-POLY-3	P=0.122N	P=0.135N	P=1.000	P=0.020N*	P=0.059N	P=0.135N

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DOSE	Males					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
Liver						
Cytoplasmic Alteration						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	---	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

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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
Liver						
Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	5/10 (50%)	4/10 (40%)	7/10 (70%)	4/10 (40%)	4/10 (40%)	6/10 (60%)
POLY-3 RATE (b)	5/10.00	4/10.00	7/10.00	4/10.00	4/10.00	6/10.00
POLY-3 PERCENT (g)	50%	40%	70%	40%	40%	60%
TERMINAL (d)	5/10 (50%)	4/10 (40%)	7/10 (70%)	4/10 (40%)	4/10 (40%)	6/10 (60%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P=0.442	P=0.500N	P=0.329	P=0.500N	P=0.500N	P=0.500
POLY 1.5	P=0.442	P=0.500N	P=0.329	P=0.500N	P=0.500N	P=0.500
POLY 6	P=0.442	P=0.500N	P=0.329	P=0.500N	P=0.500N	P=0.500
COCH-ARM / FISHERS	P=0.440	P=0.500N	P=0.325	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.471	P=0.334N	P=0.187	P=0.334N	P=0.334N	P=0.334

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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
Preputial Gland Inflammation Chronic						
LESION RATES						
OVERALL (a)	10/10 (100%)	7/10 (70%)	8/10 (80%)	9/10 (90%)	9/10 (90%)	10/10 (100%)
POLY-3 RATE (b)	10/10.00	7/10.00	8/10.00	9/10.00	9/10.00	10/10.00
POLY-3 PERCENT (g)	100%	70%	80%	90%	90%	100%
TERMINAL (d)	10/10 (100%)	7/10 (70%)	8/10 (80%)	9/10 (90%)	9/10 (90%)	10/10 (100%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P=0.160	P=0.095N	P=0.227N	P=0.500N	P=0.500N	(e)
POLY 1.5	P=0.160	P=0.095N	P=0.227N	P=0.500N	P=0.500N	(e)
POLY 6	P=0.160	P=0.095N	P=0.227N	P=0.500N	P=0.500N	(e)
COCH-ARM / FISHERS	P=0.162	P=0.105N	P=0.237N	P=0.500N	P=0.500N	(e)
MAX-ISO-POLY-3	P=0.222	P=0.024N*	P=0.067N	P=0.158N	P=0.158N	(e)

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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
Testes Atrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	1/10 (10%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	1/10.00	1/10.00	0/10.00	1/10.00	3/10.00
POLY-3 PERCENT (g)	0%	10%	10%	0%	10%	30%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	1/10 (10%)	3/10 (30%)
FIRST INCIDENCE	---	92 (T)	92 (T)	---	92 (T)	92 (T)
STATISTICAL TESTS						
POLY 3	P=0.030*	P=0.500	P=0.500	(e)	P=0.500	P=0.095
POLY 1.5	P=0.030*	P=0.500	P=0.500	(e)	P=0.500	P=0.095
POLY 6	P=0.030*	P=0.500	P=0.500	(e)	P=0.500	P=0.095
COCH-ARM / FISHERS	P=0.031*	P=0.500	P=0.500	(e)	P=0.500	P=0.105
MAX-ISO-POLY-3	P=0.022*	P=0.158	P=0.158	(e)	P=0.158	P=0.024*

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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 ***