

Experiment Number: 93027-11
Test Type: 90-DAY
Route: DOSED FEED
Species/Strain: Rat/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Peroxisome project (Dibutyl phthalate)

CAS Number: 84-74-2

Date Report Requested: 10/23/2014

Time Report Requested: 06:15:38

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 RAT

Organ

Kidney

Liver

Preputial Gland

Testes

Morphology

Nephropathy

Cytoplasmic Alteration

Inflammation Chronic

Atrophy

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(HSD)
LAST REMOVAL AT 14286 WEEKS

DOSE	MALE					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
Adrenal Cortex Hypertrophy						
LESION RATES						
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)
STATISTICAL TESTS						
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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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(HSD)
LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
Heart						
Infiltration Cellular Mononuclear CI						
LESION RATES						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	92(T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159N
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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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(HSD)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	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=0.123N	P=0.138N	P=1.000	P=0.020N*	P=0.059N	P=0.138N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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Test Type: 90-DAY

Route: DOSED FEED

Species/Strain: Rat/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Peroxisome project (Dibutyl phthalate)

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First Dose M/F: NA / NA

Lab: BAT

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

DOSE	MALE					
	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=0.000**	(e)	(e)	(e)	P=NA	P=NA
POLY 1.5	P=0.000**	(e)	(e)	(e)	P=NA	P=NA
POLY 6	P=0.000**	(e)	(e)	(e)	P=NA	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	(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

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First Dose M/F: NA / NA

Lab: BAT

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

DOSE	MALE					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
Liver						
Infiltration Cellular Mononuclear CI						
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=0.470	P=0.334N	P=0.189	P=0.334N	P=0.334N	P=0.334
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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Test Type: 90-DAY

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Species/Strain: Rat/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Peroxisome project (Dibutyl phthalate)

CAS Number: 84-74-2

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First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(HSD)
LAST REMOVAL AT 14286 WEEKS

DOSE	MALE					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
Liver						
Necrosis						
LESION RATES						
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)	---	---	---	---
STATISTICAL TESTS						
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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First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(HSD)
LAST REMOVAL AT 14286 WEEKS

DOSE	MALE					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
Lung						
Hemorrhage Focal						
LESION RATES						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	10%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	92(T)	---	---	---	---	92(T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.760
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.760
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.760
COCH-ARM / FISHERS	P=0.645	(e)	(e)	(e)	(e)	P=0.763N
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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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(HSD)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
Pancreas						
Atrophy Focal						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	1/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	10%	10%	10%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	---	92(T)	92(T)	92(T)	---
STATISTICAL TESTS						
POLY 3	P=0.607N	(e)	P=0.500	P=0.500	P=0.500	(e)
POLY 1.5	P=0.607N	(e)	P=0.500	P=0.500	P=0.500	(e)
POLY 6	P=0.607N	(e)	P=0.500	P=0.500	P=0.500	(e)
COCH-ARM / FISHERS	P=0.610N	(e)	P=0.500	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.416	(e)	P=0.159	P=0.159	P=0.159	(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

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First Dose M/F: NA / NA

Lab: BAT

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

DOSE	MALE					
	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=0.223	P=0.025N*	P=0.067N	P=0.159N	P=0.159N	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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Species/Strain: Rat/HSD

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 RAT(HSD)
LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	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=0.021*	P=0.159	P=0.159	(e)	P=0.159	P=0.025*
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 ****