

Experiment Number: 93027-14
Test Type: 90-DAY
Route: DOSED FEED
Species/Strain: Mouse/B6C3F1

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: 02:11:38

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 MOUSE

Organ

Liver

Morphology

Cytoplasmic Alteration

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 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)	2/10 (20%)	1/10 (10%)	0/10 (0%)	2/10 (20%)	1/10 (10%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	1/10.00	0/10.00	2/10.00	1/10.00	1/10.00
POLY-3 PERCENT (g)	20%	10%	0%	20%	10%	10%
TERMINAL (d)	2/10 (20%)	1/10 (10%)	0/10 (0%)	2/10 (20%)	1/10 (10%)	1/10 (10%)
FIRST INCIDENCE	92(T)	92(T)	---	92(T)	92(T)	92(T)
STATISTICAL TESTS						
POLY 3	P=0.524N	P=0.500N	P=0.227N	P=0.702	P=0.500N	P=0.500N
POLY 1.5	P=0.524N	P=0.500N	P=0.227N	P=0.702	P=0.500N	P=0.500N
POLY 6	P=0.524N	P=0.500N	P=0.227N	P=0.702	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.525N	P=0.500N	P=0.237N	P=0.709N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.457N	P=0.274N	P=0.067N	P=1.000	P=0.274N	P=0.274N
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 MOUSE(B6C3F1)
 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%)	2/10 (20%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	2/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	20%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	---	92(T)	92(T)
STATISTICAL TESTS						
POLY 3	P=0.000**	(e)	(e)	(e)	P=0.227	P=NA
POLY 1.5	P=0.000**	(e)	(e)	(e)	P=0.227	P=NA
POLY 6	P=0.000**	(e)	(e)	(e)	P=0.227	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	P=0.237	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	(e)	P=0.067	(e)
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 MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	1000 PPM	2500 PPM	5000 PPM	10,000 PPM	20,000 PPM
Liver						
Infiltration Cellular Mixed Cell						
LESION RATES						
OVERALL(a)	2/10 (20%)	1/10 (10%)	2/10 (20%)	1/10 (10%)	3/10 (30%)	4/10 (40%)
POLY-3 RATE (b)	2/10.00	1/10.00	2/10.00	1/10.00	3/10.00	4/10.00
POLY-3 PERCENT (g)	20%	10%	20%	10%	30%	40%
TERMINAL (d)	2/10 (20%)	1/10 (10%)	2/10 (20%)	1/10 (10%)	3/10 (30%)	4/10 (40%)
FIRST INCIDENCE	92(T)	92(T)	92(T)	92(T)	92(T)	92(T)
STATISTICAL TESTS						
POLY 3	P=0.073	P=0.500N	P=0.702	P=0.500N	P=0.500	P=0.318
POLY 1.5	P=0.073	P=0.500N	P=0.702	P=0.500N	P=0.500	P=0.318
POLY 6	P=0.073	P=0.500N	P=0.702	P=0.500N	P=0.500	P=0.318
COCH-ARM / FISHERS	P=0.069	P=0.500N	P=0.709N	P=0.500N	P=0.500	P=0.314
MAX-ISO-POLY-3	P=0.132	P=0.274N	P=1.000	P=0.274N	P=0.311	P=0.172
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 MOUSE(B6C3F1)
 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)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	92(T)	---	---	92(T)
STATISTICAL TESTS						
POLY 3	P=0.316	(e)	P=0.500	(e)	(e)	P=0.500
POLY 1.5	P=0.316	(e)	P=0.500	(e)	(e)	P=0.500
POLY 6	P=0.316	(e)	P=0.500	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.313	(e)	P=0.500	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.202	(e)	P=0.159	(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 MOUSE(B6C3F1)
 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)	0/10 (0%)	0/7 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/7.00	0/10.00	1/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	0%	0%
TERMINAL (d)	0/10 (0%)	0/7 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	92(T)	---	---
STATISTICAL TESTS						
POLY 3	P=0.682N	(e)	(e)	P=0.500	(e)	(e)
POLY 1.5	P=0.682N	(e)	(e)	P=0.500	(e)	(e)
POLY 6	P=0.682N	(e)	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.684N	(e)	(e)	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.523	(e)	(e)	P=0.159	(e)	(e)
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
Thyroid Gland						
Infiltration Cellular Lymphocyte						
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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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 ****