

TDMS No. 20320 - 02
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Tetrabromobisphenol A
CAS Number: 79-94-7

Date Report Reqsted: 11/07/2007
Time Report Reqsted: 14:48:44
First Dose M/F: 12/15/05 / 12/14/05
Lab: BAT

F1_M3

C Number: C20320
Lock Date: 10/16/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
TDMSE Version: 1.9.1

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF Tetrabromobisphenol A

MALE MICE

Organ

Kidney: Renal Tubule

Morphology

Cytoplasmic Alteration

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	10 mg/kg	50 mg/kg	100 mg/kg	500 mg/kg	1000 mg/kg

**Kidney
 Casts Protein**

LESION RATES

OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	2/10 (20%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	1/10.00	1/10.00	2/10.00
POLY-3 PERCENT (g)	10%	0%	0%	10%	10%	20%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	2/10 (20%)
FIRST INCIDENCE	93 (T)	---	---	93 (T)	93 (T)	93 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.111	P=0.500N	P=0.500N	P=0.766	P=0.766	P=0.500
POLY 3	P=0.113	P=0.500N	P=0.500N	P=0.760	P=0.760	P=0.500
POLY 1.5	P=0.113	P=0.500N	P=0.500N	P=0.760	P=0.760	P=0.500
POLY 6	P=0.113	P=0.500N	P=0.500N	P=0.760	P=0.760	P=0.500
LOGISTIC REGRESSION	P=0.111	(e)	(e)	P=0.766	P=0.766	P=0.500
COCH-ARM / FISHERS	P=0.109	P=0.500N	P=0.500N	P=0.763N	P=0.763N	P=0.500
ORDER RESTRICTED	P=0.159	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.175	(e)	(e)	(e)	(e)	(e)

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DOSE	Males					
	0 mg/kg	10 mg/kg	50 mg/kg	100 mg/kg	500 mg/kg	1000 mg/kg

**Kidney: Renal Tubule
 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	---	---	---	---	93 (T)	93 (T)

STATISTICAL TESTS

LIFE TABLE	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
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**
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	10 mg/kg	50 mg/kg	100 mg/kg	500 mg/kg	1000 mg/kg

**Kidney: Renal Tubule
 Regeneration**

LESION RATES

OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	1/10 (10%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	2/10.00	1/10.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	20%	10%	10%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	1/10 (10%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	---	---	93 (T)	93 (T)	93 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.466	P=0.500N	P=0.500N	P=0.500	P=0.766	P=0.766
POLY 3	P=0.467	P=0.500N	P=0.500N	P=0.500	P=0.760	P=0.760
POLY 1.5	P=0.467	P=0.500N	P=0.500N	P=0.500	P=0.760	P=0.760
POLY 6	P=0.467	P=0.500N	P=0.500N	P=0.500	P=0.760	P=0.760
LOGISTIC REGRESSION	P=0.466	(e)	(e)	P=0.500	P=0.766	P=0.766
COCH-ARM / FISHERS	P=0.466	P=0.500N	P=0.500N	P=0.500	P=0.763N	P=0.763N
ORDER RESTRICTED	P=0.393	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.399	(e)	(e)	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	10 mg/kg	50 mg/kg	100 mg/kg	500 mg/kg	1000 mg/kg

**Kidney
 Casts Protein**

LESION RATES

OVERALL (a)	1/10 (10%)	2/10 (20%)	1/10 (10%)	3/10 (30%)	2/10 (20%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	2/10.00	1/10.00	3/10.00	2/10.00	0/10.00
POLY-3 PERCENT (g)	10%	20%	10%	30%	20%	0%
TERMINAL (d)	1/10 (10%)	2/10 (20%)	1/10 (10%)	3/10 (30%)	2/10 (20%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.197N	P=0.500	P=0.766	P=0.293	P=0.500	P=0.500N
POLY 3	P=0.199N	P=0.500	P=0.760	P=0.292	P=0.500	P=0.500N
POLY 1.5	P=0.199N	P=0.500	P=0.760	P=0.292	P=0.500	P=0.500N
POLY 6	P=0.199N	P=0.500	P=0.760	P=0.292	P=0.500	P=0.500N
LOGISTIC REGRESSION	P=0.197N	P=0.500	P=0.766	P=0.293	P=0.500	(e)
COCH-ARM / FISHERS	P=0.195N	P=0.500	P=0.763N	P=0.291	P=0.500	P=0.500N
ORDER RESTRICTED	P=0.236N	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.250N	(e)	(e)	(e)	(e)	(e)

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DOSE	Females					
	0 mg/kg	10 mg/kg	50 mg/kg	100 mg/kg	500 mg/kg	1000 mg/kg

**Kidney: Renal Tubule
 Cytoplasmic Alteration**

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---

STATISTICAL TESTS

LIFE TABLE	(e)	(e)	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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**Kidney: Renal Tubule
 Regeneration**

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---

STATISTICAL TESTS

LIFE TABLE	(e)	(e)	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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.
 - (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. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death.
 - (e) Value of Statistic cannot be computed.
 - (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
- Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors.
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***