

TDMS No. 20321 - 02
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Tetrabromobisphenol A-bis(2,3-dibromopropyl ether)

CAS Number: 21850-44-2

Date Report Reqsted: 12/28/2007

Time Report Reqsted: 13:02:03

First Dose M/F: 01/12/06 / 01/11/06

Lab: BAT

F1_M3

C Number: C20321
Lock Date: 01/05/2007
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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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Males | | | | | |
|------|---------|-----------|-----------|-----------|------------|------------|
| | 0 mg/kg | 125 mg/kg | 250 mg.kg | 500 mg/kg | 1000 mg/kg | 2000 mg/kg |

**Kidney
 Infiltration Cellular Mononuclear Cell**

LESION RATES

| | | | | | | |
|--------------------|------------|----------|----------|----------|----------|------------|
| OVERALL (a) | 3/10 (30%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 3/10 (30%) |
| POLY-3 RATE (b) | 3/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 3/10.00 |
| POLY-3 PERCENT (g) | 30% | 0% | 0% | 0% | 0% | 30% |
| TERMINAL (d) | 3/10 (30%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 3/10 (30%) |
| FIRST INCIDENCE | 93 (T) | --- | --- | --- | --- | 93 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|---------|-----|-----|-----|-----|----------|
| LIFE TABLE | P=0.594 | (e) | (e) | (e) | (e) | P=0.683 |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.678 |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.678 |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.678 |
| LOGISTIC REGRESSION | P=0.594 | (e) | (e) | (e) | (e) | P=0.683 |
| COCH-ARM / FISHERS | P=0.596 | (e) | (e) | (e) | (e) | P=0.686N |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

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| DOSE | Males | | | | | |
|------|---------|-----------|-----------|-----------|------------|------------|
| | 0 mg/kg | 125 mg/kg | 250 mg.kg | 500 mg/kg | 1000 mg/kg | 2000 mg/kg |

Liver
 Infiltration Cellular Mononuclear Cell

LESION RATES

| | | | | | | |
|--------------------|------------|----------|----------|----------|----------|------------|
| OVERALL (a) | 3/10 (30%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 4/10 (40%) |
| POLY-3 RATE (b) | 3/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 4/10.00 |
| POLY-3 PERCENT (g) | 30% | 0% | 0% | 0% | 0% | 40% |
| TERMINAL (d) | 3/10 (30%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 4/10 (40%) |
| FIRST INCIDENCE | 93 (T) | --- | --- | --- | --- | 93 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|---------|-----|-----|-----|-----|---------|
| LIFE TABLE | P=0.410 | (e) | (e) | (e) | (e) | P=0.500 |
| 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 |
| LOGISTIC REGRESSION | P=0.410 | (e) | (e) | (e) | (e) | P=0.500 |
| COCH-ARM / FISHERS | P=0.407 | (e) | (e) | (e) | (e) | P=0.500 |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

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

| DOSE | Males | | | | | |
|------|---------|-----------|-----------|-----------|------------|------------|
| | 0 mg/kg | 125 mg/kg | 250 mg.kg | 500 mg/kg | 1000 mg/kg | 2000 mg/kg |

**Prostate
Infiltration Cellular Mononuclear Cell**

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 | 93 (T) | --- | --- | --- | --- | 93 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|---------|-----|-----|-----|-----|----------|
| LIFE TABLE | P=0.588 | (e) | (e) | (e) | (e) | P=0.672 |
| 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 |
| LOGISTIC REGRESSION | P=0.588 | (e) | (e) | (e) | (e) | P=0.672 |
| COCH-ARM / FISHERS | P=0.590 | (e) | (e) | (e) | (e) | P=0.675N |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

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 Lab: BAT

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

| DOSE | Females | | | | | |
|------|---------|-----------|-----------|-----------|------------|------------|
| | 0 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg | 2000 mg/kg |

**Kidney
 Infiltration Cellular Mononuclear Cell**

LESION RATES

| | | | | | | |
|--------------------|------------|----------|----------|----------|----------|------------|
| OVERALL (a) | 4/10 (40%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 7/10 (70%) |
| POLY-3 RATE (b) | 4/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 7/10.00 |
| POLY-3 PERCENT (g) | 40% | 0% | 0% | 0% | 0% | 70% |
| TERMINAL (d) | 4/10 (40%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 7/10 (70%) |
| FIRST INCIDENCE | 93 (T) | --- | --- | --- | --- | 93 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|---------|-----|-----|-----|-----|---------|
| LIFE TABLE | P=0.137 | (e) | (e) | (e) | (e) | P=0.190 |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.186 |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.186 |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.186 |
| LOGISTIC REGRESSION | P=0.137 | (e) | (e) | (e) | (e) | P=0.190 |
| COCH-ARM / FISHERS | P=0.131 | (e) | (e) | (e) | (e) | P=0.185 |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

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|------|---------|-----------|-----------|-----------|------------|------------|
| | 0 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg | 2000 mg/kg |

Liver
 Infiltration Cellular Mononuclear Cell

LESION RATES

| | | | | | | |
|--------------------|------------|----------|----------|----------|----------|--------------|
| OVERALL (a) | 9/10 (90%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 10/10 (100%) |
| POLY-3 RATE (b) | 9/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 10/10.00 |
| POLY-3 PERCENT (g) | 90% | 0% | 0% | 0% | 0% | 100% |
| TERMINAL (d) | 9/10 (90%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 10/10 (100%) |
| FIRST INCIDENCE | 93 (T) | --- | --- | --- | --- | 93 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|---------|-----|-----|-----|-----|---------|
| LIFE TABLE | P=0.309 | (e) | (e) | (e) | (e) | P=0.500 |
| 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 |
| LOGISTIC REGRESSION | P=0.309 | (e) | (e) | (e) | (e) | P=0.500 |
| COCH-ARM / FISHERS | P=0.304 | (e) | (e) | (e) | (e) | P=0.500 |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

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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.
 - (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 ***