

**Experiment Number:** 20209 - 03  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** RATS/Wistar Han

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
Pentabromodiphenyl oxide (technical) (DE 71)  
**CAS Number:** 32534-81-9

**Date Report Requested:** 09/19/2014  
**Time Report Requested:** 15:44:42  
**First Dose M/F:** 08/26/08 / 08/26/08  
**Lab:** SRI

Custom Report - Liver Special Pool

|                             |             |             |            |
|-----------------------------|-------------|-------------|------------|
| <b>NTP Study Number:</b>    | C20209      |             |            |
| <b>Lock Date:</b>           | 08/31/2011  |             |            |
| <b>Cage Range:</b>          | ALL         |             |            |
| <b>Date Range:</b>          | ALL         |             |            |
| <b>Reasons For Removal:</b> | 25021 TSAC  | 25020 NATD  | 25019 MSAC |
|                             | 25018 DACC  | 25026 Other |            |
| <b>Removal Date Range:</b>  | ALL         |             |            |
| <b>Treatment Groups:</b>    | Include ALL |             |            |
| <b>Study Gender:</b>        | Both        |             |            |
| <b>TDMSE Version:</b>       | 2.5.0.0_sfh |             |            |
| <b>PWG Approval Date:</b>   | 08/06/2014  |             |            |

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## **HISTORICAL CONTROL STUDIES**

**From June 2013 report**

### **SAME ROUTE**

20320-03 -- Tetrabromobisphenol A (GAVAGE CORN OIL)

### **ALL ROUTES**

20203-03 -- Green tea extract (GAVAGE WATER)

20515-03 -- Metal working fluids (CIMSTAR 3800) (INHALATION AIR)

20320-03 -- Tetrabromobisphenol A (GAVAGE CORN OIL)

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**FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES EXAMINED.  
IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.**

Liver

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## SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF PENTABROMODIPHENYL OXIDE (TECHNICAL) (DE 71)

### MALE RATS

#### Organ

Liver

#### Morphology

Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatocholangioma

### FEMALE RATS

#### Organ

Liver

#### Morphology

Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatocholangioma

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)  
 TERMINAL SACRIFICE AT 105 WEEKS**

| DOSE  | Males      |           |            |             |
|---|------------|-----------|------------|-------------|
|   | 0 MG/KG    | 3 MG/KG   | 15 MG/KG   | 50 MG/KG    |
| <b>Liver</b>  |            |           |            |             |
| <b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatocholangioma</b> |            |           |            |             |
| <b>TUMOR RATES</b>  |            |           |            |             |
| OVERALL (a)   | 3/49 (6%)  | 2/50 (4%) | 4/50 (8%)  | 11/50 (22%) |
| POLY-3 RATE (b)   | 3/42.38    | 2/42.11   | 4/43.29    | 11/40.49    |
| POLY-3 PERCENT (g)  | 7.1%       | 4.8%      | 9.2%       | 27.2%       |
| TERMINAL (d)  | 3/36 (8%)  | 1/35 (3%) | 4/38 (11%) | 5/25 (20%)  |
| FIRST INCIDENCE   | 729 (T)    | 658       | 729 (T)    | 595         |
| HC TUMORS SAME ROUTE  | 0/50 (0%)  |           |            |             |
| HC TUMORS ALL ROUTES  | 0/150 (0%) |           |            |             |
| <b>STATISTICAL TESTS</b>  |            |           |            |             |
| POLY 3  | P<0.001**  | P=0.503N  | P=0.512    | P=0.014*    |
| POLY 1.5  | P<0.001**  | P=0.498N  | P=0.517    | P=0.017*    |
| POLY 6  | P<0.001**  | P=0.504N  | P=0.509    | P=0.011*    |
| COCH-ARM / FISHERS  | P<0.001**  | P=0.490N  | P=0.511    | P=0.022*    |
| MAX-ISO-POLY-3  | P<0.001**  | P=0.327N  | P=0.358    | P=0.007**   |
| HISTCONT SAME RTE   | P=0.077    | P=0.313   | P=0.229    | P=0.167     |
| HISTCONT ALL RTES   | P=0.010**  | P=0.078   | P=0.034*   | P=0.015*    |
| CURR VS HC SAME RTE   | P=0.078    |           |            |             |
| CURR VS HC ALL RTES   | P=0.002**  |           |            |             |

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)  
 TERMINAL SACRIFICE AT 105 WEEKS**

| DOSE  | Females    |           |            |             |
|---|------------|-----------|------------|-------------|
|   | 0 MG/KG    | 3 MG/KG   | 15 MG/KG   | 50 MG/KG    |
| <b>Liver</b>  |            |           |            |             |
| <b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatocholangioma</b> |            |           |            |             |
| <b>TUMOR RATES</b>  |            |           |            |             |
| OVERALL (a)   | 3/50 (6%)  | 2/49 (4%) | 8/50 (16%) | 21/47 (45%) |
| POLY-3 RATE (b)   | 3/43.21    | 2/45.55   | 8/44.09    | 21/39.05    |
| POLY-3 PERCENT (g)  | 6.9%       | 4.4%      | 18.2%      | 53.8%       |
| TERMINAL (d)  | 3/37 (8%)  | 2/39 (5%) | 6/33 (18%) | 15/28 (54%) |
| FIRST INCIDENCE   | 729 (T)    | 729 (T)   | 656        | 490         |
| HC TUMORS SAME ROUTE  | 1/50 (2%)  |           |            |             |
| HC TUMORS ALL ROUTES  | 2/150 (1%) |           |            |             |
| <b>STATISTICAL TESTS</b>  |            |           |            |             |
| POLY 3  | P<0.001**  | P=0.476N  | P=0.103    | P<0.001**   |
| POLY 1.5  | P<0.001**  | P=0.485N  | P=0.105    | P<0.001**   |
| POLY 6  | P<0.001**  | P=0.468N  | P=0.100    | P<0.001**   |
| COCH-ARM / FISHERS  | P<0.001**  | P=0.510N  | P=0.100    | P<0.001**   |
| MAX-ISO-POLY-3  | P<0.001**  | P=0.308N  | P=0.058    | P<0.001**   |
| HISTCONT SAME RTE   | P=0.050*   | P=1.000   | P=0.192    | P=0.129     |
| HISTCONT ALL RTES   | P=0.004**  | P=0.210   | P=0.023*   | P=0.006**   |
| CURR VS HC SAME RTE   | P=0.346    |           |            |             |
| CURR VS HC ALL RTES   | P=0.051    |           |            |             |

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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.
- (h) Historical Controls statistic is not calculated when the HC Poly-3 rate is higher than the Poly-3 rates for all dose groups.
- (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 \*\*\*