

**Experiment Number:** 95011-98  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

**Test Compound:** 5-(Hydroxymethyl)-2-furfural

**CAS Number:** 67-47-0

**Date Report Requested:** 10/18/2014

**Time Report Requested:** 18:38:52

**First Dose M/F:** NA / NA

**Lab:** BAT

|                             |            |
|-----------------------------|------------|
| <b>C Number:</b>            | C95011     |
| <b>Lock Date:</b>           | 11/10/1997 |
| <b>Cage Range:</b>          | All        |
| <b>Date Range:</b>          | All        |
| <b>Reasons For Removal:</b> | All        |
| <b>Removal Date Range:</b>  | All        |
| <b>Treatment Groups:</b>    | All        |
| <b>Study Gender:</b>        | Both       |
| <b>PWG Approval Date</b>    | NONE       |

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 5 WEEKS**

| DOSE                             | MALE     |          |           |           |           |            |
|----------------------------------|----------|----------|-----------|-----------|-----------|------------|
|                                  | 0 MG/KG  | 94 MG/KG | 188 MG/KG | 375 MG/KG | 750 MG/KG | 1500 MG/KG |
| <b>Spinal Cord</b>               |          |          |           |           |           |            |
| <b>Cyst Epithelial Inclusion</b> |          |          |           |           |           |            |
| <b>LESION RATES</b>              |          |          |           |           |           |            |
| OVERALL(a)                       | 0/5 (0%) | 0/5 (0%) | 0/5 (0%)  | 0/5 (0%)  | 0/5 (0%)  | 0/5 (0%)   |
| POLY-3 RATE (b)                  | 0/5.00   | 0/5.00   | 0/5.00    | 0/5.00    | 0/5.00    | 0/5.00     |
| POLY-3 PERCENT (g)               | 0%       | 0%       | 0%        | 0%        | 0%        | 0%         |
| TERMINAL (d)                     | 0/5 (0%) | 0/5 (0%) | 0/5 (0%)  | 0/5 (0%)  | 0/5 (0%)  | 0/5 (0%)   |
| FIRST INCIDENCE                  | ---      | ---      | ---       | ---       | ---       | ---        |
| <b>STATISTICAL TESTS</b>         |          |          |           |           |           |            |
| POLY 3                           | (n)      | (n)      | (n)       | (n)       | (n)       | (n)        |
| POLY 1.5                         | (n)      | (n)      | (n)       | (n)       | (n)       | (n)        |
| POLY 6                           | (n)      | (n)      | (n)       | (n)       | (n)       | (n)        |
| COCH-ARM / FISHERS               | (n)      | (n)      | (n)       | (n)       | (n)       | (n)        |
| MAX-ISO-POLY-3                   | (n)      | (n)      | (n)       | (n)       | (n)       | (n)        |
| HISTCONT SAME RTE                |          |          |           |           |           |            |
| HISTCONT ALL RTES                |          |          |           |           |           |            |
| CURR VS HC SAME RTE              |          |          |           |           |           |            |
| CURR VS HC ALL RTES              |          |          |           |           |           |            |

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS

| DOSE                             | FEMALE   |           |           |           |           |            |
|----------------------------------|----------|-----------|-----------|-----------|-----------|------------|
|                                  | 0 MG/KG  | 94 MG/KG  | 188 MG/KG | 375 MG/KG | 750 MG/KG | 1500 MG/KG |
| <b>Spinal Cord</b>               |          |           |           |           |           |            |
| <b>Cyst Epithelial Inclusion</b> |          |           |           |           |           |            |
| <b>LESION RATES</b>              |          |           |           |           |           |            |
| OVERALL(a)                       | 0/5 (0%) | 1/5 (20%) | 0/5 (0%)  | 0/5 (0%)  | 0/5 (0%)  | 0/5 (0%)   |
| POLY-3 RATE (b)                  | 0/5.00   | 1/5.00    | 0/5.00    | 0/5.00    | 0/5.00    | 0/5.00     |
| POLY-3 PERCENT (g)               | 0%       | 20%       | 0%        | 0%        | 0%        | 0%         |
| TERMINAL (d)                     | 0/5 (0%) | 1/5 (20%) | 0/5 (0%)  | 0/5 (0%)  | 0/5 (0%)  | 0/5 (0%)   |
| FIRST INCIDENCE                  | ---      | 94(T)     | ---       | ---       | ---       | ---        |
| <b>STATISTICAL TESTS</b>         |          |           |           |           |           |            |
| POLY 3                           | P=0.488N | P=0.500   | (e)       | (e)       | (e)       | (e)        |
| POLY 1.5                         | P=0.488N | P=0.500   | (e)       | (e)       | (e)       | (e)        |
| POLY 6                           | P=0.488N | P=0.500   | (e)       | (e)       | (e)       | (e)        |
| COCH-ARM / FISHERS               | P=0.488N | 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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**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 \*\***