

TDMS No. 99013 - 05
Test Type: Chronic PN
Route: DOSED FEED
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Styrene-acrylonitrile trimer
CAS Number: SANTRIMER2

Date Report Requested: 12/17/2010
Time Report Requested: 16:43:48
First Dose M/F: 05/12/05 / 05/13/05
Lab: BAT

Custom Report - Nerve Degen

C Number: C99013
Lock Date: 03/27/2008
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.3.0
PWG Approval Date: 01/04/2010

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF STYRENE-ACRYLONITRILE TRIMER

MALE RATS

Organ

Spinal Cord: Nerve

Morphology

Degeneration

FEMALE RATS

Organ

Peripheral Nerve: Sciatic

Morphology

Degeneration

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

| DOSE | Males | | | |
|---|-------------|-------------|-------------|-------------|
| | 0 PPM | 400 PPM | 800 PPM | 1600 PPM |
| Peripheral Nerve: Sciatic Degeneration | | | | |
| LESION RATES | | | | |
| OVERALL (a) | 37/50 (74%) | 40/50 (80%) | 41/50 (82%) | 43/50 (86%) |
| POLY-3 RATE (b) | 37/46.51 | 40/47.99 | 41/45.30 | 43/48.10 |
| POLY-3 PERCENT (g) | 79.6% | 83.4% | 90.5% | 89.4% |
| TERMINAL (d) | 31/36 (86%) | 34/39 (87%) | 37/39 (95%) | 40/44 (91%) |
| FIRST INCIDENCE | 474 | 474 | 575 | 677 |
| STATISTICAL TESTS | | | | |
| POLY 3 | P=0.082 | P=0.413 | P=0.103 | P=0.137 |
| POLY 1.5 | P=0.074 | P=0.396 | P=0.128 | P=0.118 |
| POLY 6 | P=0.101 | P=0.416 | P=0.091 | P=0.166 |
| COCH-ARM / FISHERS | P=0.087 | P=0.318 | P=0.235 | P=0.105 |
| MAX-ISO-POLY-3 | P=0.102 | P=0.312 | P=0.059 | P=0.086 |

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 TERMINAL SACRIFICE AT 104 WEEKS**

| DOSE | Males | | | |
|--|-------------|-------------|-------------|-------------|
| | 0 PPM | 400 PPM | 800 PPM | 1600 PPM |
| Spinal Cord: Nerve Degeneration | | | | |
| LESION RATES | | | | |
| OVERALL (a) | 34/47 (72%) | 37/48 (77%) | 37/50 (74%) | 43/50 (86%) |
| POLY-3 RATE (b) | 34/45.43 | 37/45.42 | 37/45.30 | 43/48.10 |
| POLY-3 PERCENT (g) | 74.8% | 81.5% | 81.7% | 89.4% |
| TERMINAL (d) | 25/36 (69%) | 34/39 (87%) | 33/39 (85%) | 40/44 (91%) |
| FIRST INCIDENCE | 523 | 624 | 575 | 677 |
| STATISTICAL TESTS | | | | |
| POLY 3 | P=0.041* | P=0.300 | P=0.292 | P=0.052 |
| POLY 1.5 | P=0.045* | P=0.347 | P=0.347 | P=0.056 |
| POLY 6 | P=0.039* | P=0.225 | P=0.242 | P=0.047* |
| COCH-ARM / FISHERS | P=0.074 | P=0.384 | P=0.517 | P=0.079 |
| MAX-ISO-POLY-3 | P=0.044* | P=0.218 | P=0.214 | P=0.030* |

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 TERMINAL SACRIFICE AT 104 WEEKS**

| DOSE | Females | | | |
|---|-------------|-------------|-------------|-------------|
| | 0 PPM | 400 PPM | 800 PPM | 1600 PPM |
| Peripheral Nerve: Sciatic Degeneration | | | | |
| LESION RATES | | | | |
| OVERALL (a) | 28/49 (57%) | 35/49 (71%) | 43/49 (88%) | 40/50 (80%) |
| POLY-3 RATE (b) | 28/47.17 | 35/47.22 | 43/46.42 | 40/47.99 |
| POLY-3 PERCENT (g) | 59.4% | 74.1% | 92.6% | 83.4% |
| TERMINAL (d) | 25/40 (63%) | 30/38 (79%) | 35/36 (97%) | 40/46 (87%) |
| FIRST INCIDENCE | 512 | 617 | 422 | 727 (T) |
| STATISTICAL TESTS | | | | |
| POLY 3 | P=0.002** | P=0.092 | P<0.001** | P=0.007** |
| POLY 1.5 | P=0.003** | P=0.104 | P<0.001** | P=0.009** |
| POLY 6 | P<0.001** | P=0.079 | P<0.001** | P=0.005** |
| COCH-ARM / FISHERS | P=0.006** | P=0.103 | P<0.001** | P=0.012* |
| MAX-ISO-POLY-3 | P<0.001** | P=0.060 | P<0.001** | P=0.003** |

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 TERMINAL SACRIFICE AT 104 WEEKS**

| DOSE | Females | | | |
|--|-------------|-------------|-------------|-------------|
| | 0 PPM | 400 PPM | 800 PPM | 1600 PPM |
| Spinal Cord: Nerve Degeneration | | | | |
| LESION RATES | | | | |
| OVERALL (a) | 43/49 (88%) | 40/50 (80%) | 42/50 (84%) | 45/49 (92%) |
| POLY-3 RATE (b) | 43/47.16 | 40/48.31 | 42/46.51 | 45/47.81 |
| POLY-3 PERCENT (g) | 91.2% | 82.8% | 90.3% | 94.1% |
| TERMINAL (d) | 38/41 (93%) | 32/38 (84%) | 36/37 (97%) | 44/46 (96%) |
| FIRST INCIDENCE | 512 | 617 | 558 | 611 |
| STATISTICAL TESTS | | | | |
| POLY 3 | P=0.185 | P=0.170N | P=0.592N | P=0.434 |
| POLY 1.5 | P=0.209 | P=0.162N | P=0.465N | P=0.446 |
| POLY 6 | P=0.171 | P=0.186N | P=0.591 | P=0.431 |
| COCH-ARM / FISHERS | P=0.206 | P=0.220N | P=0.403N | P=0.370 |
| MAX-ISO-POLY-3 | P=0.171 | P=0.103N | P=0.435N | P=0.282 |

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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 ***