

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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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 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 ***