C Number:	C20108C
Lock Date:	Not Entered.
Cage Range:	All
Date Range:	All
Reasons For Removal:	All
Removal Date Range:	All
Treatment Groups:	All
Study Gender:	Male
PWG Approval Date	NONE

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF ANTIOXIDANT MODEL (TRAMP) - N-

MALE MOUSE

Organ	Morphology
Prostate, Dorsal Lobe	Hyperplasia Grade 3 Diffuse

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Epididymis		
Atypia Cellular		
LESION RATES		
OVERALL(a)	1/12 (8%)	0/32 (0%)
POLY-3 RATE (b)	1/7.01	0/19.68
POLY-3 PERCENT (g)	14.3%	0%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	0/4 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	85(I)	---
STATISTICAL TESTS		
POLY 3	P=0.291N	P=0.291N
POLY 1.5	P=0.296N	P=0.296N
POLY 6	P=0.288N	P=0.288N
COCH-ARM / FISHERS	P=0.303N	P=0.273N
MAX-ISO-POLY-3	P=0.081N	P=0.081N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Epididymis		
Granuloma Sperm		
LESION RATES		
OVERALL(a)	0/12 (0%)	1/32 (3%)
POLY-3 RATE (b)	0/6.88	1/19.71
POLY-3 PERCENT (g)	0%	5.1%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	0/4 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	88(I)
STATISTICAL TESTS		
POLY 3	P=0.706	P=0.706
POLY 1.5	P=0.700	P=0.700
POLY 6	P=0.713	P=0.713
COCH-ARM / FISHERS	P=0.697	P=0.727
MAX-ISO-POLY-3	P=0.318	P=0.318
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Epididymis		
Inflammation		
LESION RATES		
OVERALL(a)	0/12 (0%)	1/32 (3%)
POLY-3 RATE (b)	0/6.88	1/19.71
POLY-3 PERCENT (g)	0%	5.1%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	0/4 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	88(I)
STATISTICAL TESTS		
POLY 3	P=0.706	P=0.706
POLY 1.5	P=0.700	P=0.700
POLY 6	P=0.713	P=0.713
COCH-ARM / FISHERS	P=0.697	P=0.727
MAX-ISO-POLY-3	P=0.318	P=0.318
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Kidney: Cortex, Renal Tubule Regeneration Focal		
LESION RATES		
OVERALL(a)	1/12 (8%)	5/32 (16%)
POLY-3 RATE (b)	1/6.98	5/21.58
POLY-3 PERCENT (g)	14.3%	23.2%
INT SACRIFICE 1	0/2 (0%)	1/6 (17%)
INT SACRIFICE 2	0/4 (0%)	1/6 (17%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	86(I)	33(I)
STATISTICAL TESTS		
POLY 3	P=0.514	P=0.514
POLY 1.5	P=0.483	P=0.483
POLY 6	P=0.540	P=0.540
COCH-ARM / FISHERS	P=0.447	P=0.471
MAX-ISO-POLY-3	P=0.351	P=0.351
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Liver		
Inflammation Focal		
LESION RATES		
OVERALL(a)	6/12 (50%)	8/32 (25%)
POLY-3 RATE (b)	6/8.83	8/22.51
POLY-3 PERCENT (g)	68%	35.5%
INT SACRIFICE 1	1/2 (50%)	1/6 (17%)
INT SACRIFICE 2	1/4 (25%)	2/6 (33%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	32(I)	33(I)
STATISTICAL TESTS		
POLY 3	P=0.095N	P=0.095N
POLY 1.5	P=0.103N	P=0.103N
POLY 6	P=0.089N	P=0.089N
COCH-ARM / FISHERS	P=0.111N	P=0.112N
MAX-ISO-POLY-3	P=0.073N	P=0.073N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Liver		
Tension Lipidosis		
LESION RATES		
OVERALL(a)	0/12 (0%)	1/32 (3%)
POLY-3 RATE (b)	0/6.88	1/19.78
POLY-3 PERCENT (g)	0%	5.1%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	0/4 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	86(I)
STATISTICAL TESTS		
POLY 3	P=0.707	P=0.707
POLY 1.5	P=0.700	P=0.700
POLY 6	P=0.714	P=0.714
COCH-ARM / FISHERS	P=0.697	P=0.727
MAX-ISO-POLY-3	P=0.318	P=0.318
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Anterior Lobe		
Hyperplasia Grade 2 Focal		
LESION RATES		
OVERALL(a)	0/12 (0%)	1/32 (3%)
POLY-3 RATE (b)	0/6.88	1/20.64
POLY-3 PERCENT (g)	0%	4.8%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	0/4 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	30
STATISTICAL TESTS		
POLY 3	P=0.713	P=0.713
POLY 1.5	P=0.705	P=0.705
POLY 6	P=0.720	P=0.720
COCH-ARM / FISHERS	P=0.697	P=0.727
MAX-ISO-POLY-3	P=0.325	P=0.325
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Anterior Lobe		
Hyperplasia Grade 3 Diffuse		
LESION RATES		
OVERALL(a)	0/12 (0%)	1/32 (3%)
POLY-3 RATE (b)	0/6.88	1/20.42
POLY-3 PERCENT (g)	0%	4.9%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	0/4 (0%)	1/6 (17%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	57(I)
STATISTICAL TESTS		
POLY 3	P=0.711	P=0.711
POLY 1.5	P=0.703	P=0.703
POLY 6	P=0.719	P=0.719
COCH-ARM / FISHERS	P=0.697	P=0.727
MAX-ISO-POLY-3	P=0.324	P=0.324
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Anterior Lobe		
Hyperplasia Grade 3 Focal		
LESION RATES		
OVERALL(a)	9/12 (75%)	28/32 (88%)
POLY-3 RATE (b)	9/11.21	28/30.14
POLY-3 PERCENT (g)	80.3%	92.9%
INT SACRIFICE 1	2/2 (100%)	6/6 (100%)
INT SACRIFICE 2	3/4 (75%)	5/6 (83%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	32(I)	32(I)
STATISTICAL TESTS		
POLY 3	P=0.259	P=0.259
POLY 1.5	P=0.250	P=0.250
POLY 6	P=0.279	P=0.279
COCH-ARM / FISHERS	P=0.292	P=0.282
MAX-ISO-POLY-3	P=0.150	P=0.150
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Anterior Lobe		
Hyperplasia Grade 4 Focal		
LESION RATES		
OVERALL(a)	3/12 (25%)	2/32 (6%)
POLY-3 RATE (b)	3/7.67	2/19.84
POLY-3 PERCENT (g)	39.1%	10.1%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	1/4 (25%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	58(I)	86(I)
STATISTICAL TESTS		
POLY 3	P=0.103N	P=0.103N
POLY 1.5	P=0.106N	P=0.106N
POLY 6	P=0.102N	P=0.102N
COCH-ARM / FISHERS	P=0.113N	P=0.116N
MAX-ISO-POLY-3	P=0.063N	P=0.063N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Dorsal Lobe		
Hyperplasia Grade 3 Diffuse		
LESION RATES		
OVERALL(a)	5/12 (42%)	2/29 (7%)
POLY-3 RATE (b)	5/9.93	2/18.72
POLY-3 PERCENT (g)	50.4%	10.7%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	4/4 (100%)	1/6 (17%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	57(I)	58(I)
STATISTICAL TESTS		
POLY 3	P=0.017N*	P=0.017N*
POLY 1.5	P=0.012N*	P=0.012N*
POLY 6	P=0.025N*	P=0.025N*
COCH-ARM / FISHERS	P=0.013N*	P=0.016N*
MAX-ISO-POLY-3	P=0.008N**	P=0.008N**
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Dorsal Lobe		
Hyperplasia Grade 3 Focal		
LESION RATES		
OVERALL(a)	2/12 (17%)	13/29 (45%)
POLY-3 RATE (b)	2/8.79	13/26.85
POLY-3 PERCENT (g)	22.8%	48.4%
INT SACRIFICE 1	2/2 (100%)	6/6 (100%)
INT SACRIFICE 2	0/4 (0%)	4/6 (67%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	32(I)	32(I)
STATISTICAL TESTS		
POLY 3	P=0.183	P=0.183
POLY 1.5	P=0.139	P=0.139
POLY 6	P=0.231	P=0.231
COCH-ARM / FISHERS	P=0.089	P=0.087
MAX-ISO-POLY-3	P=0.155	P=0.155
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Dorsal Lobe		
Hyperplasia Grade 4 Diffuse		
LESION RATES		
OVERALL(a)	0/12 (0%)	1/29 (3%)
POLY-3 RATE (b)	0/6.88	1/18.64
POLY-3 PERCENT (g)	0%	5.4%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	0/4 (0%)	1/6 (17%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	57(I)
STATISTICAL TESTS		
POLY 3	P=0.694	P=0.694
POLY 1.5	P=0.685	P=0.685
POLY 6	P=0.703	P=0.703
COCH-ARM / FISHERS	P=0.678	P=0.707
MAX-ISO-POLY-3	P=0.314	P=0.314
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Dorsal Lobe		
Hyperplasia Grade 4 Focal		
LESION RATES		
OVERALL(a)	5/12 (42%)	11/29 (38%)
POLY-3 RATE (b)	5/7.05	11/18.49
POLY-3 PERCENT (g)	70.9%	59.5%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	0/4 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	86(I)	85(I)
STATISTICAL TESTS		
POLY 3	P=0.467N	P=0.467N
POLY 1.5	P=0.520N	P=0.520N
POLY 6	P=0.400N	P=0.400N
COCH-ARM / FISHERS	P=0.551N	P=0.547N
MAX-ISO-POLY-3	P=0.320N	P=0.320N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Dorsal Lobe		
Hyperplasia Grade 5 Focal		
LESION RATES		
OVERALL(a)	0/12 (0%)	2/29 (7%)
POLY-3 RATE (b)	0/6.88	2/17.90
POLY-3 PERCENT (g)	0%	11.2%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	0/4 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	89(T)(I)
STATISTICAL TESTS		
POLY 3	P=0.464	P=0.464
POLY 1.5	P=0.455	P=0.455
POLY 6	P=0.474	P=0.474
COCH-ARM / FISHERS	P=0.446	P=0.495
MAX-ISO-POLY-3	P=0.231	P=0.231
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Lateral Lobe		
Hyperplasia Grade 3 Diffuse		
LESION RATES		
OVERALL(a)	7/10 (70%)	11/28 (39%)
POLY-3 RATE (b)	7/8.00	11/18.21
POLY-3 PERCENT (g)	87.5%	60.4%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	3/3 (100%)	1/6 (17%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	57(I)	58(I)
STATISTICAL TESTS		
POLY 3	P=0.148N	P=0.148N
POLY 1.5	P=0.105N	P=0.105N
POLY 6	P=0.208N	P=0.208N
COCH-ARM / FISHERS	P=0.097N	P=0.096N
MAX-ISO-POLY-3	P=0.085N	P=0.085N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Lateral Lobe		
Hyperplasia Grade 3 Focal		
LESION RATES		
OVERALL(a)	3/10 (30%)	17/28 (61%)
POLY-3 RATE (b)	3/7.64	17/26.69
POLY-3 PERCENT (g)	39.3%	63.7%
INT SACRIFICE 1	2/2 (100%)	6/6 (100%)
INT SACRIFICE 2	0/3 (0%)	5/6 (83%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	32(I)	32(I)
STATISTICAL TESTS		
POLY 3	P=0.223	P=0.223
POLY 1.5	P=0.165	P=0.165
POLY 6	P=0.281	P=0.281
COCH-ARM / FISHERS	P=0.097	P=0.096
MAX-ISO-POLY-3	P=0.182	P=0.182
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Ventral Lobe		
Hyperplasia Grade 2 Focal		
LESION RATES		
OVERALL(a)	1/7 (14%)	6/25 (24%)
POLY-3 RATE (b)	1/3.82	6/19.06
POLY-3 PERCENT (g)	26.2%	31.5%
INT SACRIFICE 1	1/2 (50%)	2/6 (33%)
INT SACRIFICE 2	0/3 (0%)	2/4 (50%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	33(I)	32(I)
STATISTICAL TESTS		
POLY 3	P=0.640	P=0.640
POLY 1.5	P=0.579	P=0.579
POLY 6	P=0.688	P=0.688
COCH-ARM / FISHERS	P=0.487	P=0.511
MAX-ISO-POLY-3	P=0.446	P=0.446
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Ventral Lobe		
Hyperplasia Grade 3 Diffuse		
LESION RATES		
OVERALL(a)	1/7 (14%)	1/25 (4%)
POLY-3 RATE (b)	1/3.60	1/15.46
POLY-3 PERCENT (g)	27.8%	6.5%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	1/3 (33%)	0/4 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	57(I)	88(I)
STATISTICAL TESTS		
POLY 3	P=0.413N	P=0.413N
POLY 1.5	P=0.428N	P=0.428N
POLY 6	P=0.407N	P=0.407N
COCH-ARM / FISHERS	P=0.456N	P=0.395N
MAX-ISO-POLY-3	P=0.194N	P=0.194N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Ventral Lobe		
Hyperplasia Grade 3 Focal		
LESION RATES		
OVERALL(a)	5/7 (71%)	17/25 (68%)
POLY-3 RATE (b)	5/5.31	17/20.61
POLY-3 PERCENT (g)	94.2%	82.5%
INT SACRIFICE 1	1/2 (50%)	4/6 (67%)
INT SACRIFICE 2	2/3 (67%)	1/4 (25%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	32(I)	32(I)
STATISTICAL TESTS		
POLY 3	P=0.506N	P=0.506N
POLY 1.5	P=0.539N	P=0.539N
POLY 6	P=0.506N	P=0.506N
COCH-ARM / FISHERS	P=0.613N	P=0.624N
MAX-ISO-POLY-3	P=0.281N	P=0.281N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Ventral Lobe		
Hyperplasia Grade 4 Focal		
LESION RATES		
OVERALL(a)	0/7 (0%)	1/25 (4%)
POLY-3 RATE (b)	0/2.87	1/16.15
POLY-3 PERCENT (g)	0%	6.2%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	0/3 (0%)	1/4 (25%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	58(I)
STATISTICAL TESTS		
POLY 3	P=0.798	P=0.798
POLY 1.5	P=0.780	P=0.780
POLY 6	P=0.810	P=0.810
COCH-ARM / FISHERS	P=0.755	P=0.781
MAX-ISO-POLY-3	P=0.394	P=0.394
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Seminal Vesicle Hyperplasia		
LESION RATES		
OVERALL(a)	3/12 (25%)	7/32 (22%)
POLY-3 RATE (b)	3/7.01	7/20.01
POLY-3 PERCENT (g)	42.8%	35%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	0/4 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	86(I)	86(I)
STATISTICAL TESTS		
POLY 3	P=0.535N	P=0.535N
POLY 1.5	P=0.559N	P=0.559N
POLY 6	P=0.512N	P=0.512N
COCH-ARM / FISHERS	P=0.573N	P=0.559N
MAX-ISO-POLY-3	P=0.382N	P=0.382N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Seminal Vesicle		
Hyperplasia Grade 2 Focal		
LESION RATES		
OVERALL(a)	2/12 (17%)	5/32 (16%)
POLY-3 RATE (b)	2/8.34	5/20.86
POLY-3 PERCENT (g)	24%	24%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	2/4 (50%)	1/6 (17%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	57(I)	58(I)
STATISTICAL TESTS		
POLY 3	P=0.685	P=0.685
POLY 1.5	P=0.675N	P=0.675N
POLY 6	P=0.684	P=0.684
COCH-ARM / FISHERS	P=0.648N	P=0.628N
MAX-ISO-POLY-3	P=0.500	P=0.500
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Seminal Vesicle		
Hyperplasia Grade 3 Focal		
LESION RATES		
OVERALL(a)	0/12 (0%)	1/32 (3%)
POLY-3 RATE (b)	0/6.88	1/19.68
POLY-3 PERCENT (g)	0%	5.1%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	0/4 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	89(T)(I)
STATISTICAL TESTS		
POLY 3	P=0.706	P=0.706
POLY 1.5	P=0.700	P=0.700
POLY 6	P=0.712	P=0.712
COCH-ARM / FISHERS	P=0.697	P=0.727
MAX-ISO-POLY-3	P=0.317	P=0.317
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Spleen		
Hematopoietic Cell Proliferation		
LESION RATES		
OVERALL(a)	0/12 (0%)	2/31 (6%)
POLY-3 RATE (b)	0/6.88	2/18.71
POLY-3 PERCENT (g)	0%	10.7%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	0/4 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	89(T)(I)
STATISTICAL TESTS		
POLY 3	P=0.475	P=0.475
POLY 1.5	P=0.467	P=0.467
POLY 6	P=0.483	P=0.483
COCH-ARM / FISHERS	P=0.463	P=0.515
MAX-ISO-POLY-3	P=0.236	P=0.236
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Testes: Germinal Epith Syncytial Alteration		
LESION RATES		
OVERALL(a)	2/12 (17%)	2/32 (6%)
POLY-3 RATE (b)	2/7.05	2/20.47
POLY-3 PERCENT (g)	28.4%	9.8%
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)
INT SACRIFICE 2	0/4 (0%)	1/6 (17%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	85(I)	58(I)
STATISTICAL TESTS		
POLY 3	P=0.281N	P=0.281N
POLY 1.5	P=0.298N	P=0.298N
POLY 6	P=0.269N	P=0.269N
COCH-ARM / FISHERS	P=0.315N	P=0.297N
MAX-ISO-POLY-3	P=0.168N	P=0.168N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Testes: Seminif Tub Atrophy		
LESION RATES		
OVERALL(a)	0/12 (0%)	1/32 (3%)
POLY-3 RATE (b)	0/6.88	1/20.63
POLY-3 PERCENT (g)	0%	4.8%
INT SACRIFICE 1	0/2 (0%)	1/6 (17%)
INT SACRIFICE 2	0/4 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	32(I)
STATISTICAL TESTS		
POLY 3	P=0.713	P=0.713
POLY 1.5	P=0.704	P=0.704
POLY 6	P=0.720	P=0.720
COCH-ARM / FISHERS	P=0.697	P=0.727
MAX-ISO-POLY-3	P=0.325	P=0.325
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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<=0.05).
**	To the right of any statistical result, indicates significance at (P<=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 **