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

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

NA

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Ventral Lobe Carcinoma		
TUMOR RATES	#	#
OVERALL(a)	0/12 (0%)	3/32 (9%)
POLY-3 RATE (b)	0/6.88	3/19.84
POLY-3 PERCENT (g)	0%	15.1%
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	---	85(I)
HC TUMORS SAME ROUTE	0/0(0%)	
HC TUMORS ALL ROUTES	0/0(0%)	
STATISTICAL TESTS		
POLY 3	P=0.354	P=0.354
POLY 1.5	P=0.342	P=0.342
POLY 6	P=0.367	P=0.367
COCH-ARM / FISHERS	P=0.335	P=0.375
MAX-ISO-POLY-3	P=0.195	P=0.195
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
All Organs		
Benign Tumors		
TUMOR RATES	#	#
OVERALL(a)	0/12 (0%)	0/32 (0%)
POLY-3 RATE (b)	0/6.88	0/19.68
POLY-3 PERCENT (g)	0%	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	---	---
HC TUMORS SAME ROUTE	0/0(0%)	
HC TUMORS ALL ROUTES	0/0(0%)	
STATISTICAL TESTS		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE	(n)	(n)
HISTCONT ALL RTES	(n)	(n)
CURR VS HC SAME RTE	(n)	
CURR VS HC ALL RTES	(n)	

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
All Organs		
Malignant Tumors		
TUMOR RATES	#	#
OVERALL(a)	1/12 (8%)	4/32 (12%)
POLY-3 RATE (b)	1/7.01	4/19.84
POLY-3 PERCENT (g)	14.3%	20.2%
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	85(I)	85(I)
HC TUMORS SAME ROUTE	0/0(0%)	
HC TUMORS ALL ROUTES	0/0(0%)	
STATISTICAL TESTS		
POLY 3	P=0.585	P=0.585
POLY 1.5	P=0.570	P=0.570
POLY 6	P=0.597	P=0.597
COCH-ARM / FISHERS	P=0.558	P=0.583
MAX-ISO-POLY-3	P=0.391	P=0.391
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MOUSE(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE

DOSE	VEHICLE CONTROL	NAC 125MG/KG
All Organs		
Malignant and Benign Tumors		
TUMOR RATES	#	#
OVERALL(a)	1/12 (8%)	4/32 (12%)
POLY-3 RATE (b)	1/7.01	4/19.84
POLY-3 PERCENT (g)	14.3%	20.2%
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	85(I)	85(I)
HC TUMORS SAME ROUTE	0/0(0%)	
HC TUMORS ALL ROUTES	0/0(0%)	
STATISTICAL TESTS		
POLY 3	P=0.585	P=0.585
POLY 1.5	P=0.570	P=0.570
POLY 6	P=0.597	P=0.597
COCH-ARM / FISHERS	P=0.558	P=0.583
MAX-ISO-POLY-3	P=0.391	P=0.391
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 **