

**Experiment Number:** 20108-02  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Mouse/TRAMP

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
**Test Compound:** Antioxidant model (TRAMP) - NAO (spinach extract)  
**CAS Number:** NAOSPINEXTR

**Date Report Requested:** 10/23/2014  
**Time Report Requested:** 11:21:59  
**First Dose M/F:** NA / NA  
**Lab:** ILS

<b>C Number:</b>	C20108A
<b>Lock Date:</b>	Not Entered.
<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>	Male
<b>PWG Approval Date</b>	NONE

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**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

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

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MALE		
DOSE	VEHICLE CONTROL	200MG/KG
<b>Prostate, Lateral Lobe Carcinoma</b>		
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<b>TUMOR RATES</b>	#	#
OVERALL(a)	0/10 (0%)	2/32 (6%)
POLY-3 RATE (b)	0/8.67	2/20.74
POLY-3 PERCENT (g)	0%	9.6%
INT SACRIFICE 1	0/0 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	87(l)
HC TUMORS SAME ROUTE	0/0(0%)	
HC TUMORS ALL ROUTES	0/0(0%)	
<hr/>		
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.440	P=0.440
POLY 1.5	P=0.461	P=0.461
POLY 6	P=0.428	P=0.428
COCH-ARM / FISHERS	P=0.516	P=0.576
MAX-ISO-POLY-3	P=0.190	P=0.190
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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

MALE		
DOSE	VEHICLE CONTROL	200MG/KG
<b>All Organs</b>		
<b>Benign Tumors</b>		
<b>TUMOR RATES</b>	#	#
OVERALL(a)	0/10 (0%)	0/32 (0%)
POLY-3 RATE (b)	0/8.67	0/20.61
POLY-3 PERCENT (g)	0%	0%
INT SACRIFICE 1	0/0 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (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%)	
<b>STATISTICAL TESTS</b>		
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)	

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LAST REMOVAL AT 13 WEEKS

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MALE		
DOSE	VEHICLE CONTROL	200MG/KG
<b>All Organs</b>		
<b>Malignant Tumors</b>		
<hr/>		
<b>TUMOR RATES</b>	#	#
OVERALL(a)	0/10 (0%)	4/32 (12%)
POLY-3 RATE (b)	0/8.67	4/21.61
POLY-3 PERCENT (g)	0%	18.5%
INT SACRIFICE 1	0/0 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	1/6 (17%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	57(l)
HC TUMORS SAME ROUTE	0/0(0%)	
HC TUMORS ALL ROUTES	0/0(0%)	
<hr/>		
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.207	P=0.207
POLY 1.5	P=0.227	P=0.227
POLY 6	P=0.199	P=0.199
COCH-ARM / FISHERS	P=0.288	P=0.321
MAX-ISO-POLY-3	P=0.104	P=0.104
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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MALE		
DOSE	VEHICLE CONTROL	200MG/KG
<b>All Organs</b>		
<b>Malignant and Benign Tumors</b>		
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<b>TUMOR RATES</b>	#	#
OVERALL(a)	0/10 (0%)	4/32 (12%)
POLY-3 RATE (b)	0/8.67	4/21.61
POLY-3 PERCENT (g)	0%	18.5%
INT SACRIFICE 1	0/0 (0%)	0/6 (0%)
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TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	57(l)
HC TUMORS SAME ROUTE	0/0(0%)	
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<b>STATISTICAL TESTS</b>		
POLY 3	P=0.207	P=0.207
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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 \*\***