

TDMS No. 20537 - 02
Test Type: 90-DAY
Route: INTRADUCTAL CANNULATION
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Adenoviral Vector (AdhAQP1)
CAS Number: ADN VIRVECAQP

Date Report Requested: 09/10/2009
Time Report Requested: 11:38:02
First Dose M/F: NA / 07/25/05
Lab: MBA

F1_R2_14Wk_TSAC

C Number:	C20537
Lock Date:	11/19/2007
Cage Range:	ALL
Date Range:	ALL
Reasons For Removal:	25021 TSAC
Removal Date Range:	ALL
Treatment Groups:	Include 005 VEHCONTRCOHRTE Include 010 2-8ADHAQP1COHTE Include 015 8-9ADHAQP1COHTE Include 020 2-11ADHAQP1COHTE
Study Gender:	Female
TDMSE Version:	2.1.0

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

Females			
DOSE	VEHCONTRCOHRTE	2-11ADHAQP1COHTE	8-9ADHAQP1COHTE
Harderian Gland Inflammation			
LESION RATES			
OVERALL (a)	2/5 (40%)	2/10 (20%)	0/5 (0%)
POLY-3 RATE (b)	2/5.00	2/10.00	0/5.00
POLY-3 PERCENT (g)	40%	20%	0%
TERMINAL (d)	2/5 (40%)	2/10 (20%)	0/5 (0%)
FIRST INCIDENCE	92 (T)	92 (T)	---
STATISTICAL TESTS			
POLY 3	P=0.179N	P=0.422N	P=0.207N
POLY 1.5	P=0.179N	P=0.422N	P=0.207N
POLY 6	P=0.179N	P=0.422N	P=0.207N
COCH-ARM / FISHERS	P=0.176N	P=0.407N	P=0.222N
MAX-ISO-POLY-3	P=0.085N	P=0.248N	P=0.051N

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TERMINAL SACRIFICE AT 14 WEEKS**

Females			
DOSE	VEHCONTRCOHRTE	2-11ADHAQP1COHTE	8-9ADHAQP1COHTE
Heart Cardiomyopathy			
LESION RATES			
OVERALL (a)	1/5 (20%)	5/10 (50%)	2/5 (40%)
POLY-3 RATE (b)	1/5.00	5/10.00	2/5.00
POLY-3 PERCENT (g)	20%	50%	40%
TERMINAL (d)	1/5 (20%)	5/10 (50%)	2/5 (40%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS			
POLY 3	P=0.558	P=0.293	P=0.500
POLY 1.5	P=0.558	P=0.293	P=0.500
POLY 6	P=0.558	P=0.293	P=0.500
COCH-ARM / FISHERS	P=0.560	P=0.294	P=0.500
MAX-ISO-POLY-3	P=0.292	P=0.174	P=0.264

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Lab: MBA

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

Females			
DOSE	VEHCONTRCOHRTE	2-11ADHAQP1COHTE	8-9ADHAQP1COHTE
Kidney Cyst			
LESION RATES			
OVERALL (a)	0/5 (0%)	2/10 (20%)	0/5 (0%)
POLY-3 RATE (b)	0/5.00	2/10.00	0/5.00
POLY-3 PERCENT (g)	0%	20%	0%
TERMINAL (d)	0/5 (0%)	2/10 (20%)	0/5 (0%)
FIRST INCIDENCE	---	92 (T)	---
STATISTICAL TESTS			
POLY 3	P=0.596N	P=0.397	(e)
POLY 1.5	P=0.596N	P=0.397	(e)
POLY 6	P=0.596N	P=0.397	(e)
COCH-ARM / FISHERS	P=0.598N	P=0.429	(e)
MAX-ISO-POLY-3	P=0.346	P=0.184	(e)

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N) TERMINAL SACRIFICE AT 14 WEEKS

Females			
DOSE	VEHCONTRCOHRTE	2-11ADHAQP1COHTE	8-9ADHAQP1COHTE
Liver Inflammation			
LESION RATES			
OVERALL (a)	5/5 (100%)	10/10 (100%)	5/5 (100%)
POLY-3 RATE (b)	5/5.00	10/10.00	5/5.00
POLY-3 PERCENT (g)	100%	100%	100%
TERMINAL (d)	5/5 (100%)	10/10 (100%)	5/5 (100%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

Females			
DOSE	VEHCONTRCOHRTE	2-11ADHAQP1COHTE	8-9ADHAQP1COHTE
Salivary Glands: Submandibular Gland, Right Regeneration			
LESION RATES			
OVERALL (a)	4/4 (100%)	7/7 (100%)	2/3 (67%)
POLY-3 RATE (b)	4/4.00	7/7.00	2/3.00
POLY-3 PERCENT (g)	100%	100%	66.7%
TERMINAL (d)	4/4 (100%)	7/7 (100%)	2/3 (67%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS			
POLY 3	P=0.195N	(e)	P=0.441N
POLY 1.5	P=0.195N	(e)	P=0.441N
POLY 6	P=0.195N	(e)	P=0.441N
COCH-ARM / FISHERS	P=0.206N	(e)	P=0.429N
MAX-ISO-POLY-3	P=0.069N	(e)	P=0.132N

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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.
 - (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 ***