

TDMS No. 20537 - 01
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: 09:40:22
First Dose M/F: 07/18/05 / NA
Lab: MBA

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF ADENOVIRAL VECTOR (ADHAQP1)

MALE RATS

Organ

Liver
Salivary Glands: Submandibular Gland, Right

Morphology

Inflammation
Inflammation

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N) LAST REMOVAL AT 5 WEEKS

Males			
DOSE	VEHCONTRCOHRTC	2-8ADHAQP1COHTC	8-9ADHAQP1COHTC
Heart Cardiomyopathy			
LESION RATES			
OVERALL (a)	1/5 (20%)	4/10 (40%)	2/5 (40%)
POLY-3 RATE (b)	1/5.00	4/10.00	2/5.00
POLY-3 PERCENT (g)	20%	40%	40%
INT SACRIFICE 1	0/4 (0%)	4/10 (40%)	2/5 (40%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	24	29 (I)	29 (I)
STATISTICAL TESTS			
POLY 3	P=0.500	P=0.427	P=0.500
POLY 1.5	P=0.500	P=0.427	P=0.500
POLY 6	P=0.500	P=0.427	P=0.500
COCH-ARM / FISHERS	P=0.500	P=0.434	P=0.500
MAX-ISO-POLY-3	P=0.375	P=0.262	P=0.264

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Males			
DOSE	VEHCONTRCOHRTC	2-8ADHAQP1COHTC	8-9ADHAQP1COHTC
Liver Inflammation			
LESION RATES			
OVERALL (a)	3/5 (60%)	1/10 (10%)	1/5 (20%)
POLY-3 RATE (b)	3/4.57	1/10.00	1/5.00
POLY-3 PERCENT (g)	65.7%	10%	20%
INT SACRIFICE 1	3/4 (75%)	1/10 (10%)	1/5 (20%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	29 (I)	29 (I)	29 (I)
STATISTICAL TESTS			
POLY 3	P=0.365N	P=0.040N*	P=0.216N
POLY 1.5	P=0.362N	P=0.046N*	P=0.237N
POLY 6	P=0.371N	P=0.032N*	P=0.190N
COCH-ARM / FISHERS	P=0.365N	P=0.077N	P=0.262N
MAX-ISO-POLY-3	P=0.044N*	P=0.019N*	P=0.082N

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Males			
DOSE	VEHCONTRCOHRTC	2-8ADHAQP1COHTC	8-9ADHAQP1COHTC
Salivary Glands: Submandibular Gland, Left Regeneration			
LESION RATES			
OVERALL (a)	0/5 (0%)	1/10 (10%)	2/5 (40%)
POLY-3 RATE (b)	0/4.57	1/10.00	2/5.00
POLY-3 PERCENT (g)	0%	10%	40%
INT SACRIFICE 1	0/4 (0%)	1/10 (10%)	2/5 (40%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	29 (I)	29 (I)
STATISTICAL TESTS			
POLY 3	P=0.112	P=0.651	P=0.230
POLY 1.5	P=0.107	P=0.644	P=0.219
POLY 6	P=0.119	P=0.660	P=0.245
COCH-ARM / FISHERS	P=0.105	P=0.667	P=0.222
MAX-ISO-POLY-3	P=0.072	P=0.292	P=0.068

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Males			
DOSE	VEHCONTRCOHRTC	2-8ADHAQP1COHTC	8-9ADHAQP1COHTC
Salivary Glands: Submandibular Gland, Right Inflammation			
LESION RATES			
OVERALL (a)	0/5 (0%)	5/10 (50%)	0/5 (0%)
POLY-3 RATE (b)	0/4.57	5/10.00	0/5.00
POLY-3 PERCENT (g)	0%	50%	0%
INT SACRIFICE 1	0/4 (0%)	5/10 (50%)	0/5 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	29 (I)	---
STATISTICAL TESTS			
POLY 3	P=0.300N	P=0.092	(e)
POLY 1.5	P=0.321N	P=0.083	(e)
POLY 6	P=0.273N	P=0.106	(e)
COCH-ARM / FISHERS	P=0.365N	P=0.084	(e)
MAX-ISO-POLY-3	P=0.140N	P=0.050*	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
LAST REMOVAL AT 5 WEEKS**

Males			
DOSE	VEHCONTRCOHRTC	2-8ADHAQP1COHTC	8-9ADHAQP1COHTC
Salivary Glands: Submandibular Gland, Right Regeneration			
LESION RATES			
OVERALL (a)	5/5 (100%)	9/10 (90%)	5/5 (100%)
POLY-3 RATE (b)	5/5.00	9/10.00	5/5.00
POLY-3 PERCENT (g)	100%	90%	100%
INT SACRIFICE 1	4/4 (100%)	9/10 (90%)	5/5 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	24	29 (I)	29 (I)
STATISTICAL TESTS			
POLY 3	P=0.741	P=0.636N	(e)
POLY 1.5	P=0.741	P=0.636N	(e)
POLY 6	P=0.741	P=0.636N	(e)
COCH-ARM / FISHERS	P=0.753	P=0.667N	(e)
MAX-ISO-POLY-3	P=0.448	P=0.274N	(e)

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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 ***