

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: 11:35:30
First Dose M/F: NA / 07/25/05
Lab: MBA

F1_R2_5Wk_SSAC

C Number:	C20537
Lock Date:	11/19/2007
Cage Range:	ALL
Date Range:	ALL
Reasons For Removal:	25017 SSAC
Removal Date Range:	ALL
Treatment Groups:	Include 003 VEHCONTRCOHRTC Include 008 2-8ADHAQP1COHTC Include 013 8-9ADHAQP1COHTC Include 018 2-11ADHAQP1COHTC
Study Gender:	Female
TDMSE Version:	2.1.0

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF ADENOVIRAL VECTOR (ADHAQP1)

FEMALE RATS

Organ

Salivary Glands: Submandibular Gland, Right

Morphology

Inflammation

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

Females			
DOSE	VEHCONTRCOHRTC	2-11ADHAQP1COHTC	8-9ADHAQP1COHTC
Salivary Glands: Submandibular Gland, Right Inflammation			
LESION RATES			
OVERALL (a)	0/4 (0%)	2/9 (22%)	3/5 (60%)
POLY-3 RATE (b)	0/4.00	2/9.00	3/5.00
POLY-3 PERCENT (g)	0%	22.2%	60%
INT SACRIFICE 1	0/4 (0%)	2/9 (22%)	3/5 (60%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	29 (I)	29 (I)
STATISTICAL TESTS			
POLY 3	P=0.055	P=0.427	P=0.088
POLY 1.5	P=0.055	P=0.427	P=0.088
POLY 6	P=0.055	P=0.427	P=0.088
COCH-ARM / FISHERS	P=0.063	P=0.462	P=0.119
MAX-ISO-POLY-3	P=0.034*	P=0.202	P=0.020*

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

Females			
DOSE	VEHCONTRCOHRTC	2-11ADHAQP1COHTC	8-9ADHAQP1COHTC
Salivary Glands: Submandibular Gland, Right Regeneration			
LESION RATES			
OVERALL (a)	4/4 (100%)	9/9 (100%)	5/5 (100%)
POLY-3 RATE (b)	4/4.00	9/9.00	5/5.00
POLY-3 PERCENT (g)	100%	100%	100%
INT SACRIFICE 1	4/4 (100%	9/9 (100%	5/5 (100%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	29 (I)	29 (I)	29 (I)
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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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 ***