

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: 09:43:56
First Dose M/F: 07/18/05 / NA
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 VEHCONTRCOHR E Include 010 2-8ADHAQP1COHTE Include 015 8-9AJDAQP1COHTE Include 020 2-11ADHAQP1COHTE
Study Gender:	Male
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

Males			
DOSE	VEHCONTRCOHR E	2-11ADHAQP1COHTE	8-9AJDAQP1COHTE
Heart Cardiomyopathy			
LESION RATES			
OVERALL (a)	3/5 (60%)	7/10 (70%)	4/5 (80%)
POLY-3 RATE (b)	3/5.00	7/10.00	4/5.00
POLY-3 PERCENT (g)	60%	70%	80%
TERMINAL (d)	3/5 (60%)	7/10 (70%)	4/5 (80%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS			
POLY 3	P=0.440	P=0.572	P=0.500
POLY 1.5	P=0.440	P=0.572	P=0.500
POLY 6	P=0.440	P=0.572	P=0.500
COCH-ARM / FISHERS	P=0.435	P=0.566	P=0.500
MAX-ISO-POLY-3	P=0.365	P=0.375	P=0.264

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TERMINAL SACRIFICE AT 14 WEEKS**

Males			
DOSE	VEHCONTRCOHR E	2-11ADHAQP1COHTE	8-9AJDAQP1COHTE
Salivary Glands: Submandibular Gland, Right Regeneration			
LESION RATES			
OVERALL (a)	4/4 (100%)	6/8 (75%)	2/3 (67%)
POLY-3 RATE (b)	4/4.00	6/8.00	2/3.00
POLY-3 PERCENT (g)	100%	75%	66.7%
TERMINAL (d)	4/4 (100%)	6/8 (75%)	2/3 (67%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)
STATISTICAL TESTS			
POLY 3	P=0.414N	P=0.396N	P=0.441N
POLY 1.5	P=0.414N	P=0.396N	P=0.441N
POLY 6	P=0.414N	P=0.396N	P=0.441N
COCH-ARM / FISHERS	P=0.409N	P=0.424N	P=0.429N
MAX-ISO-POLY-3	P=0.239N	P=0.181N	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 ***