

Experiment Number: 20601 - 03
Test Type: CHRONIC
Route: RESPIRATORY EXPOSURE WHOLE BODY
Species/Strain: RATS/Wistar Han

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Antimony trioxide
CAS Number: 1309-64-4

Date Report Requested: 03/12/2015
Time Report Requested: 12:53:26
First Dose M/F: 09/22/08 / 09/22/08
Lab: BNW

Custom Report - Artery Chronic Active Inflammation

NTP Study Number:	C20601		
Lock Date:	06/13/2011		
Cage Range:	ALL		
Date Range:	ALL		
Reasons For Removal:	25021 TSAC	25020 NATD	25019 MSAC
Removal Date Range:	ALL		
Treatment Groups:	Include ALL		
Study Gender:	Both		
TDMSE Version:	2.5.0.0_sfh		
PWG Approval Date:	10/21/2014		

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HISTORICAL CONTROL STUDIES
From November 2014 report

SAME ROUTE

20515-03 -- Metal Working Fluids: CIMSTAR 3800 (INHALATION AIR)
20523-03 -- Metal Working Fluids: Trim VX (INHALATION AIR)

ALL ROUTES

20203-03 -- Green Tea Extract (GAVAGE WATER)
20515-03 -- Metal Working Fluids: CIMSTAR 3800 (INHALATION AIR)
20523-03 -- Metal Working Fluids: Trim VX (INHALATION AIR)
20209-03 -- Pentabromodiphenyl Oxide (Technical) (DE 71) (GAVAGE CORN OIL)
20320-03 -- Tetrabromobisphenol A (GAVAGE CORN OIL)

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF ANTIMONY TRIOXIDE

MALE RATS

Organ

Artery (All Locations)

FEMALE RATS

Organ

Artery (All Locations)

Morphology

Chronic Active Inflammation

Morphology

Chronic Active Inflammation

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	3 mg/m3	10 mg/m3	30 mg/m3
Artery (All Locations)				
Chronic Active Inflammation				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	5/50 (10%)	16/50 (32%)
POLY-3 RATE (b)	1/41.07	1/41.41	5/42.61	16/43.53
POLY-3 PERCENT (g)	2.4%	2.4%	11.7%	36.8%
TERMINAL (d)	1/30 (3%)	0/30 (0%)	3/28 (11%)	4/18 (22%)
FIRST INCIDENCE	729 (T)	514	705	409
HC TUMORS SAME ROUTE	0/100 (0%)			
HC TUMORS ALL ROUTES	0/249 (0%)			
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.759N	P=0.109	P<0.001**
POLY 1.5	P<0.001**	P=0.760N	P=0.103	P<0.001**
POLY 6	P<0.001**	P=0.757N	P=0.116	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.753N	P=0.102	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.497N	P=0.051	P<0.001**
HISTCONT SAME RTE	P=0.015*	P=0.333	P=0.078	P=0.038*
HISTCONT ALL RTES	P<0.001**	P=0.126	P=0.004**	P<0.001**
CURR VS HC SAME RTE	P=0.039*			
CURR VS HC ALL RTES	P=0.017*			

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	3 mg/m3	10 mg/m3	30 mg/m3
Artery (All Locations)				
Chronic Active Inflammation				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	5/50 (10%)	15/50 (30%)
POLY-3 RATE (b)	0/46.10	0/45.65	5/43.73	15/40.49
POLY-3 PERCENT (g)	0%	0%	11.4%	37.1%
TERMINAL (d)	0/39 (0%)	0/38 (0%)	2/28 (7%)	4/20 (20%)
FIRST INCIDENCE	---	---	562	676
HC TUMORS SAME ROUTE	0/100 (0%)			
HC TUMORS ALL ROUTES	0/250 (0%)			
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.026*	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.028*	P<0.001**
POLY 6	P<0.001**	(e)	P=0.023*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.028*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.010**	P<0.001**
HISTCONT SAME RTE	P=0.017*	(e)	P=0.077	P=0.040*
HISTCONT ALL RTES	P<0.001**	(e)	P=0.004**	P<0.001**
CURR VS HC SAME RTE	P=1.000			
CURR VS HC ALL RTES	P=1.000			

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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.
- (h) Historical Controls statistic is not calculated when the HC Poly-3 rate is higher than the Poly-3 rates for all dose groups.
- (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 ***