

**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:** 17:07:20  
**First Dose M/F:** 09/22/08 / 09/22/08  
**Lab:** BNW

Custom Report - Lung Pool

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

**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:** 17:07:20  
**First Dose M/F:** 09/22/08 / 09/22/08  
**Lab:** BNW

**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)

**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:** 17:07:20

**First Dose M/F:** 09/22/08 / 09/22/08

**Lab:** BNW

**FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES EXAMINED.  
IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.**

Lung

**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:** 17:07:20  
**First Dose M/F:** 09/22/08 / 09/22/08  
**Lab:** BNW

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

### MALE RATS

#### Organ

Lung

#### Morphology

Alveolar/Bronchiolar Adenoma, Alveolar/Bronchiolar Carcinoma, Squamous Cell Carcinoma, or Cystic Keratinizing Epithelioma

### FEMALE RATS

#### Organ

Lung

#### Morphology

Alveolar/Bronchiolar Adenoma, Alveolar/Bronchiolar Carcinoma, Squamous Cell Carcinoma, or Cystic Keratinizing Epithelioma

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: 17:07:20  
 First Dose M/F: 09/22/08 / 09/22/08  
 Lab: BNW

**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
<b>Lung</b>				
Alveolar/Bronchiolar Adenoma, Alveolar/Bronchiolar Carcinoma, Squamous Cell Carcinoma, or Cystic Keratinizing Epithelioma				
<b>TUMOR RATES</b>				
OVERALL (a)	3/50 (6%)	4/50 (8%)	8/50 (16%)	8/50 (16%)
POLY-3 RATE (b)	3/42.46	4/40.76	8/43.53	8/40.72
POLY-3 PERCENT (g)	7.1%	9.8%	18.4%	19.7%
TERMINAL (d)	1/30 (3%)	4/30 (13%)	3/28 (11%)	4/18 (22%)
FIRST INCIDENCE	369	729 (T)	534	649
HC TUMORS SAME ROUTE	1/100 (1%)			
HC TUMORS ALL ROUTES	1/249 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.067	P=0.478	P=0.104	P=0.083
POLY 1.5	P=0.073	P=0.485	P=0.098	P=0.090
POLY 6	P=0.057	P=0.473	P=0.114	P=0.072
COCH-ARM / FISHERS	P=0.080	P=0.500	P=0.100	P=0.100
MAX-ISO-POLY-3	P=0.082	P=0.329	P=0.059	P=0.046*
HISTCONT SAME RTE	P=0.069	P=0.104	P=0.065	P=0.066
HISTCONT ALL RTEs	P=0.010**	P=0.009**	P=0.003**	P=0.003**
CURR VS HC SAME RTE	P=0.068			
CURR VS HC ALL RTEs	P=0.008**			

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: 17:07:20  
 First Dose M/F: 09/22/08 / 09/22/08  
 Lab: BNW

**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
<b>Lung</b>				
Alveolar/Bronchiolar Adenoma, Alveolar/Bronchiolar Carcinoma, Squamous Cell Carcinoma, or Cystic Keratinizing Epithelioma				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	2/50 (4%)	6/50 (12%)	6/50 (12%)
POLY-3 RATE (b)	0/46.10	2/45.65	6/43.59	6/40.98
POLY-3 PERCENT (g)	0%	4.4%	13.8%	14.6%
TERMINAL (d)	0/39 (0%)	2/38 (5%)	4/28 (14%)	2/20 (10%)
FIRST INCIDENCE	---	730 (T)	534	534
HC TUMORS SAME ROUTE	0/100 (0%)			
HC TUMORS ALL ROUTES	0/250 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.011*	P=0.235	P=0.012*	P=0.010**
POLY 1.5	P=0.015*	P=0.237	P=0.014*	P=0.012*
POLY 6	P=0.008**	P=0.232	P=0.010**	P=0.007**
COCH-ARM / FISHERS	P=0.023*	P=0.247	P=0.013*	P=0.013*
MAX-ISO-POLY-3	P=0.013*	P=0.076	P=0.004**	P=0.004**
HISTCONT SAME RTE	P=0.068	P=0.154	P=0.069	P=0.071
HISTCONT ALL RTEs	P=0.009**	P=0.019*	P=0.003**	P=0.004**
CURR VS HC SAME RTE	P=1.000			
CURR VS HC ALL RTEs	P=1.000			

**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:** 17:07:20  
**First Dose M/F:** 09/22/08 / 09/22/08  
**Lab:** BNW

**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 \*\*\*