

**Experiment Number:** 20523 - 03  
**Test Type:** CHRONIC  
**Route:** RESPIRATORY EXPOSURE WHOLE BODY  
**Species/Strain:** RATS/Wistar Han

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
Metal Working Fluids: Trim VX  
**CAS Number:** TRIMVX

**Date Report Requested:** 05/27/2015  
**Time Report Requested:** 13:58:42  
**First Dose M/F:** 07/20/09 / 07/20/09  
**Lab:** BNW

### Custom Report - Ovary and Uterus Pools

**NTP Study Number:** C20523  
**Lock Date:** 06/04/2012  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include 002 Control                      Include 004 10 mg/m3                      Include 006 30 mg/m3  
                                  Include 008 100 mg/m3  
**Study Gender:** Both  
**TDMSE Version:** 2.5.0.0\_sfh  
**PWG Approval Date:** 11/04/2014

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**HISTORICAL CONTROL STUDIES**  
From November 2014 report

**SAME ROUTE**

20601-03 -- Antimony trioxide (INHALATION AIR)  
20515-03 -- Metal Working Fluids: CIMSTAR 3800 (INHALATION AIR)

**ALL ROUTES**

20601-03 -- Antimony trioxide (INHALATION AIR)  
20203-03 -- Green Tea Extract (GAVAGE WATER)  
20515-03 -- Metal Working Fluids: CIMSTAR 3800 (INHALATION AIR)  
20209-03 -- Pentabromodiphenyl Oxide (Technical) (DE 71) (GAVAGE CORN OIL)  
20320-03 -- Tetrabromobisphenol A (GAVAGE CORN OIL)

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**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.**

Ovary

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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF METAL WORKING FLUIDS: TRIM VX**

**FEMALE RATS**

**Organ**

Ovary

**Morphology**

Tubulostromal Carcinoma or Tubulostromal Adenoma

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

DOSE	Females			
	Control	10 mg/m3	30 mg/m3	100 mg/m3
<b>Ovary</b>				
<b>Granulosa Cell Tumor: Benign or Malignant</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	1/50 (2%)	3/50 (6%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/41.92	3/42.23	0/44.19	2/43.95
POLY-3 PERCENT (g)	2.4%	7.1%	0%	4.6%
TERMINAL (d)	1/30 (3%)	3/33 (9%)	0/33 (0%)	2/30 (7%)
FIRST INCIDENCE	731 (T)	731 (T)	---	731 (T)
HC TUMORS SAME ROUTE	1/100 (1%)			
HC TUMORS ALL ROUTES	4/250 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.581	P=0.307	P=0.489N	P=0.516
POLY 1.5	P=0.575	P=0.302	P=0.493N	P=0.510
POLY 6	P=0.587	P=0.317	P=0.486N	P=0.524
COCH-ARM / FISHERS	P=0.567	P=0.309	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.435N	P=0.156	P=0.158N	P=0.298
HISTCONT SAME RTE	P=0.311	P=0.138	P=1.000	P=0.236
HISTCONT ALL RTEs	P=0.311	P=0.052	P=1.000	P=0.219
CURR VS HC SAME RTE	P=0.611			
CURR VS HC ALL RTEs	P=0.830			

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DOSE	Females			
	Control	10 mg/m3	30 mg/m3	100 mg/m3
<b>Ovary</b>				
<b>Tubulostromal Carcinoma or Tubulostromal Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/41.92	0/42.23	0/44.19	3/43.95
POLY-3 PERCENT (g)	0%	0%	0%	6.8%
TERMINAL (d)	0/30 (0%)	0/33 (0%)	0/33 (0%)	3/30 (10%)
FIRST INCIDENCE	---	---	---	731 (T)
HC TUMORS SAME ROUTE	2/100 (2%)			
HC TUMORS ALL ROUTES	2/250 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.008**	(e)	(e)	P=0.127
POLY 1.5	P=0.008**	(e)	(e)	P=0.124
POLY 6	P=0.008**	(e)	(e)	P=0.130
COCH-ARM / FISHERS	P=0.009**	(e)	(e)	P=0.121
MAX-ISO-POLY-3	P=0.013*	(e)	(e)	P=0.045*
HISTCONT SAME RTE	P=0.130	(e)	(e)	P=0.211
HISTCONT ALL RTES	P=0.040*	(e)	(e)	P=0.034*
CURR VS HC SAME RTE	P=0.406			
CURR VS HC ALL RTES	P=0.576			

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	10 mg/m3	30 mg/m3	100 mg/m3
<b>Uterus</b>				
<b>Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	2/50 (4%)	6/50 (12%)	2/50 (4%)
POLY-3 RATE (b)	2/41.92	2/42.53	6/44.56	2/44.05
POLY-3 PERCENT (g)	4.8%	4.7%	13.5%	4.5%
TERMINAL (d)	2/30 (7%)	1/33 (3%)	4/33 (12%)	1/30 (3%)
FIRST INCIDENCE	731 (T)	649	677	705
HC TUMORS SAME ROUTE	4/100 (4%)			
HC TUMORS ALL ROUTES	12/250 (5%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.519N	P=0.689N	P=0.152	P=0.676N
POLY 1.5	P=0.528N	P=0.693	P=0.145	P=0.683N
POLY 6	P=0.513N	P=0.678N	P=0.161	P=0.668N
COCH-ARM / FISHERS	P=0.550N	P=0.691N	P=0.134	P=0.691N
MAX-ISO-POLY-3	P=0.362	P=0.493N	P=0.087	P=0.479N
HISTCONT SAME RTE	P=0.332	P=1.000	P=0.108	P=1.000
HISTCONT ALL RTES	P=0.292	P=1.000	P=0.018*	P=1.000
CURR VS HC SAME RTE	P=0.888			
CURR VS HC ALL RTES	P=0.849			

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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 \*\*\*