

**Experiment Number:** 20536 - 01  
**Test Type:** 14-DAY  
**Route:** RESPIRATORY EXPOSURE WHOLE BODY  
**Species/Strain:** RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Abrasive Blasting Agents: Specular Hematite

**CAS Number:** HEMATITESPEC

**Date Report Requested:** 04/05/2018

**Time Report Requested:** 14:35:42

**First Dose M/F:** 08/14/06 / NA

**Lab:** BNW

**NTP Study Number:** C20536  
**Lock Date:** 07/19/2010  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Male  
**TDMSE Version:** 3.0.2.3\_002  
**PWG Approval Date:** NONE

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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF ABRASIVE BLASTING AGENTS: SPECULAR HEMATITE**

**MALE RATS**

**Organ**

Lung

Lung: Alveolus

Nose: Nasopharyngeal Duct, Goblet Cell

**Morphology**

Foreign Body

Infiltration Cellular Histiocyte

Hypertrophy

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 3 WEEKS**

DOSE	Males				
	0 mg/m3	3 mg/m3	15 mg/m3	30 mg/m3	60 mg/m3
<b>Lung</b>					
<b>Foreign Body</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/5 (0%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)
POLY-3 RATE (b)	0/5.00	5/5.00	5/5.00	5/5.00	5/5.00
POLY-3 PERCENT (g)	0%	100%	100%	100%	100%
TERMINAL (d)	0/5 (0%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)
FIRST INCIDENCE	---	16 (T)	16 (T)	16 (T)	16 (T)
<b>STATISTICAL TESTS</b>					
POLY 3	P=0.017*	P=0.004**	P=0.004**	P=0.004**	P=0.004**
POLY 1.5	P=0.017*	P=0.004**	P=0.004**	P=0.004**	P=0.004**
POLY 6	P=0.017*	P=0.004**	P=0.004**	P=0.004**	P=0.004**
COCH-ARM / FISHERS	P=0.017*	P=0.004**	P=0.004**	P=0.004**	P=0.004**
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)

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DOSE	Males				
	0 mg/m3	3 mg/m3	15 mg/m3	30 mg/m3	60 mg/m3
<b>Lung</b>					
<b>Inflammation Chronic</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/5 (0%)	1/5 (20%)	0/5 (0%)	0/5 (0%)	0/5 (0%)
POLY-3 RATE (b)	0/5.00	1/5.00	0/5.00	0/5.00	0/5.00
POLY-3 PERCENT (g)	0%	20%	0%	0%	0%
TERMINAL (d)	0/5 (0%)	1/5 (20%)	0/5 (0%)	0/5 (0%)	0/5 (0%)
FIRST INCIDENCE	---	16 (T)	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	P=0.435N	P=0.500	(e)	(e)	(e)
POLY 1.5	P=0.435N	P=0.500	(e)	(e)	(e)
POLY 6	P=0.435N	P=0.500	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.433N	P=0.500	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.378N	P=0.158	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 3 WEEKS**

DOSE	Males				
	0 mg/m3	3 mg/m3	15 mg/m3	30 mg/m3	60 mg/m3
<b>Lung: Alveolus Infiltration Cellular Histiocyte</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/5 (0%)	0/5 (0%)	2/5 (40%)	5/5 (100%)	5/5 (100%)
POLY-3 RATE (b)	0/5.00	0/5.00	2/5.00	5/5.00	5/5.00
POLY-3 PERCENT (g)	0%	0%	40%	100%	100%
TERMINAL (d)	0/5 (0%)	0/5 (0%)	2/5 (40%)	5/5 (100%)	5/5 (100%)
FIRST INCIDENCE	---	---	16 (T)	16 (T)	16 (T)
<b>STATISTICAL TESTS</b>					
POLY 3	P<0.001**	(e)	P=0.207	P=0.004**	P=0.004**
POLY 1.5	P<0.001**	(e)	P=0.207	P=0.004**	P=0.004**
POLY 6	P<0.001**	(e)	P=0.207	P=0.004**	P=0.004**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.222	P=0.004**	P=0.004**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.051	(e)	(e)

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 TERMINAL SACRIFICE AT 3 WEEKS**

DOSE	Males				
	0 mg/m3	3 mg/m3	15 mg/m3	30 mg/m3	60 mg/m3
<b>Nose: Nasopharyngeal Duct, Goblet Cell Hypertrophy</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/5 (0%)	0/5 (0%)	0/5 (0%)	1/5 (20%)	5/5 (100%)
POLY-3 RATE (b)	0/5.00	0/5.00	0/5.00	1/5.00	5/5.00
POLY-3 PERCENT (g)	0%	0%	0%	20%	100%
TERMINAL (d)	0/5 (0%)	0/5 (0%)	0/5 (0%)	1/5 (20%)	5/5 (100%)
FIRST INCIDENCE	---	---	---	16 (T)	16 (T)
<b>STATISTICAL TESTS</b>					
POLY 3	P<0.001**	(e)	(e)	P=0.500	P=0.004**
POLY 1.5	P<0.001**	(e)	(e)	P=0.500	P=0.004**
POLY 6	P<0.001**	(e)	(e)	P=0.500	P=0.004**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.500	P=0.004**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.158	(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.
  - (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 \*\*\*