

Experiment Number: 20536 - 02
Test Type: 39-WEEK
Route: RESPIRATORY EXPOSURE WHOLE BODY
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Abrasive blasting agents (specular hematite)
CAS Number: HEMATITESPEC

Date Report Requested: 09/13/2012
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First Dose M/F: 07/27/09 / NA
Lab: BNW

F1_Rev.1_4 Wk. SSAC

NTP Study Number: C20536
Lock Date: 07/19/2010
Cage Range: ALL
Date Range: ALL
Reasons For Removal: 25017 SSAC
Removal Date Range: 21-Aug-2009 - 21-Aug-2009
Treatment Groups: Include ALL
Study Gender: Male
TDMSE Version: 2.6.0.0_007
PWG Approval Date: 02/08/2012

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

MALE RATS

Organ

Larynx
Larynx: Epiglottis
Lung

Lymph Node, Bronchial

Morphology

Foreign Body
Metaplasia
Foreign Body
Infiltration Cellular Histiocyte
Foreign Body

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
 LAST REMOVAL AT 4 WEEKS**

DOSE	Males			
	Control	15 mg/m3	30 mg/m3	60 mg/m3
Larynx				
Foreign Body				
LESION RATES				
OVERALL (a)	0/8 (0%)	7/8 (88%)	8/8 (100%)	8/8 (100%)
POLY-3 RATE (b)	0/8.00	7/8.00	8/8.00	8/8.00
POLY-3 PERCENT (g)	0%	87.5%	100%	100%
INT SACRIFICE 1	0/8 (0%)	7/8 (88%)	8/8 (100%)	8/8 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	26 (l)	26 (l)	26 (l)
STATISTICAL TESTS				
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	(e)	(e)

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 LAST REMOVAL AT 4 WEEKS**

DOSE	Males			
	Control	15 mg/m3	30 mg/m3	60 mg/m3
Larynx: Epiglottis Metaplasia				
LESION RATES				
OVERALL (a)	0/8 (0%)	1/8 (13%)	4/8 (50%)	5/8 (63%)
POLY-3 RATE (b)	0/8.00	1/8.00	4/8.00	5/8.00
POLY-3 PERCENT (g)	0%	12.5%	50%	62.5%
INT SACRIFICE 1	0/8 (0%)	1/8 (13%)	4/8 (50%)	5/8 (63%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	26 (I)	26 (I)	26 (I)
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.500	P=0.024*	P=0.003**
POLY 1.5	P<0.001**	P=0.500	P=0.024*	P=0.003**
POLY 6	P<0.001**	P=0.500	P=0.024*	P=0.003**
COCH-ARM / FISHERS	P=0.003**	P=0.500	P=0.038*	P=0.013*
MAX-ISO-POLY-3	P=0.002**	P=0.159	P=0.004**	P<0.001**

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 LAST REMOVAL AT 4 WEEKS**

DOSE	Males			
	Control	15 mg/m3	30 mg/m3	60 mg/m3
Lung				
Foreign Body				
LESION RATES				
OVERALL (a)	0/8 (0%)	8/8 (100%)	8/8 (100%)	8/8 (100%)
POLY-3 RATE (b)	0/8.00	8/8.00	8/8.00	8/8.00
POLY-3 PERCENT (g)	0%	100%	100%	100%
INT SACRIFICE 1	0/8 (0%)	8/8 (100%)	8/8 (100%)	8/8 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	26 (I)	26 (I)	26 (I)
STATISTICAL TESTS				
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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 LAST REMOVAL AT 4 WEEKS**

DOSE	Males			
	Control	15 mg/m3	30 mg/m3	60 mg/m3
Lung				
Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	1/8 (13%)	1/8 (13%)	1/8 (13%)	8/8 (100%)
POLY-3 RATE (b)	1/8.00	1/8.00	1/8.00	8/8.00
POLY-3 PERCENT (g)	12.5%	12.5%	12.5%	100%
INT SACRIFICE 1	1/8 (13%)	1/8 (13%)	1/8 (13%)	8/8 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	26 (I)	26 (I)	26 (I)	26 (I)
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.760	P=0.760	P<0.001**
POLY 1.5	P<0.001**	P=0.760	P=0.760	P<0.001**
POLY 6	P<0.001**	P=0.760	P=0.760	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.767N	P=0.767N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=1.000	P=1.000	P<0.001**

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 LAST REMOVAL AT 4 WEEKS**

DOSE	Males			
	Control	15 mg/m3	30 mg/m3	60 mg/m3
Lung				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)
POLY-3 RATE (b)	0/8.00	0/8.00	0/8.00	1/8.00
POLY-3 PERCENT (g)	0%	0%	0%	12.5%
INT SACRIFICE 1	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	26 (I)
STATISTICAL TESTS				
POLY 3	P=0.197	(e)	(e)	P=0.500
POLY 1.5	P=0.197	(e)	(e)	P=0.500
POLY 6	P=0.197	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.193	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.124	(e)	(e)	P=0.159

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
 LAST REMOVAL AT 4 WEEKS**

DOSE	Males			
	Control	15 mg/m3	30 mg/m3	60 mg/m3
Lung				
Metaplasia Osseous				
LESION RATES				
OVERALL (a)	0/8 (0%)	1/8 (13%)	1/8 (13%)	0/8 (0%)
POLY-3 RATE (b)	0/8.00	1/8.00	1/8.00	0/8.00
POLY-3 PERCENT (g)	0%	12.5%	12.5%	0%
INT SACRIFICE 1	0/8 (0%)	1/8 (13%)	1/8 (13%)	0/8 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	26 (l)	26 (l)	---
STATISTICAL TESTS				
POLY 3	P=0.592N	P=0.500	P=0.500	(e)
POLY 1.5	P=0.592N	P=0.500	P=0.500	(e)
POLY 6	P=0.592N	P=0.500	P=0.500	(e)
COCH-ARM / FISHERS	P=0.595N	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.407N	P=0.159	P=0.159	(e)

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 LAST REMOVAL AT 4 WEEKS**

DOSE	Males			
	Control	15 mg/m3	30 mg/m3	60 mg/m3
Lymph Node, Bronchial Foreign Body				
LESION RATES				
OVERALL (a)	0/8 (0%)	0/8 (0%)	2/7 (29%)	5/8 (63%)
POLY-3 RATE (b)	0/8.00	0/8.00	2/7.00	5/8.00
POLY-3 PERCENT (g)	0%	0%	28.6%	62.5%
INT SACRIFICE 1	0/8 (0%)	0/8 (0%)	2/7 (29%)	5/8 (63%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	26 (I)	26 (I)
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.188	P=0.003**
POLY 1.5	P<0.001**	(e)	P=0.188	P=0.003**
POLY 6	P<0.001**	(e)	P=0.188	P=0.003**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.200	P=0.013*
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.053	P<0.001**

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 LAST REMOVAL AT 4 WEEKS**

DOSE	Males			
	Control	15 mg/m3	30 mg/m3	60 mg/m3
Lymph Node, Mediastinal Foreign Body				
LESION RATES				
OVERALL (a)	0/5 (0%)	0/6 (0%)	0/6 (0%)	1/5 (20%)
POLY-3 RATE (b)	0/5.00	0/6.00	0/6.00	1/5.00
POLY-3 PERCENT (g)	0%	0%	0%	20%
INT SACRIFICE 1	0/5 (0%)	0/6 (0%)	0/6 (0%)	1/5 (20%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	26 (I)
STATISTICAL TESTS				
POLY 3	P=0.180	(e)	(e)	P=0.500
POLY 1.5	P=0.180	(e)	(e)	P=0.500
POLY 6	P=0.180	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.178	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.105	(e)	(e)	P=0.159

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 LAST REMOVAL AT 4 WEEKS**

DOSE	Males			
	Control	15 mg/m3	30 mg/m3	60 mg/m3
Nose				
Foreign Body				
LESION RATES				
OVERALL (a)	1/8 (13%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
POLY-3 RATE (b)	1/8.00	0/8.00	0/8.00	0/8.00
POLY-3 PERCENT (g)	12.5%	0%	0%	0%
INT SACRIFICE 1	1/8 (13%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	26 (I)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.301N	P=0.500N	P=0.500N	P=0.500N
POLY 1.5	P=0.301N	P=0.500N	P=0.500N	P=0.500N
POLY 6	P=0.301N	P=0.500N	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.298N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.124N	P=0.159N	P=0.159N	P=0.159N

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 LAST REMOVAL AT 4 WEEKS**

DOSE	Males			
	Control	15 mg/m3	30 mg/m3	60 mg/m3
Nose Inflammation				
LESION RATES				
OVERALL (a)	1/8 (13%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
POLY-3 RATE (b)	1/8.00	0/8.00	0/8.00	0/8.00
POLY-3 PERCENT (g)	12.5%	0%	0%	0%
INT SACRIFICE 1	1/8 (13%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	26 (l)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.301N	P=0.500N	P=0.500N	P=0.500N
POLY 1.5	P=0.301N	P=0.500N	P=0.500N	P=0.500N
POLY 6	P=0.301N	P=0.500N	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.298N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.124N	P=0.159N	P=0.159N	P=0.159N

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DOSE	Males			
	Control	15 mg/m3	30 mg/m3	60 mg/m3
Nose				
Inflammation Chronic Focal				
LESION RATES				
OVERALL (a)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)
POLY-3 RATE (b)	0/8.00	0/8.00	0/8.00	1/8.00
POLY-3 PERCENT (g)	0%	0%	0%	12.5%
INT SACRIFICE 1	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	26 (I)
STATISTICAL TESTS				
POLY 3	P=0.197	(e)	(e)	P=0.500
POLY 1.5	P=0.197	(e)	(e)	P=0.500
POLY 6	P=0.197	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.193	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.124	(e)	(e)	P=0.159

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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 ***