

**Experiment Number:** 20214 - 01  
**Test Type:** 90-DAY  
**Route:** SKIN APPLICATION  
**Species/Strain:** RATS/F344/N Tac

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
5-Amino-o-cresol  
**CAS Number:** 2835-95-2

**Date Report Requested:** 10/16/2017  
**Time Report Requested:** 08:52:23  
**First Dose M/F:** 05/08/06 / 05/09/06  
**Lab:** BAT

**NTP Study Number:** C20214  
**Lock Date:** 12/04/2006  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 3.0.2.1\_cartox  
**PWG Approval Date:** NONE

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## SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF 5-AMINO-O-CRESOL

### MALE RATS

#### Organ

Liver  
Lung

Thyroid Gland

### FEMALE RATS

#### Organ

Kidney  
Liver  
Lung

Lymph Node, Mesenteric  
Ovary: Left

Thyroid Gland

#### Morphology

Inflammation Chronic  
Infiltration Cellular Histiocyte  
Inflammation Chronic  
Metaplasia Osseous  
Infiltration Cellular Mononuclear Cell

#### Morphology

Nephropathy  
Inflammation Chronic  
Infiltration Cellular Histiocyte  
Inflammation Chronic  
Inflammation Histiocytic  
Cyst  
Inflammation  
Infiltration Cellular Mononuclear Cell

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Adrenal Medulla Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	20%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.377	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.274

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Bone Marrow Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Epididymis</b>						
<b>Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Epididymis Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.132	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.066

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Harderian Gland Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Harderian Gland Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	10%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.760
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.760
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.760
COCH-ARM / FISHERS	P=0.645	(e)	(e)	(e)	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=1.000



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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Heart</b>						
<b>Cardiomyopathy</b>						
<b>LESION RATES</b>						
OVERALL (a)	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	10/10 (100%)
POLY-3 RATE (b)	10/10.00	0/0.00	0/0.00	0/0.00	0/0.00	10/10.00
POLY-3 PERCENT (g)	100%	0%	0%	0%	0%	100%
TERMINAL (d)	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	10/10 (100%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Intestine Large, Rectum Parasite Metazoan</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.132	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.066

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Kidney</b>						
<b>Infiltration Cellular</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Kidney</b>						
<b>Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	10%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.760
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.760
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.760
COCH-ARM / FISHERS	P=0.645	(e)	(e)	(e)	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=1.000

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Kidney Mineralization</b>						
<b>LESION RATES</b>						
OVERALL (a)	6/10 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	6/10 (60%)
POLY-3 RATE (b)	6/10.00	0/0.00	0/0.00	0/0.00	0/0.00	6/10.00
POLY-3 PERCENT (g)	60%	0%	0%	0%	0%	60%
TERMINAL (d)	6/10 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	6/10 (60%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.667
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.667
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.667
COCH-ARM / FISHERS	P=0.590	(e)	(e)	(e)	(e)	P=0.675N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=1.000

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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Kidney</b>						
<b>Nephropathy</b>						
<b>LESION RATES</b>						
OVERALL (a)	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	10/10 (100%)
POLY-3 RATE (b)	10/10.00	0/0.00	0/0.00	0/0.00	0/0.00	10/10.00
POLY-3 PERCENT (g)	100%	0%	0%	0%	0%	100%
TERMINAL (d)	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	10/10 (100%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

Experiment Number: 20214 - 01  
Test Type: 90-DAY  
Route: SKIN APPLICATION  
Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
5-Amino-o-cresol  
CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
Time Report Requested: 08:52:23  
First Dose M/F: 05/08/06 / 05/09/06  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
Liver						
Hematopoietic Cell Proliferation						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
Liver						
Hepatodiaphragmatic Nodule						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	1/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	93 (T)	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
POLY 1.5	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
POLY 6	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.699N	(e)	(e)	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.282	(e)	(e)	P=0.158	(e)	(e)



Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Liver</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL (a)	9/10 (90%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	9/10 (90%)
POLY-3 RATE (b)	9/10.00	0/10.00	0/10.00	1/10.00	0/10.00	9/10.00
POLY-3 PERCENT (g)	90%	0%	0%	10%	0%	90%
TERMINAL (d)	9/10 (90%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	9/10 (90%)
FIRST INCIDENCE	93 (T)	---	---	93 (T)	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P<0.001**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	P=0.760
POLY 1.5	P<0.001**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	P=0.760
POLY 6	P<0.001**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	P=0.760
COCH-ARM / FISHERS	P=0.010**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	P=0.763N
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	P=1.000

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Lung</b>						
<b>Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	4/10 (40%)
POLY-3 RATE (b)	2/10.00	0/10.00	0/10.00	0/10.00	0/10.00	4/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	40%
TERMINAL (d)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	4/10 (40%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.006**	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.318
POLY 1.5	P=0.006**	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.318
POLY 6	P=0.006**	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.318
COCH-ARM / FISHERS	P=0.012*	P=0.237N	P=0.237N	P=0.237N	P=0.237N	P=0.314
MAX-ISO-POLY-3	P<0.001**	P=0.066N	P=0.066N	P=0.066N	P=0.066N	P=0.172

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Lung Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL (a)	3/10 (30%)	5/10 (50%)	7/10 (70%)	8/10 (80%)	6/10 (60%)	5/10 (50%)
POLY-3 RATE (b)	3/10.00	5/10.00	7/10.00	8/10.00	6/10.00	5/10.00
POLY-3 PERCENT (g)	30%	50%	70%	80%	60%	50%
TERMINAL (d)	3/10 (30%)	5/10 (50%)	7/10 (70%)	8/10 (80%)	6/10 (60%)	5/10 (50%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.513	P=0.329	P=0.082	P=0.024*	P=0.186	P=0.329
POLY 1.5	P=0.513	P=0.329	P=0.082	P=0.024*	P=0.186	P=0.329
POLY 6	P=0.513	P=0.329	P=0.082	P=0.024*	P=0.186	P=0.329
COCH-ARM / FISHERS	P=0.513	P=0.325	P=0.089	P=0.035*	P=0.185	P=0.325
MAX-ISO-POLY-3	P=0.056	P=0.188	P=0.032*	P=0.007**	P=0.089	P=0.188

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Lung</b>						
<b>Metaplasia Osseous</b>						
<b>LESION RATES</b>						
OVERALL (a)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	10%
TERMINAL (d)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.649	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.500N
POLY 1.5	P=0.649	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.500N
POLY 6	P=0.649	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.500N
COCH-ARM / FISHERS	P=0.647	P=0.237N	P=0.237N	P=0.237N	P=0.237N	P=0.500N
MAX-ISO-POLY-3	P=0.030N*	P=0.066N	P=0.066N	P=0.066N	P=0.066N	P=0.274N

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Lymph Node, Mesenteric Inflammation Histiocytic</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Nose</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Pancreas</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158N

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Pancreas: Acinus Atrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.132	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.066



Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Pituitary Gland Cyst</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158N

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Salivary Glands</b>						
<b>Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Thyroid Gland Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 6	P=0.107	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.041*	(e)	(e)	(e)	(e)	P=0.158

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Trachea</b>						
<b>Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	5/10.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	50%	0%	0%	0%	0%	30%
TERMINAL (d)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.329N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.329N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.329N
COCH-ARM / FISHERS	P=0.247N	(e)	(e)	(e)	(e)	P=0.325N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.188N

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Urinary Bladder</b>						
<b>Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Adrenal Medulla</b>						
<b>Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Bone Marrow Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Harderian Gland Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.132	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.066



Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Harderian Gland Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	30%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.292
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.292
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.292
COCH-ARM / FISHERS	P=0.201	(e)	(e)	(e)	(e)	P=0.291
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.136

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Heart</b>						
<b>Cardiomyopathy</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	9/10 (90%)
<b>POLY-3 RATE (b)</b>	10/10.00	0/0.00	0/0.00	0/0.00	0/0.00	9/10.00
<b>POLY-3 PERCENT (g)</b>	100%	0%	0%	0%	0%	90%
<b>TERMINAL (d)</b>	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	9/10 (90%)
<b>FIRST INCIDENCE</b>	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	(e)	(e)	(e)	(e)	(e)	P=0.500N
<b>POLY 1.5</b>	(e)	(e)	(e)	(e)	(e)	P=0.500N
<b>POLY 6</b>	(e)	(e)	(e)	(e)	(e)	P=0.500N
<b>COCH-ARM / FISHERS</b>	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	(e)	(e)	P=0.158N

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Intestine Large, Rectum Parasite Metazoan</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158N

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Kidney</b>						
<b>Infiltration Cellular</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158N

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Kidney</b>						
<b>Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158N

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Kidney Mineralization</b>						
<b>LESION RATES</b>						
OVERALL (a)	7/10 (70%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	7/10 (70%)
POLY-3 RATE (b)	7/10.00	0/0.00	0/0.00	0/0.00	0/0.00	7/10.00
POLY-3 PERCENT (g)	70%	0%	0%	0%	0%	70%
TERMINAL (d)	7/10 (70%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	7/10 (70%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.678
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.678
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.678
COCH-ARM / FISHERS	P=0.596	(e)	(e)	(e)	(e)	P=0.686N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=1.000

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Kidney Nephropathy</b>						
<b>LESION RATES</b>						
OVERALL (a)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	3/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	30%	0%	0%	0%	0%	0%
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.095N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.095N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.095N
COCH-ARM / FISHERS	P=0.059N	(e)	(e)	(e)	(e)	P=0.105N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.025N*

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Liver</b>						
<b>Hematopoietic Cell Proliferation</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	1/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	93 (T)	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
POLY 1.5	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
POLY 6	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.699N	(e)	(e)	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.282	(e)	(e)	P=0.158	(e)	(e)



Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Liver</b>						
<b>Hepatodiaphragmatic Nodule</b>						
<b>LESION RATES</b>						
OVERALL (a)	2/10 (20%)	3/10 (30%)	2/10 (20%)	3/10 (30%)	2/10 (20%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	3/10.00	2/10.00	3/10.00	2/10.00	1/10.00
POLY-3 PERCENT (g)	20%	30%	20%	30%	20%	10%
TERMINAL (d)	2/10 (20%)	3/10 (30%)	2/10 (20%)	3/10 (30%)	2/10 (20%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.252N	P=0.500	P=0.702	P=0.500	P=0.702	P=0.500N
POLY 1.5	P=0.252N	P=0.500	P=0.702	P=0.500	P=0.702	P=0.500N
POLY 6	P=0.252N	P=0.500	P=0.702	P=0.500	P=0.702	P=0.500N
COCH-ARM / FISHERS	P=0.244N	P=0.500	P=0.709N	P=0.500	P=0.709N	P=0.500N
MAX-ISO-POLY-3	P=0.216N	P=0.310	P=1.000	P=0.310	P=1.000	P=0.274N

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Liver</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	10/10 (100%)	1/10 (10%)	2/10 (20%)	2/10 (20%)	2/10 (20%)	10/10 (100%)
<b>POLY-3 RATE (b)</b>	10/10.00	1/10.00	2/10.00	2/10.00	2/10.00	10/10.00
<b>POLY-3 PERCENT (g)</b>	100%	10%	20%	20%	20%	100%
<b>TERMINAL (d)</b>	10/10 (100%)	1/10 (10%)	2/10 (20%)	2/10 (20%)	2/10 (20%)	10/10 (100%)
<b>FIRST INCIDENCE</b>	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P<0.001**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	(e)
<b>POLY 1.5</b>	P<0.001**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	(e)
<b>POLY 6</b>	P<0.001**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	(e)
<b>COCH-ARM / FISHERS</b>	P=0.016*	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	(e)
<b>MAX-ISO-POLY-3</b>	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	(e)

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Lung</b>						
<b>Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 6	P=0.107	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.041*	(e)	(e)	(e)	(e)	P=0.158

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Lung Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL (a)	2/10 (20%)	2/10 (20%)	6/10 (60%)	3/10 (30%)	5/10 (50%)	6/10 (60%)
POLY-3 RATE (b)	2/10.00	2/10.00	6/10.00	3/10.00	5/10.00	6/10.00
POLY-3 PERCENT (g)	20%	20%	60%	30%	50%	60%
TERMINAL (d)	2/10 (20%)	2/10 (20%)	6/10 (60%)	3/10 (30%)	5/10 (50%)	6/10 (60%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.049*	P=0.702	P=0.077	P=0.500	P=0.174	P=0.077
POLY 1.5	P=0.049*	P=0.702	P=0.077	P=0.500	P=0.174	P=0.077
POLY 6	P=0.049*	P=0.702	P=0.077	P=0.500	P=0.174	P=0.077
COCH-ARM / FISHERS	P=0.051	P=0.709N	P=0.085	P=0.500	P=0.175	P=0.085
MAX-ISO-POLY-3	P=0.032*	P=1.000	P=0.029*	P=0.310	P=0.079	P=0.029*

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Lung</b>						
<b>Metaplasia Osseous</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Lymph Node, Mesenteric Inflammation Histiocytic</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/10 (50%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	5/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	50%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/10 (50%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.008**
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.008**
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.008**
COCH-ARM / FISHERS	P=0.010**	(e)	(e)	(e)	(e)	P=0.016*
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P<0.001**

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Nose</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.132	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.066

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Ovary: Left Cyst</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/1.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	100%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	93 (T)	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	P=0.091	(e)	(e)
POLY 1.5	(e)	(e)	(e)	P=0.091	(e)	(e)
POLY 6	(e)	(e)	(e)	P=0.091	(e)	(e)
COCH-ARM / FISHERS	P=0.510N	(e)	(e)	P=0.091	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	P<0.001**	(e)	(e)



Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Ovary: Left Inflammation</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/1.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	100%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	93 (T)	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	P=0.091	(e)	(e)
POLY 1.5	(e)	(e)	(e)	P=0.091	(e)	(e)
POLY 6	(e)	(e)	(e)	P=0.091	(e)	(e)
COCH-ARM / FISHERS	P=0.510N	(e)	(e)	P=0.091	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	P<0.001**	(e)	(e)

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Pancreas</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Pancreas: Acinus Atrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	10%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.377N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.274N

Experiment Number: 20214 - 01  
Test Type: 90-DAY  
Route: SKIN APPLICATION  
Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
5-Amino-o-cresol  
CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
Time Report Requested: 08:52:23  
First Dose M/F: 05/08/06 / 05/09/06  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Pituitary Gland Cyst</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Salivary Glands</b>						
<b>Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Thyroid Gland Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 6	P=0.107	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.041*	(e)	(e)	(e)	(e)	P=0.158

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Trachea</b>						
<b>Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	3/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	30%	0%	0%	0%	0%	10%
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.292N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.292N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.292N
COCH-ARM / FISHERS	P=0.201N	(e)	(e)	(e)	(e)	P=0.291N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.136N

Experiment Number: 20214 - 01  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 5-Amino-o-cresol  
 CAS Number: 2835-95-2

Date Report Requested: 10/16/2017  
 Time Report Requested: 08:52:23  
 First Dose M/F: 05/08/06 / 05/09/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg
<b>Urinary Bladder Infiltration Cellular Mononuclear Cell</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	10%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.760
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.760
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.760
COCH-ARM / FISHERS	P=0.645	(e)	(e)	(e)	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=1.000



**Experiment Number:** 20214 - 01  
**Test Type:** 90-DAY  
**Route:** SKIN APPLICATION  
**Species/Strain:** RATS/F344/N Tac

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

5-Amino-o-cresol  
**CAS Number:** 2835-95-2

**Date Report Requested:** 10/16/2017  
**Time Report Requested:** 08:52:23  
**First Dose M/F:** 05/08/06 / 05/09/06  
**Lab:** BAT

**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 \*\*\*