

Experiment Number: 20214 - 02
Test Type: 90-DAY
Route: SKIN APPLICATION
Species/Strain: MICE/B6C3F1

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: 05/11/06 / 05/10/06
Lab: BAT

NTP Study Number: C20214
Lock Date: 12/06/2006
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: 04/28/2008

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

MALE MICE

Organ

Kidney

Kidney: Renal Tubule

Liver

FEMALE MICE

Organ

Kidney

Lung: Alveolar Epithelium

Lung: Alveolar Epithelium, Bronchiole

Morphology

Inflammation

Nephropathy

Nephropathy

Regeneration

Inflammation

Morphology

Inflammation

Hyperplasia

Metaplasia

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Adrenal Cortex Fibrosis						
LESION RATES						
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)
STATISTICAL TESTS						
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 MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Adrenal Cortex Hypertrophy						
LESION RATES						
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)	---	---	---	---	---
STATISTICAL TESTS						
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 MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Adrenal Cortex: Subcapsular Hyperplasia						
LESION RATES						
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227N
COCH-ARM / FISHERS	P=0.132N	(e)	(e)	(e)	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.066N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Heart						
Cardiomyopathy						
LESION RATES						
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	---	---	---	---	---	---
STATISTICAL TESTS						
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	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Heart: Epicardium Hyperplasia Focal						
LESION RATES						
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	---	---	---	---	---	---
STATISTICAL TESTS						
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	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Kidney Inflammation						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	P=0.416N	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.500N
POLY 1.5	P=0.416N	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.500N
POLY 6	P=0.416N	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.415N	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.041N*	P=0.158N	P=0.158N	P=0.158N	P=0.158N	P=0.158N

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Kidney Mineralization						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	10%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	P=0.415	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.760
POLY 1.5	P=0.415	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.760
POLY 6	P=0.415	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.760
COCH-ARM / FISHERS	P=0.414	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.763N
MAX-ISO-POLY-3	P=0.163	P=0.158N	P=0.158N	P=0.158N	P=0.158N	P=1.000

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Kidney						
Nephropathy						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00	0/10.00	3/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	30%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	P=0.010**	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.292
POLY 1.5	P=0.010**	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.292
POLY 6	P=0.010**	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.292
COCH-ARM / FISHERS	P=0.014*	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.291
MAX-ISO-POLY-3	P=0.004**	P=0.158N	P=0.158N	P=0.158N	P=0.158N	P=0.136

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Kidney: Renal Tubule Nephropathy						
LESION RATES						
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)
STATISTICAL TESTS						
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

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Kidney: Renal Tubule Regeneration						
LESION RATES						
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)
STATISTICAL TESTS						
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

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Liver Inflammation						
LESION RATES						
OVERALL (a)	7/10 (70%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	10/10 (100%)
POLY-3 RATE (b)	7/10.00	0/0.00	0/0.00	0/0.00	0/0.00	10/10.00
POLY-3 PERCENT (g)	70%	0%	0%	0%	0%	100%
TERMINAL (d)	7/10 (70%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	10/10 (100%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.095
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.095
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.095
COCH-ARM / FISHERS	P=0.059	(e)	(e)	(e)	(e)	P=0.105
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.025*

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Lung						
Inflammation Chronic						
LESION RATES						
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	---	---	---	---	---	---
STATISTICAL TESTS						
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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Species/Strain: MICE/B6C3F1

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: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Lung: Alveolar Epithelium Hyperplasia						
LESION RATES						
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	---	---	---	---	---	---
STATISTICAL TESTS						
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 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

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: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Lung: Alveolar Epithelium, Bronchiole Metaplasia						
LESION RATES						
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	---	---	---	---	---	---
STATISTICAL TESTS						
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 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

5-Amino-o-cresol

CAS Number: 2835-95-2

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First Dose M/F: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Lung: Bronchiole Hyperplasia						
LESION RATES						
OVERALL (a)	0/10 (0%)	2/10 (20%)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	2/10.00	2/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	20%	20%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	2/10 (20%)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	93 (T)	93 (T)	---	---	---
STATISTICAL TESTS						
POLY 3	P=0.151N	P=0.227	P=0.227	(e)	(e)	(e)
POLY 1.5	P=0.151N	P=0.227	P=0.227	(e)	(e)	(e)
POLY 6	P=0.151N	P=0.227	P=0.227	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.157N	P=0.237	P=0.237	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.109N	P=0.066	P=0.066	(e)	(e)	(e)

Experiment Number: 20214 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

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: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Preputial Gland Inflammation						
LESION RATES						
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)
STATISTICAL TESTS						
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 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

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: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Stomach, Glandular Cyst						
LESION RATES						
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	---	---	---	---	---	---
STATISTICAL TESTS						
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 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

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: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Stomach, Glandular: Muscularis Hypertrophy						
LESION RATES						
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)	---	---	---	---	---
STATISTICAL TESTS						
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 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

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: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Adrenal Cortex Fibrosis						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.48	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	---	---	---	---	---	---
STATISTICAL TESTS						
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 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

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: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Adrenal Cortex Hypertrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.48	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	---	---	---	---	---	---
STATISTICAL TESTS						
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 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

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: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Adrenal Cortex: Subcapsular Hyperplasia						
LESION RATES						
OVERALL (a)	10/10 (100%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	9/10 (90%)
POLY-3 RATE (b)	10/10.00	0/0.00	0/0.00	1/1.00	0/0.00	9/10.00
POLY-3 PERCENT (g)	100%	0%	0%	100%	0%	90%
TERMINAL (d)	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	9/10 (90%)
FIRST INCIDENCE	93 (T)	---	---	73	---	93 (T)
STATISTICAL TESTS						
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=0.292N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158N

Experiment Number: 20214 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

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: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Heart						
Cardiomyopathy						
LESION RATES						
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.48	0/0.00	0/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	P=0.842N	(e)	P=0.227N
POLY 1.5	(e)	(e)	(e)	P=0.820N	(e)	P=0.227N
POLY 6	(e)	(e)	(e)	P=0.864N	(e)	P=0.227N
COCH-ARM / FISHERS	P=0.136N	(e)	(e)	P=0.818N	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.433N	(e)	P=0.066N

Experiment Number: 20214 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

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: 05/11/06 / 05/10/06

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Heart: Epicardium Hyperplasia Focal						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.48	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)
STATISTICAL TESTS						
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=0.292	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158

Experiment Number: 20214 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

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: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Kidney Inflammation						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/9.48	0/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	P=0.414N	P=0.500N	P=0.500N	P=0.511N	P=0.500N	P=0.500N
POLY 1.5	P=0.415N	P=0.500N	P=0.500N	P=0.506N	P=0.500N	P=0.500N
POLY 6	P=0.414N	P=0.500N	P=0.500N	P=0.516N	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.415N	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.041N*	P=0.158N	P=0.158N	P=0.172N	P=0.158N	P=0.158N

Experiment Number: 20214 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

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: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Kidney Mineralization						
LESION RATES						
OVERALL (a)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	2/10.00	0/10.00	0/10.00	0/9.48	0/10.00	2/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	20%
TERMINAL (d)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	P=0.242	P=0.227N	P=0.227N	P=0.239N	P=0.227N	P=0.702
POLY 1.5	P=0.241	P=0.227N	P=0.227N	P=0.234N	P=0.227N	P=0.702
POLY 6	P=0.243	P=0.227N	P=0.227N	P=0.246N	P=0.227N	P=0.702
COCH-ARM / FISHERS	P=0.245	P=0.237N	P=0.237N	P=0.237N	P=0.237N	P=0.709N
MAX-ISO-POLY-3	P=0.071	P=0.066N	P=0.066N	P=0.077N	P=0.066N	P=1.000

Experiment Number: 20214 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

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: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Kidney Nephropathy						
LESION RATES						
OVERALL (a)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	2/10.00	0/10.00	0/10.00	0/9.48	0/10.00	2/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	20%
TERMINAL (d)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	P=0.242	P=0.227N	P=0.227N	P=0.239N	P=0.227N	P=0.702
POLY 1.5	P=0.241	P=0.227N	P=0.227N	P=0.234N	P=0.227N	P=0.702
POLY 6	P=0.243	P=0.227N	P=0.227N	P=0.246N	P=0.227N	P=0.702
COCH-ARM / FISHERS	P=0.245	P=0.237N	P=0.237N	P=0.237N	P=0.237N	P=0.709N
MAX-ISO-POLY-3	P=0.071	P=0.066N	P=0.066N	P=0.077N	P=0.066N	P=1.000

Experiment Number: 20214 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

5-Amino-o-cresol

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Kidney: Renal Tubule Nephropathy						
LESION RATES						
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	0/9.48	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%)	0/9 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
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 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

5-Amino-o-cresol

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First Dose M/F: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Kidney: Renal Tubule Regeneration						
LESION RATES						
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	0/9.48	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%)	0/9 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
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 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

5-Amino-o-cresol

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First Dose M/F: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Liver Inflammation						
LESION RATES						
OVERALL (a)	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	8/10 (80%)
POLY-3 RATE (b)	10/10.00	0/0.00	0/0.00	0/0.48	0/0.00	8/10.00
POLY-3 PERCENT (g)	100%	0%	0%	0%	0%	80%
TERMINAL (d)	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	8/10 (80%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	P=0.091N	(e)	P=0.227N
POLY 1.5	(e)	(e)	(e)	P=0.091N	(e)	P=0.227N
POLY 6	(e)	(e)	(e)	P=0.091N	(e)	P=0.227N
COCH-ARM / FISHERS	P=0.248N	(e)	(e)	P=0.091N	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.066N

Experiment Number: 20214 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

5-Amino-o-cresol

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First Dose M/F: 05/11/06 / 05/10/06

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Lung						
Inflammation Chronic						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	1/9.48	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10.5%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/9 (11%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	93 (T)	---	93 (T)
STATISTICAL TESTS						
POLY 3	P=0.232	(e)	(e)	P=0.489	(e)	P=0.500
POLY 1.5	P=0.232	(e)	(e)	P=0.494	(e)	P=0.500
POLY 6	P=0.231	(e)	(e)	P=0.484	(e)	P=0.500
COCH-ARM / FISHERS	P=0.229	(e)	(e)	P=0.500	(e)	P=0.500
MAX-ISO-POLY-3	P=0.109	(e)	(e)	P=0.158	(e)	P=0.158

Experiment Number: 20214 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

5-Amino-o-cresol

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First Dose M/F: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Lung: Alveolar Epithelium Hyperplasia						
LESION RATES						
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	0/9.48	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%)	0/9 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
STATISTICAL TESTS						
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 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

5-Amino-o-cresol

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First Dose M/F: 05/11/06 / 05/10/06

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Lung: Alveolar Epithelium, Bronchiole Metaplasia						
LESION RATES						
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	0/9.48	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%)	0/9 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
STATISTICAL TESTS						
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 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Lung: Bronchiole Hyperplasia						
LESION RATES						
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	0/9.48	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%)	0/9 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
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 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Stomach, Glandular Cyst						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.48	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)
STATISTICAL TESTS						
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=0.292	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158

Experiment Number: 20214 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg	64 mg/kg	128 mg/kg
Stomach, Glandular: Muscularis Hypertrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.48	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	---	---	---	---	---	---
STATISTICAL TESTS						
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 - 02

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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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 ***