

TDMS No. 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 Reqsted: 04/02/2008
Time Report Reqsted: 09:26:22
First Dose M/F: 05/11/06 / 05/10/06
Lab: BAT

F1_M3

C 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
TDMSE Version: 1.9.1

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF 5-Amino-o-cresol

MALE MICE

Organ

Kidney

Morphology

Nephropathy

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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

LIFE TABLE	P=0.138N	(e)	(e)	(e)	(e)	P=0.234N
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
LOGISTIC REGRESSION	P=0.138N	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.132N	(e)	(e)	(e)	(e)	P=0.237N
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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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

LIFE TABLE	(e)	(e)	(e)	(e)	(e)	(e)
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)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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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

LIFE TABLE	P=0.414	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.766
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
LOGISTIC REGRESSION	P=0.414	(e)	(e)	(e)	(e)	P=0.766
COCH-ARM / FISHERS	P=0.414	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.763N
ORDER RESTRICTED	P=0.295	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.300	(e)	(e)	(e)	(e)	(e)

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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

LIFE TABLE	P=0.015*	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.293
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
LOGISTIC REGRESSION	P=0.015*	(e)	(e)	(e)	(e)	P=0.293
COCH-ARM / FISHERS	P=0.014*	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.291
ORDER RESTRICTED	P=0.005**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.007**	(e)	(e)	(e)	(e)	(e)

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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

**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

LIFE TABLE	P=0.064	(e)	(e)	(e)	(e)	P=0.111
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
LOGISTIC REGRESSION	P=0.064	(e)	(e)	(e)	(e)	P=0.111
COCH-ARM / FISHERS	P=0.059	(e)	(e)	(e)	(e)	P=0.105
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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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
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						
LIFE TABLE	P=0.159N	P=0.234	P=0.234	(e)	(e)	(e)
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)
LOGISTIC REGRESSION	(e)	P=0.234	P=0.234	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.157N	P=0.237	P=0.237	(e)	(e)	(e)
ORDER RESTRICTED	P=0.192N	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.201N	(e)	(e)	(e)	(e)	(e)

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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

**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

LIFE TABLE	P=0.297N	(e)	(e)	(e)	(e)	P=0.500N
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
LOGISTIC REGRESSION	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.292N	(e)	(e)	(e)	(e)	P=0.500N
ORDER RESTRICTED	(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	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

LIFE TABLE	P=0.138N	(e)	(e)	(e)	(e)	P=0.234N
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
LOGISTIC REGRESSION	P=0.138N	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.136N	(e)	(e)	P=0.818N	(e)	P=0.237N
ORDER RESTRICTED	(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	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						
LIFE TABLE	P=0.250	P=0.234N	P=0.234N	P=0.257N	P=0.234N	P=0.707
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
LOGISTIC REGRESSION	P=0.249	(e)	(e)	(e)	(e)	P=0.707
COCH-ARM / FISHERS	P=0.245	P=0.237N	P=0.237N	P=0.237N	P=0.237N	P=0.709N
ORDER RESTRICTED	P=0.119	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.129	(e)	(e)	(e)	(e)	(e)

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 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

LIFE TABLE	P=0.250	P=0.234N	P=0.234N	P=0.257N	P=0.234N	P=0.707
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
LOGISTIC REGRESSION	P=0.249	(e)	(e)	(e)	(e)	P=0.707
COCH-ARM / FISHERS	P=0.245	P=0.237N	P=0.237N	P=0.237N	P=0.237N	P=0.709N
ORDER RESTRICTED	P=0.119	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.129	(e)	(e)	(e)	(e)	(e)

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 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

LIFE TABLE	P=0.138N	(e)	(e)	(e)	(e)	P=0.234N
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
LOGISTIC REGRESSION	P=0.138N	(e)	(e)	(e)	(e)	P=0.234N
COCH-ARM / FISHERS	P=0.248N	(e)	(e)	P=0.091N	(e)	P=0.237N
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

TDMS No. 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: 04/02/2008
 Time Report Requested: 09:26:22
 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: 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

LIFE TABLE	(e)	(e)	(e)	(e)	(e)	(e)
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)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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.
 - (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. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death.
 - (e) Value of Statistic cannot be computed.
 - (g) Poly-3 adjusted lifetime tumor incidence.
 - (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
- Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors.
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***