

TDMS No. 20724 - 04

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Acetoin

CAS Number: 513-86-0

Date Report Requested: 07/28/2011

Time Report Requested: 10:24:59

First Dose M/F: 06/29/09 / 06/29/09

Lab: BNW

F1_M3

C Number: C20724
Lock Date: 03/04/2010
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.4.2.1_003
PWG Approval Date: NONE

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

DOSE	Males			
	CONTROL	50 ppm	400 ppm	800 ppm
<hr/>				
Kidney Cyst				
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LESION RATES				
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/1.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
FIRST INCIDENCE	95 (T)	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	P=0.913N	P=0.500N
POLY 1.5	(e)	(e)	P=0.913N	P=0.500N
POLY 6	(e)	(e)	P=0.913N	P=0.500N
COCH-ARM / FISHERS	P=0.300N	(e)	P=0.909N	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.409N	P=0.158N

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TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males			
	CONTROL	50 ppm	400 ppm	800 ppm
Larynx				
Infiltration Cellular Neutrophil				
LESION RATES				
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	20%	0%	0%	10%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	95 (T)	---	---	95 (T)
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.377N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.274N

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

DOSE	Males			
	CONTROL	50 ppm	400 ppm	800 ppm
Larynx: Squamous Epithelium Ulcer				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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

DOSE	Males			
	CONTROL	50 ppm	400 ppm	800 ppm
Lung				
Metaplasia Osseous				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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

Females

DOSE	CONTROL	800 ppm
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Kidney
Cyst

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

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TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	CONTROL	800 ppm
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Larynx
Infiltration Cellular Neutrophil

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

POLY 3	(n)
POLY 1.5	(n)
POLY 6	(n)
COCH-ARM / FISHERS	(n)
MAX-ISO-POLY-3	(n)

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TERMINAL SACRIFICE AT 14 WEEKS

Females

DOSE	CONTROL	800 ppm
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Larynx: Squamous Epithelium
Ulcer

LESION RATES

OVERALL (a)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	96 (T)	---

STATISTICAL TESTS

POLY 3	P=0.500N
POLY 1.5	P=0.500N
POLY 6	P=0.500N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.158N

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TERMINAL SACRIFICE AT 14 WEEKS**

Females

DOSE	CONTROL	800 ppm
Lung		
Metaplasia Osseous		
LESION RATES		
OVERALL (a)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	2/10.00
POLY-3 PERCENT (g)	0%	20%
TERMINAL (d)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	---	96 (T)

STATISTICAL TESTS

POLY 3	P=0.227
POLY 1.5	P=0.227
POLY 6	P=0.227
COCH-ARM / FISHERS	P=0.237
MAX-ISO-POLY-3	P=0.066

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 ***