

TDMS No. 20302-04
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE WHOLE BODY
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
ALPHA-PINENE
CAS Number: 80-56-8
Pathologist: GRUMBEIN, S. - LIEUALLEN, W.
F1_M3

Date Report Reqsted: 11/17/2006
Time Report Reqsted: 7:33:10
First Dose M/F: 03/28/05 / 03/28/05
Lab: BNW

C Number: C20302
Lock Date: 12/07/2005
Cage Range: 1 - 9999
Date Range: 1-JAN-1940 to 17-SEP-2040
Reasons For Removal: ALL
Removal Date Range: JAN /1 /1940 - SEP /17 /2040
Treatment Groups: Include 1 control
Include 4 25 ppm
Include 7 100 ppm
Include 10 200 ppm

Include 2 control
Include 5 50 ppm
Include 8 100 ppm
Include 11 400 ppm

Include 3 25 ppm
Include 6 50 ppm
Include 9 200 ppm
Include 12 400 ppm

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF ALPHA-PINENE

MALE MICE

Organ

Urinary Bladder: Transitional Epithelium

Morphology

Hyperplasia

FEMALE MICE

Organ

Urinary Bladder: Transitional Epithelium

Morphology

Hyperplasia

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

DOSE	Males					
	control	25 ppm	50 ppm	100 ppm	200 ppm	400 ppm

**Adrenal Cortex
Hypertrophy**

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	95 (T)	---	---	---	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.138N	P=1.000N	P=1.000N	P=1.000N	P=1.000N	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	P=1.000	P=1.000	P=1.000	P=1.000	P=0.237N
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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

DOSE	Males					
	control	25 ppm	50 ppm	100 ppm	200 ppm	400 ppm
Kidney						
Nephropathy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	1/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%	10%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	95 (T)	95 (T)	---	95 (T)
STATISTICAL TESTS						
LIFE TABLE	P=0.395	(e)	P=0.500	P=0.500	(e)	P=0.500
POLY 3	P=0.396	(e)	P=0.500	P=0.500	(e)	P=0.500
POLY 1.5	P=0.396	(e)	P=0.500	P=0.500	(e)	P=0.500
POLY 6	P=0.396	(e)	P=0.500	P=0.500	(e)	P=0.500
LOGISTIC REGRESSION	(e)	(e)	P=0.500	P=0.500	(e)	P=0.500
COCH-ARM / FISHERS	P=0.394	(e)	P=0.500	P=0.500	(e)	P=0.500
ORDER RESTRICTED	P=0.283	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.292	(e)	(e)	(e)	(e)	(e)

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

DOSE	Males					
	control	25 ppm	50 ppm	100 ppm	200 ppm	400 ppm

**Urinary Bladder: Transitional Epithelium
Hyperplasia**

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	7/10 (70%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	7/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	70%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	7/10 (70%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	95 (T)	95 (T)	95 (T)

STATISTICAL TESTS

LIFE TABLE	P<0.001**	(e)	(e)	P=0.003**	P<0.001**	P<0.001**
POLY 3	P<0.001**	(e)	(e)	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	(e)	P<0.001**	P<0.001**	P<0.001**
LOGISTIC REGRESSION	(e)	(e)	(e)	P=0.003**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.002**	P<0.001**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

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

DOSE	Females					
	control	25 ppm	50 ppm	100 ppm	200 ppm	400 ppm

**Adrenal Cortex
 Hypertrophy**

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)

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

DOSE	Females					
	control	25 ppm	50 ppm	100 ppm	200 ppm	400 ppm

**Kidney
Nephropathy**

LESION RATES

OVERALL (a)	2/10 (20%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	0/10.00	1/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	20%	0%	10%	0%	0%	10%
TERMINAL (d)	2/10 (20%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	96 (T)	---	96 (T)	---	---	96 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.550N	P=0.234N	P=0.500N	P=0.234N	P=0.234N	P=0.500N
POLY 3	P=0.550N	P=0.227N	P=0.500N	P=0.227N	P=0.227N	P=0.500N
POLY 1.5	P=0.550N	P=0.227N	P=0.500N	P=0.227N	P=0.227N	P=0.500N
POLY 6	P=0.550N	P=0.227N	P=0.500N	P=0.227N	P=0.227N	P=0.500N
LOGISTIC REGRESSION	P=0.550N	(e)	P=0.500N	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.550N	P=0.237N	P=0.500N	P=0.237N	P=0.237N	P=0.500N
ORDER RESTRICTED	P=0.112N	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.126N	(e)	(e)	(e)	(e)	(e)

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

DOSE	Females					
	control	25 ppm	50 ppm	100 ppm	200 ppm	400 ppm

**Urinary Bladder: Transitional Epithelium
Hyperplasia**

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	6/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	60%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	96 (T)	96 (T)	96 (T)

STATISTICAL TESTS

LIFE TABLE	P<0.001**	(e)	(e)	P=0.009**	P<0.001**	P<0.001**
POLY 3	P<0.001**	(e)	(e)	P<0.001**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001**	(e)	(e)	P<0.001**	P<0.001N**	P<0.001N**
POLY 6	P<0.001**	(e)	(e)	P<0.001**	P<0.001N**	P<0.001N**
LOGISTIC REGRESSION	(e)	(e)	(e)	P=0.009**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.005**	P<0.001**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(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 ***