

TDMS No. 20302-03
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE WHOLE BODY
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
ALPHA-PINENE
CAS Number: 80-56-8
Pathologist: RENNE, R. - GRUMBEIN, S. - LIEUALLEN, W.
F1_R2

Date Report Reqsted: 11/17/2006
Time Report Reqsted: 7:32:51
First Dose M/F: 03/28/05 / 03/29/05
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 RATS

Organ

Kidney

Morphology

Accumulation, Hyaline Droplet

Casts Granular

FEMALE RATS

Organ

Lung

Morphology

Inflammation Chronic

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 14 WEEKS**

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

**Heart
 Cardiomyopathy**

LESION RATES

OVERALL (a)	6/10 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	8/10 (80%)
POLY-3 RATE (b)	6/10.00	0/0.00	0/0.00	0/0.00	0/0.00	8/10.00
POLY-3 PERCENT (g)	60%	0%	0%	0%	0%	80%
TERMINAL (d)	6/10 (60%)	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=0.238	P=1.000N	P=1.000N	P=1.000N	P=1.000N	P=0.317
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.318
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.318
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.318
LOGISTIC REGRESSION	P=0.238	(e)	(e)	(e)	(e)	P=0.317
COCH-ARM / FISHERS	P=0.232	P=1.000	P=1.000	P=1.000	P=1.000	P=0.314
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 RATS(F 344)
 TERMINAL SACRIFICE AT 14 WEEKS**

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

**Kidney
 Accumulation, Hyaline Droplet**

LESION RATES

OVERALL (a)	1/10 (10%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	1/10.00	10/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	10%	100%	100%	100%	100%	100%
TERMINAL (d)	1/10 (10%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.003**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
LOGISTIC REGRESSION	P=0.003**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P=0.003**	P<0.001**	P<0.001**	P<0.001**	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 RATS(F 344)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	CONTROL	25 ppm	50 ppm	100 ppm	200 ppm	400 ppm
Kidney						
Casts Granular						
LESION RATES						
OVERALL (a)	0/10 (0%)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	9/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	90%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
STATISTICAL TESTS						
LIFE TABLE	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
LOGISTIC REGRESSION	(e)	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**	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 RATS(F 344)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	CONTROL	25 ppm	50 ppm	100 ppm	200 ppm	400 ppm
Kidney Nephropathy						
LESION RATES						
OVERALL (a)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	9/10.00	10/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	90%	100%	100%	100%	100%	100%
TERMINAL (d)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
STATISTICAL TESTS						
LIFE TABLE	P=0.416	P=0.500	P=0.500	P=0.500	P=0.500	P=0.500
POLY 3	P=0.416	P=0.500	P=0.500	P=0.500	P=0.500	P=0.500
POLY 1.5	P=0.416	P=0.500	P=0.500	P=0.500	P=0.500	P=0.500
POLY 6	P=0.416	P=0.500	P=0.500	P=0.500	P=0.500	P=0.500
LOGISTIC REGRESSION	P=0.416	P=0.500	P=0.500	P=0.500	P=0.500	P=0.500
COCH-ARM / FISHERS	P=0.415	P=0.500	P=0.500	P=0.500	P=0.500	P=0.500
ORDER RESTRICTED	P=0.064	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.076	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 14 WEEKS**

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

**Lung
 Inflammation Chronic**

LESION RATES

OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/10 (50%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	5/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	50%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/10 (50%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.127	P=1.000N	P=1.000N	P=1.000N	P=1.000N	P=0.180
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.174
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.174
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.174
LOGISTIC REGRESSION	P=0.127	(e)	(e)	(e)	(e)	P=0.180
COCH-ARM / FISHERS	P=0.121	P=1.000	P=1.000	P=1.000	P=1.000	P=0.175
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 RATS(F 344)
TERMINAL SACRIFICE AT 14 WEEKS**

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

**Mesentery: Fat
Necrosis**

LESION RATES

OVERALL (a)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	1/1.00	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	100%	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	93 (T)	---	---	---	---

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 RATS(F 344)
 TERMINAL SACRIFICE AT 14 WEEKS**

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

**Heart
 Cardiomyopathy**

LESION RATES

OVERALL (a)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)	1/10 (10%)
POLY-3 RATE (b)	3/10.00	0/0.00	0/0.00	0/0.00	2/10.00	1/6.17
POLY-3 PERCENT (g)	30%	0%	0%	0%	20%	16.2%
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)	0/4 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	93 (T)	50

STATISTICAL TESTS

LIFE TABLE	P=0.550N	P=1.000	P=1.000	P=1.000	P=0.500N	P=0.621N
POLY 3	(e)	(e)	(e)	(e)	P=0.500N	P=0.489N
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500N	P=0.440N
POLY 6	(e)	(e)	(e)	(e)	P=0.500N	P=0.507N
LOGISTIC REGRESSION	P=0.206N	(e)	(e)	(e)	P=0.500N	P=0.316N
COCH-ARM / FISHERS	P=0.201N	P=1.000	P=1.000	P=1.000	P=0.500N	P=0.291N
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 RATS(F 344)
 TERMINAL SACRIFICE AT 14 WEEKS**

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

**Kidney
 Accumulation, Hyaline Droplet**

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	0/5.32
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%)	0/4 (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 RATS(F 344)
TERMINAL SACRIFICE AT 14 WEEKS**

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

**Kidney
Casts Granular**

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	0/5.32
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%)	0/4 (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 RATS(F 344)
TERMINAL SACRIFICE AT 14 WEEKS**

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

**Kidney
Nephropathy**

LESION RATES

OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00	1/10.00	0/5.32
POLY-3 PERCENT (g)	10%	0%	0%	0%	10%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/4 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	93 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.740	P=0.500N	P=0.500N	P=0.500N	P=0.766	P=0.682N
POLY 3	P=0.603	P=0.500N	P=0.500N	P=0.500N	P=0.760	P=0.614N
POLY 1.5	P=0.629	P=0.500N	P=0.500N	P=0.500N	P=0.760	P=0.587N
POLY 6	P=0.592	P=0.500N	P=0.500N	P=0.500N	P=0.760	P=0.626N
LOGISTIC REGRESSION	P=0.740	(e)	(e)	(e)	P=0.766	(e)
COCH-ARM / FISHERS	P=0.586N	P=0.500N	P=0.500N	P=0.500N	P=0.763N	P=0.500N
ORDER RESTRICTED	P=0.377N	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.470N	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 14 WEEKS**

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

**Lung
 Inflammation Chronic**

LESION RATES

OVERALL (a)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)	5/9 (56%)
POLY-3 RATE (b)	4/10.00	0/0.00	0/0.00	0/0.00	2/10.00	5/6.27
POLY-3 PERCENT (g)	40%	0%	0%	0%	20%	79.7%
TERMINAL (d)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)	3/4 (75%)
FIRST INCIDENCE	93 (T)	---	---	---	93 (T)	36

STATISTICAL TESTS

LIFE TABLE	P=0.042*	P=1.000	P=1.000	P=1.000	P=0.317N	P=0.089
POLY 3	(e)	(e)	(e)	(e)	P=0.318N	P=0.150
POLY 1.5	(e)	(e)	(e)	(e)	P=0.318N	P=0.207
POLY 6	(e)	(e)	(e)	(e)	P=0.318N	P=0.130
LOGISTIC REGRESSION	P=0.358	(e)	(e)	(e)	P=0.317N	P=0.309
COCH-ARM / FISHERS	P=0.339	P=1.000	P=1.000	P=1.000	P=0.314N	P=0.414
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 RATS(F 344)
TERMINAL SACRIFICE AT 14 WEEKS**

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

**Mesentery: Fat
Necrosis**

LESION RATES

OVERALL (a)	1/1 (100%)	1/1 (100%)	3/3 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	1/1.00	1/1.00	3/3.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	100%	100%	100%	0%	0%	0%
TERMINAL (d)	1/1 (100%)	1/1 (100%)	3/3 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	---	---	---

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)

TDMS No. 20302-03

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

ALPHA-PINENE

CAS Number: 80-56-8

Pathologist: RENNE, R. - GRUMBEIN, S. - LIEUALLEN, W.

Date Report Requested: 11/17/2006

Time Report Requested: 7:32:51

First Dose M/F: 03/28/05 / 03/29/05

Lab: BNW

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 ***