

**TDMS No.** 20214 - 01  
**Test Type:** 90-DAY  
**Route:** SKIN APPLICATION  
**Species/Strain:** RATS/F344/N Tac

**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:** 09:24:09  
**First Dose M/F:** 05/08/06 / 05/09/06  
**Lab:** BAT

F1\_RD

**C Number:** C20214  
**Lock Date:** 12/04/2006  
**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 RATS**

**Organ**

Liver

Lung

Lung: Interstitium

**FEMALE RATS**

**Organ**

Liver

Lung

Lung: Interstitium

Lymph Node, Mesenteric

**Morphology**

Inflammation Chronic

Infiltration Cellular Histiocyte

Inflammation Chronic

Metaplasia Osseous

Inflammation Chronic

**Morphology**

Inflammation Chronic

Inflammation Chronic

Inflammation Chronic

Inflammation Histiocytic

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Adrenal Medulla  
Infiltration Cellular Mononuclear Cell**

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.380	(e)	(e)	(e)	(e)	P=0.500
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
LOGISTIC REGRESSION	P=0.380	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.377	(e)	(e)	(e)	(e)	P=0.500
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Epididymis  
Inflammation Chronic**

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.138	(e)	(e)	(e)	(e)	P=0.234
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.234
COCH-ARM / FISHERS	P=0.132	(e)	(e)	(e)	(e)	P=0.237
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Harderian Gland  
Infiltration Cellular Mononuclear Cell**

**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**

LIFE TABLE	P=0.309	(e)	(e)	(e)	(e)	P=0.500
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
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Harderian Gland  
Inflammation Chronic**

**LESION RATES**

OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	10%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.642	(e)	(e)	(e)	(e)	P=0.766
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.760
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.760
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.760
LOGISTIC REGRESSION	P=0.642	(e)	(e)	(e)	(e)	P=0.766
COCH-ARM / FISHERS	P=0.645	(e)	(e)	(e)	(e)	P=0.763N
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Heart  
Cardiomyopathy**

**LESION RATES**

OVERALL (a)	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	10/10 (100%)
POLY-3 RATE (b)	10/10.00	0/0.00	0/0.00	0/0.00	0/0.00	10/10.00
POLY-3 PERCENT (g)	100%	0%	0%	0%	0%	100%
TERMINAL (d)	10/10 (100%)	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	(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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Intestine Large, Rectum  
Parasite Metazoan**

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.138	(e)	(e)	(e)	(e)	P=0.234
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.234
COCH-ARM / FISHERS	P=0.132	(e)	(e)	(e)	(e)	P=0.237
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Kidney  
Mineralization**

**LESION RATES**

OVERALL (a)	6/10 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	6/10 (60%)
POLY-3 RATE (b)	6/10.00	0/0.00	0/0.00	0/0.00	0/0.00	6/10.00
POLY-3 PERCENT (g)	60%	0%	0%	0%	0%	60%
TERMINAL (d)	6/10 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	6/10 (60%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.588	(e)	(e)	(e)	(e)	P=0.672
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.667
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.667
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.667
LOGISTIC REGRESSION	P=0.588	(e)	(e)	(e)	(e)	P=0.672
COCH-ARM / FISHERS	P=0.590	(e)	(e)	(e)	(e)	P=0.675N
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Kidney  
Nephropathy**

**LESION RATES**

OVERALL (a)	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	10/10 (100%)
POLY-3 RATE (b)	10/10.00	0/0.00	0/0.00	0/0.00	0/0.00	10/10.00
POLY-3 PERCENT (g)	100%	0%	0%	0%	0%	100%
TERMINAL (d)	10/10 (100%)	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	(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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

Liver  
Hepatodiaphragmatic Nodule

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
POLY 3	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
POLY 1.5	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
POLY 6	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.699N	(e)	(e)	P=0.500	(e)	(e)
ORDER RESTRICTED	P=0.516	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.516	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Liver  
Inflammation Chronic**

**LESION RATES**

OVERALL (a)	9/10 (90%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	9/10 (90%)
POLY-3 RATE (b)	9/10.00	0/10.00	0/10.00	1/10.00	0/10.00	9/10.00
POLY-3 PERCENT (g)	90%	0%	0%	10%	0%	90%
TERMINAL (d)	9/10 (90%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	9/10 (90%)
FIRST INCIDENCE	93 (T)	---	---	93 (T)	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.011*	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	P=0.766
POLY 3	P<0.001**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	P=0.760
POLY 1.5	P<0.001**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	P=0.760
POLY 6	P<0.001**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	P=0.760
LOGISTIC REGRESSION	P=0.011*	(e)	(e)	P<0.001N**	(e)	P=0.766
COCH-ARM / FISHERS	P=0.010**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	P=0.763N
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001N**	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Lung  
Infiltration Cellular Histiocyte**

**LESION RATES**

OVERALL (a)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	4/10 (40%)
POLY-3 RATE (b)	2/10.00	0/10.00	0/10.00	0/10.00	0/10.00	4/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	40%
TERMINAL (d)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	4/10 (40%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.012*	P=0.234N	P=0.234N	P=0.234N	P=0.234N	P=0.317
POLY 3	P=0.006**	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.318
POLY 1.5	P=0.006**	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.318
POLY 6	P=0.006**	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.318
LOGISTIC REGRESSION	P=0.012*	(e)	(e)	(e)	(e)	P=0.317
COCH-ARM / FISHERS	P=0.012*	P=0.237N	P=0.237N	P=0.237N	P=0.237N	P=0.314
ORDER RESTRICTED	P=0.002**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.003**	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Lung  
Inflammation Chronic**

**LESION RATES**

OVERALL (a)	3/10 (30%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	5/10 (50%)
POLY-3 RATE (b)	3/10.00	0/10.00	0/10.00	0/10.00	0/10.00	5/10.00
POLY-3 PERCENT (g)	30%	0%	0%	0%	0%	50%
TERMINAL (d)	3/10 (30%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	5/10 (50%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.009**	P=0.111N	P=0.111N	P=0.111N	P=0.111N	P=0.328
POLY 3	P=0.003**	P=0.095N	P=0.095N	P=0.095N	P=0.095N	P=0.329
POLY 1.5	P=0.003**	P=0.095N	P=0.095N	P=0.095N	P=0.095N	P=0.329
POLY 6	P=0.003**	P=0.095N	P=0.095N	P=0.095N	P=0.095N	P=0.329
LOGISTIC REGRESSION	P=0.009**	(e)	(e)	(e)	(e)	P=0.328
COCH-ARM / FISHERS	P=0.008**	P=0.105N	P=0.105N	P=0.105N	P=0.105N	P=0.325
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Lung  
Metaplasia Osseous**

**LESION RATES**

OVERALL (a)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	10%
TERMINAL (d)	2/10 (20%)	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=0.646	P=0.234N	P=0.234N	P=0.234N	P=0.234N	P=0.500N
POLY 3	P=0.649	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.500N
POLY 1.5	P=0.649	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.500N
POLY 6	P=0.649	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.500N
LOGISTIC REGRESSION	P=0.646	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.647	P=0.237N	P=0.237N	P=0.237N	P=0.237N	P=0.500N
ORDER RESTRICTED	P=0.046N*	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.054N	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Lung: Interstitium  
Inflammation Chronic**

**LESION RATES**

OVERALL (a)	0/10 (0%)	5/10 (50%)	7/10 (70%)	8/10 (80%)	6/10 (60%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	5/10.00	7/10.00	8/10.00	6/10.00	0/10.00
POLY-3 PERCENT (g)	0%	50%	70%	80%	60%	0%
TERMINAL (d)	0/10 (0%)	5/10 (50%)	7/10 (70%)	8/10 (80%)	6/10 (60%)	0/10 (0%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	93 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.070N	P=0.022*	P=0.003**	P<0.001**	P=0.009**	(e)
POLY 3	P=0.032N*	P=0.008**	P<0.001**	P<0.001**	P<0.001**	(e)
POLY 1.5	P=0.032N*	P=0.008**	P<0.001**	P<0.001**	P<0.001**	(e)
POLY 6	P=0.032N*	P=0.008**	P<0.001**	P<0.001**	P<0.001**	(e)
LOGISTIC REGRESSION	(e)	P=0.022*	P=0.003**	P<0.001**	P=0.009**	(e)
COCH-ARM / FISHERS	P=0.069N	P=0.016*	P=0.002**	P<0.001**	P=0.005**	(e)
ORDER RESTRICTED	P=0.002**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.003**	(e)	(e)	(e)	(e)	(e)



**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Lymph Node, Mesenteric  
Inflammation Histiocytic**

**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**

LIFE TABLE	P=0.309	(e)	(e)	(e)	(e)	P=0.500
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
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Nose  
Inflammation Chronic**

**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 RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Pancreas: Acinus Atrophy**

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.138	(e)	(e)	(e)	(e)	P=0.234
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.234
COCH-ARM / FISHERS	P=0.132	(e)	(e)	(e)	(e)	P=0.237
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Trachea  
Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	5/10.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	50%	0%	0%	0%	0%	30%
TERMINAL (d)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.252N	(e)	(e)	(e)	(e)	P=0.328N
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.329N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.329N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.329N
LOGISTIC REGRESSION	P=0.252N	(e)	(e)	(e)	(e)	P=0.328N
COCH-ARM / FISHERS	P=0.247N	(e)	(e)	(e)	(e)	P=0.325N
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Adrenal Medulla  
Infiltration Cellular Mononuclear Cell**

**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 RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Harderian Gland  
Infiltration Cellular Mononuclear Cell**

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.138	(e)	(e)	(e)	(e)	P=0.234
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.234
COCH-ARM / FISHERS	P=0.132	(e)	(e)	(e)	(e)	P=0.237
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Harderian Gland  
Inflammation Chronic**

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.207	(e)	(e)	(e)	(e)	P=0.293
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.292
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.292
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.292
LOGISTIC REGRESSION	P=0.207	(e)	(e)	(e)	(e)	P=0.293
COCH-ARM / FISHERS	P=0.201	(e)	(e)	(e)	(e)	P=0.291
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Heart  
Cardiomyopathy**

**LESION RATES**

OVERALL (a)	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	9/10 (90%)
POLY-3 RATE (b)	10/10.00	0/0.00	0/0.00	0/0.00	0/0.00	9/10.00
POLY-3 PERCENT (g)	100%	0%	0%	0%	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)	---	---	---	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.309N	(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=0.309N	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(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)



**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Intestine Large, Rectum  
Parasite Metazoan**

**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**

LIFE TABLE	P=0.309N	(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=0.309N	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.304N	(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)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Kidney  
Mineralization**

**LESION RATES**

OVERALL (a)	7/10 (70%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	7/10 (70%)
POLY-3 RATE (b)	7/10.00	0/0.00	0/0.00	0/0.00	0/0.00	7/10.00
POLY-3 PERCENT (g)	70%	0%	0%	0%	0%	70%
TERMINAL (d)	7/10 (70%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	7/10 (70%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.594	(e)	(e)	(e)	(e)	P=0.683
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.678
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.678
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.678
LOGISTIC REGRESSION	P=0.594	(e)	(e)	(e)	(e)	P=0.683
COCH-ARM / FISHERS	P=0.596	(e)	(e)	(e)	(e)	P=0.686N
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Kidney  
Nephropathy**

**LESION RATES**

OVERALL (a)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	3/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	30%	0%	0%	0%	0%	0%
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.064N	(e)	(e)	(e)	(e)	P=0.111N
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.095N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.095N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.095N
LOGISTIC REGRESSION	P=0.064N	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.059N	(e)	(e)	(e)	(e)	P=0.105N
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

Liver  
Hepatodiaphragmatic Nodule

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.246N	P=0.500	P=0.707	P=0.500	P=0.707	P=0.500N
POLY 3	P=0.252N	P=0.500	P=0.702	P=0.500	P=0.702	P=0.500N
POLY 1.5	P=0.252N	P=0.500	P=0.702	P=0.500	P=0.702	P=0.500N
POLY 6	P=0.252N	P=0.500	P=0.702	P=0.500	P=0.702	P=0.500N
LOGISTIC REGRESSION	P=0.246N	P=0.500	P=0.707	P=0.500	P=0.707	P=0.500N
COCH-ARM / FISHERS	P=0.244N	P=0.500	P=0.709N	P=0.500	P=0.709N	P=0.500N
ORDER RESTRICTED	P=0.397N	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.399N	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Liver  
Inflammation Chronic**

**LESION RATES**

OVERALL (a)	10/10 (100%)	1/10 (10%)	2/10 (20%)	2/10 (20%)	2/10 (20%)	10/10 (100%)
POLY-3 RATE (b)	10/10.00	1/10.00	2/10.00	2/10.00	2/10.00	10/10.00
POLY-3 PERCENT (g)	100%	10%	20%	20%	20%	100%
TERMINAL (d)	10/10 (100%)	1/10 (10%)	2/10 (20%)	2/10 (20%)	2/10 (20%)	10/10 (100%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.016*	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	(e)
POLY 3	P<0.001**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	(e)
POLY 1.5	P<0.001**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	(e)
POLY 6	P<0.001**	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	(e)
LOGISTIC REGRESSION	P=0.016*	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	(e)
COCH-ARM / FISHERS	P=0.016*	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**	(e)
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001N**	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Lung  
Infiltration Cellular Histiocyte**

**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**

LIFE TABLE	P=0.107	(e)	(e)	(e)	(e)	P=0.500
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
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
ORDER RESTRICTED	P=0.065	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.074	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Lung  
Inflammation Chronic**

**LESION RATES**

OVERALL (a)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)
POLY-3 RATE (b)	2/10.00	0/10.00	0/10.00	0/10.00	0/10.00	6/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	60%
TERMINAL (d)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.234N	P=0.234N	P=0.234N	P=0.234N	P=0.091
POLY 3	P<0.001**	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.077
POLY 1.5	P<0.001**	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.077
POLY 6	P<0.001**	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.077
LOGISTIC REGRESSION	P<0.001**	(e)	(e)	(e)	(e)	P=0.091
COCH-ARM / FISHERS	P<0.001**	P=0.237N	P=0.237N	P=0.237N	P=0.237N	P=0.085
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Lung  
Metaplasia Osseous**

**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**

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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Lung: Interstitium  
Inflammation Chronic**

**LESION RATES**

OVERALL (a)	0/10 (0%)	2/10 (20%)	6/10 (60%)	3/10 (30%)	5/10 (50%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	2/10.00	6/10.00	3/10.00	5/10.00	0/10.00
POLY-3 PERCENT (g)	0%	20%	60%	30%	50%	0%
TERMINAL (d)	0/10 (0%)	2/10 (20%)	6/10 (60%)	3/10 (30%)	5/10 (50%)	0/10 (0%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	93 (T)	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.252N	P=0.234	P=0.009**	P=0.111	P=0.022*	(e)
POLY 3	P=0.228N	P=0.227	P<0.001**	P=0.095	P=0.008**	(e)
POLY 1.5	P=0.228N	P=0.227	P<0.001**	P=0.095	P=0.008**	(e)
POLY 6	P=0.228N	P=0.227	P<0.001**	P=0.095	P=0.008**	(e)
LOGISTIC REGRESSION	(e)	P=0.234	P=0.009**	P=0.111	P=0.022*	(e)
COCH-ARM / FISHERS	P=0.250N	P=0.237	P=0.005**	P=0.105	P=0.016*	(e)
ORDER RESTRICTED	P=0.037*	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.044*	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Lymph Node, Mesenteric  
Inflammation Histiocytic**

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.012*	(e)	(e)	(e)	(e)	P=0.022*
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.008**
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.008**
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.008**
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.022*
COCH-ARM / FISHERS	P=0.010**	(e)	(e)	(e)	(e)	P=0.016*
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Nose  
Inflammation Chronic**

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.138	(e)	(e)	(e)	(e)	P=0.234
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.234
COCH-ARM / FISHERS	P=0.132	(e)	(e)	(e)	(e)	P=0.237
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(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Pancreas: Acinus Atrophy**

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.380N	(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=0.380N	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.377N	(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)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F344/N Tac)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/kg	2 mg/kg	4 mg/kg	8 mg/kg	16 mg/kg	32 mg/kg

**Trachea  
Infiltration Cellular Mononuclear Cell**

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.207N	(e)	(e)	(e)	(e)	P=0.293N
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.292N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.292N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.292N
LOGISTIC REGRESSION	P=0.207N	(e)	(e)	(e)	(e)	P=0.293N
COCH-ARM / FISHERS	P=0.201N	(e)	(e)	(e)	(e)	P=0.291N
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 \*\*\*