

TDMS No. 99019 - 03

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Triethylamine

CAS Number: 121-44-8

Date Report Requested: 10/15/2008

Time Report Requested: 07:47:08

First Dose M/F: 01/20/03 / 01/21/03

Lab: BNW

F1_Rev.1_R2

C Number: C99019
Lock Date: 09/16/2003
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.0.0

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

MALE RATS

Organ

Harderian Gland

Larynx

Liver

Nose: Olfactory Epithelium

Nose: Respiratory Epithelium

Morphology

Infiltration Cellular Mononuclear Cell

Infiltration Cellular Mononuclear Cell

Hepatodiaphragmatic Nodule

Atrophy

Degeneration Hyaline

Hyperplasia

FEMALE RATS

Organ

Eye: Cornea

Lung: Alveolus

Nose: Olfactory Epithelium

Nose: Respiratory Epithelium

Morphology

Mineralization

Infiltration Cellular Histiocyte

Atrophy

Hyperplasia

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

DOSE	Males					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

Eye: Cornea
Mineralization

LESION RATES

OVERALL (a)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.00	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)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---

STATISTICAL TESTS

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)
COCH-ARM / FISHERS	(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/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

Eye: Retina
Hypoplasia

LESION RATES

OVERALL (a)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.00	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)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---

STATISTICAL TESTS

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)
COCH-ARM / FISHERS	(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/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Harderian Gland
Infiltration Cellular Mononuclear Cell**

LESION RATES

OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	1/1.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	100%	10%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	---	---	---	93 (T)	93 (T)

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)	P=0.146	P=0.760
POLY 1.5	(e)	(e)	(e)	(e)	P=0.146	P=0.760
POLY 6	(e)	(e)	(e)	(e)	P=0.146	P=0.760
COCH-ARM / FISHERS	P=0.625	(e)	(e)	(e)	P=0.182	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.022*	P=1.000

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

DOSE	Males					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Larynx
Infiltration Cellular Mononuclear Cell**

LESION RATES

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

STATISTICAL TESTS

POLY 3	P=0.167N	P=0.095	(e)	P=0.500	(e)	(e)
POLY 1.5	P=0.167N	P=0.095	(e)	P=0.500	(e)	(e)
POLY 6	P=0.167N	P=0.095	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.181N	P=0.105	(e)	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.076N	P=0.025*	(e)	P=0.158	(e)	(e)

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

DOSE	Males					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Liver
Hepatodiaphragmatic Nodule**

LESION RATES

OVERALL (a)	0/10 (0%)	3/10 (30%)	4/10 (40%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	3/10.00	4/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	30%	40%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	3/10 (30%)	4/10 (40%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	93 (T)	93 (T)	---	---	93 (T)

STATISTICAL TESTS

POLY 3	P=0.221N	P=0.095	P=0.033*	(e)	(e)	P=0.500
POLY 1.5	P=0.221N	P=0.095	P=0.033*	(e)	(e)	P=0.500
POLY 6	P=0.221N	P=0.095	P=0.033*	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.237N	P=0.105	P=0.043*	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.078N	P=0.025*	P=0.007**	(e)	(e)	P=0.158

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

DOSE	Males					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Liver
Inflammation**

LESION RATES

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

STATISTICAL TESTS

POLY 3	P=0.590N	(e)	(e)	P=0.227	(e)	(e)
POLY 1.5	P=0.590N	(e)	(e)	P=0.227	(e)	(e)
POLY 6	P=0.590N	(e)	(e)	P=0.227	(e)	(e)
COCH-ARM / FISHERS	P=0.586N	(e)	(e)	P=0.237	(e)	(e)
MAX-ISO-POLY-3	P=0.193	(e)	(e)	P=0.066	(e)	(e)

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

DOSE	Males					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Lung
Metaplasia Osseous**

LESION RATES

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

STATISTICAL TESTS

POLY 3	P=0.189N	P=0.227N	P=0.702	P=0.702	P=0.500N	P=0.227N
POLY 1.5	P=0.189N	P=0.227N	P=0.702	P=0.702	P=0.500N	P=0.227N
POLY 6	P=0.189N	P=0.227N	P=0.702	P=0.702	P=0.500N	P=0.227N
COCH-ARM / FISHERS	P=0.186N	P=0.237N	P=0.709N	P=0.709N	P=0.500N	P=0.237N
MAX-ISO-POLY-3	P=0.083N	P=0.066N	P=1.000	P=1.000	P=0.274N	P=0.066N

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

DOSE	Males					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Lung: Alveolus
Infiltration Cellular Histiocyte**

LESION RATES

OVERALL (a)	4/10 (40%)	5/10 (50%)	3/10 (30%)	2/10 (20%)	6/10 (60%)	6/10 (60%)
POLY-3 RATE (b)	4/10.00	5/10.00	3/10.00	2/10.00	6/10.00	6/10.00
POLY-3 PERCENT (g)	40%	50%	30%	20%	60%	60%
TERMINAL (d)	4/10 (40%)	5/10 (50%)	3/10 (30%)	2/10 (20%)	6/10 (60%)	6/10 (60%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

STATISTICAL TESTS

POLY 3	P=0.122	P=0.500	P=0.500N	P=0.318N	P=0.333	P=0.333
POLY 1.5	P=0.122	P=0.500	P=0.500N	P=0.318N	P=0.333	P=0.333
POLY 6	P=0.122	P=0.500	P=0.500N	P=0.318N	P=0.333	P=0.333
COCH-ARM / FISHERS	P=0.121	P=0.500	P=0.500N	P=0.314N	P=0.328	P=0.328
MAX-ISO-POLY-3	P=0.121	P=0.332	P=0.325N	P=0.172N	P=0.193	P=0.193

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

DOSE	Males					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

Mesentery: Fat
Necrosis Chronic

LESION RATES

OVERALL (a)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---	---

STATISTICAL TESTS

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)
COCH-ARM / FISHERS	(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/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Nose
Inflammation Chronic**

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

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)
COCH-ARM / FISHERS	(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/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Nose: Olfactory Epithelium
Atrophy**

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	93 (T)	93 (T)	93 (T)

STATISTICAL TESTS

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**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P<0.001**	P<0.001**	P<0.001**

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

DOSE	Males					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Nose: Respiratory Epithelium
Degeneration Hyaline**

LESION RATES

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

STATISTICAL TESTS

POLY 3	P<0.001**	(e)	(e)	(e)	(e)	P=0.095
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	P=0.095
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	P=0.095
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P=0.105
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	P=0.025*

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

DOSE	Males					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Nose: Respiratory Epithelium
Hyperplasia**

LESION RATES

OVERALL (a)	0/10 (0%)	3/10 (30%)	9/10 (90%)	9/10 (90%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	3/10.00	9/10.00	9/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	30%	90%	90%	100%	100%
TERMINAL (d)	0/10 (0%)	3/10 (30%)	9/10 (90%)	9/10 (90%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.095	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.095	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.095	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.105	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.025*	P<0.001**	P<0.001**	P<0.001**	P<0.001**

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

DOSE	Females					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Eye: Cornea
Mineralization**

LESION RATES

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

STATISTICAL TESTS

POLY 3	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
POLY 6	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.010**	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	P=0.008**	(e)	(e)	(e)	(e)	P=0.067

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

DOSE	Females					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

Eye: Retina
Hypoplasia

LESION RATES

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

STATISTICAL TESTS

POLY 3	P=0.410	(e)	(e)	(e)	P=0.227	(e)
POLY 1.5	P=0.410	(e)	(e)	(e)	P=0.227	(e)
POLY 6	P=0.410	(e)	(e)	(e)	P=0.227	(e)
COCH-ARM / FISHERS	P=0.414	(e)	(e)	(e)	P=0.237	(e)
MAX-ISO-POLY-3	P=0.177	(e)	(e)	(e)	P=0.067	(e)

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

DOSE	Females					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Harderian Gland
Infiltration Cellular Mononuclear Cell**

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

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
COCH-ARM / FISHERS	P=0.201	(e)	(e)	(e)	(e)	P=0.291
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.135

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

DOSE	Females					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Larynx
Infiltration Cellular Mononuclear Cell**

LESION RATES

OVERALL (a)	0/9 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.00	1/10.00	1/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	10%	10%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	93 (T)	93 (T)	---	---	---

STATISTICAL TESTS

POLY 3	P=0.326N	P=0.521	P=0.521	(e)	(e)	(e)
POLY 1.5	P=0.326N	P=0.521	P=0.521	(e)	(e)	(e)
POLY 6	P=0.326N	P=0.521	P=0.521	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.323N	P=0.526	P=0.526	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.394N	P=0.178	P=0.178	(e)	(e)	(e)

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

DOSE	Females					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Liver
Hepatodiaphragmatic Nodule**

LESION RATES

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

STATISTICAL TESTS

POLY 3	P=0.119	P=0.500N	P=0.500N	P=0.760	P=0.760	P=0.500
POLY 1.5	P=0.119	P=0.500N	P=0.500N	P=0.760	P=0.760	P=0.500
POLY 6	P=0.119	P=0.500N	P=0.500N	P=0.760	P=0.760	P=0.500
COCH-ARM / FISHERS	P=0.114	P=0.500N	P=0.500N	P=0.763N	P=0.763N	P=0.500
MAX-ISO-POLY-3	P=0.170	P=0.158N	P=0.158N	P=1.000	P=1.000	P=0.274

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

DOSE	Females					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Liver
Inflammation**

LESION RATES

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

STATISTICAL TESTS

POLY 3	P=0.607N	P=0.500N	P=0.500	P=0.500	P=0.760	P=0.760
POLY 1.5	P=0.607N	P=0.500N	P=0.500	P=0.500	P=0.760	P=0.760
POLY 6	P=0.607N	P=0.500N	P=0.500	P=0.500	P=0.760	P=0.760
COCH-ARM / FISHERS	P=0.611N	P=0.500N	P=0.500	P=0.500	P=0.763N	P=0.763N
MAX-ISO-POLY-3	P=0.458	P=0.158N	P=0.274	P=0.274	P=1.000	P=1.000

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

DOSE	Females					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Lung
Metaplasia Osseous**

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

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
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.074	(e)	(e)	(e)	(e)	P=0.158

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

DOSE	Females					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Lung: Alveolus
Infiltration Cellular Histiocyte**

LESION RATES

OVERALL (a)	2/10 (20%)	1/10 (10%)	4/10 (40%)	4/10 (40%)	7/10 (70%)	7/10 (70%)
POLY-3 RATE (b)	2/10.00	1/10.00	4/10.00	4/10.00	7/10.00	7/10.00
POLY-3 PERCENT (g)	20%	10%	40%	40%	70%	70%
TERMINAL (d)	2/10 (20%)	1/10 (10%)	4/10 (40%)	4/10 (40%)	7/10 (70%)	7/10 (70%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.500N	P=0.318	P=0.318	P=0.024*	P=0.024*
POLY 1.5	P<0.001**	P=0.500N	P=0.318	P=0.318	P=0.024*	P=0.024*
POLY 6	P<0.001**	P=0.500N	P=0.318	P=0.318	P=0.024*	P=0.024*
COCH-ARM / FISHERS	P=0.002**	P=0.500N	P=0.314	P=0.314	P=0.035*	P=0.035*
MAX-ISO-POLY-3	P=0.002**	P=0.274N	P=0.171	P=0.171	P=0.007**	P=0.007**

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

DOSE	Females					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Mesentery: Fat
Necrosis Chronic**

LESION RATES

OVERALL (a)	0/0 (0%)	0/0 (0%)	2/2 (100%)	1/1 (100%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00	2/2.00	1/1.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	100%	100%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	2/2 (100%)	1/1 (100%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	93 (T)	93 (T)	---	---

STATISTICAL TESTS

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)
COCH-ARM / FISHERS	(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/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Nose
Inflammation Chronic**

LESION RATES

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

STATISTICAL TESTS

POLY 3	P=0.478	(e)	(e)	P=0.500	P=0.227	(e)
POLY 1.5	P=0.478	(e)	(e)	P=0.500	P=0.227	(e)
POLY 6	P=0.478	(e)	(e)	P=0.500	P=0.227	(e)
COCH-ARM / FISHERS	P=0.478	(e)	(e)	P=0.500	P=0.237	(e)
MAX-ISO-POLY-3	P=0.274	(e)	(e)	P=0.158	P=0.067	(e)

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

DOSE	Females					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Nose: Olfactory Epithelium
Atrophy**

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)	4/10 (40%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	4/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	40%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	4/10 (40%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	93 (T)	93 (T)	93 (T)	93 (T)

STATISTICAL TESTS

POLY 3	P<0.001**	(e)	P=0.033*	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.033*	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	P=0.033*	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.043*	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.007**	P<0.001**	P<0.001**	P<0.001**

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

DOSE	Females					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Nose: Respiratory Epithelium
Degeneration Hyaline**

LESION RATES

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

STATISTICAL TESTS

POLY 3	P=0.584	(e)	(e)	(e)	P=0.500	(e)
POLY 1.5	P=0.584	(e)	(e)	(e)	P=0.500	(e)
POLY 6	P=0.584	(e)	(e)	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.585	(e)	(e)	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.356	(e)	(e)	(e)	P=0.158	(e)

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

DOSE	Females					
	CONTROL	12.5 PPM	25 PPM	50 PPM	100 PPM	200 PPM

**Nose: Respiratory Epithelium
Hyperplasia**

LESION RATES

OVERALL (a)	0/10 (0%)	3/10 (30%)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	3/10.00	9/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	30%	90%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	3/10 (30%)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.095	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.095	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.095	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.105	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.024*	P<0.001**	P<0.001**	P<0.001**	P<0.001**

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 ***