

**TDMS No.** 20724 - 03

**Test Type:** 90-DAY

**Route:** RESPIRATORY EXPOSURE WHOLE BODY

**Species/Strain:** RATS/Wistar Han

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Acetoin

**CAS Number:** 513-86-0

**Date Report Requested:** 07/28/2011

**Time Report Requested:** 10:24:16

**First Dose M/F:** 06/29/09 / 06/30/09

**Lab:** BNW

F1\_RE

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

**MALE RATS**

**Organ**

Heart

Kidney: Pelvis

Liver

Urinary Bladder

**Morphology**

Cardiomyopathy

Dilatation

Atrophy

Calculus Gross Observation

**FEMALE RATS**

**Organ**

Liver

Urinary Bladder

Urinary Bladder: Transitional Epithelium

**Morphology**

Hepatodiaphragmatic Nodule

Necrosis

Calculus Gross Observation

Hyperplasia

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Heart</b>					
<b>Cardiomyopathy</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	30%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	(e)	P=0.095
POLY 1.5	(e)	(e)	(e)	(e)	P=0.095
POLY 6	(e)	(e)	(e)	(e)	P=0.095
COCH-ARM / FISHERS	P=0.079	(e)	(e)	(e)	P=0.105
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.025*

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Heart</b>					
<b>Necrosis Acute</b>					
<b>LESION RATES</b>					
<b>OVERALL (a)</b>	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
<b>POLY-3 RATE (b)</b>	1/10.00	0/0.00	0/0.00	0/0.00	0/10.00
<b>POLY-3 PERCENT (g)</b>	10%	0%	0%	0%	0%
<b>TERMINAL (d)</b>	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
<b>FIRST INCIDENCE</b>	93 (T)	---	---	---	---
<b>STATISTICAL TESTS</b>					
<b>POLY 3</b>	(e)	(e)	(e)	(e)	P=0.500N
<b>POLY 1.5</b>	(e)	(e)	(e)	(e)	P=0.500N
<b>POLY 6</b>	(e)	(e)	(e)	(e)	P=0.500N
<b>COCH-ARM / FISHERS</b>	P=0.399N	(e)	(e)	(e)	P=0.500N
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	(e)	P=0.158N

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Kidney Nephropathy</b>					
<b>LESION RATES</b>					
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/2 (0%)	3/10 (30%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/2.00	3/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	30%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/2 (0%)	3/10 (30%)
FIRST INCIDENCE	93 (T)	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	P=0.627N	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.627N	P=0.500
POLY 6	(e)	(e)	(e)	P=0.627N	P=0.500
COCH-ARM / FISHERS	P=0.401	(e)	(e)	P=0.682N	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.307N	P=0.310

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Kidney: Cortex</b>					
<b>Cyst</b>					
<b>LESION RATES</b>					
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/2 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/2.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/2 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	P=0.805N	P=0.500N
POLY 1.5	(e)	(e)	(e)	P=0.805N	P=0.500N
POLY 6	(e)	(e)	(e)	P=0.805N	P=0.500N
COCH-ARM / FISHERS	P=0.414N	(e)	(e)	P=0.833N	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.367N	P=0.158N

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Kidney: Medulla Inflammation Chronic</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/2 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/2.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/2 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Kidney: Pelvis Dilatation</b>					
<b>LESION RATES</b>					
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	2/2 (100%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	2/2.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	100%	10%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	2/2 (100%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	---	---	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	P=0.005**	P=0.760
POLY 1.5	(e)	(e)	(e)	P=0.005**	P=0.760
POLY 6	(e)	(e)	(e)	P=0.005**	P=0.760
COCH-ARM / FISHERS	P=0.484N	(e)	(e)	P=0.045*	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	(e)	P<0.001**	P=1.000



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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Kidney: Pelvis Inflammation Chronic</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/2 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/2.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/2 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)

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Lab: BNW

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Kidney: Transitional Epithelium Hyperplasia</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/2 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/2.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/2 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Larynx</b>					
<b>Inflammation Acute</b>					
<b>LESION RATES</b>					
<b>OVERALL (a)</b>	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
<b>POLY-3 RATE (b)</b>	1/10.00	0/0.00	0/0.00	0/0.00	2/10.00
<b>POLY-3 PERCENT (g)</b>	10%	0%	0%	0%	20%
<b>TERMINAL (d)</b>	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
<b>FIRST INCIDENCE</b>	93 (T)	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>					
<b>POLY 3</b>	(e)	(e)	(e)	(e)	P=0.500
<b>POLY 1.5</b>	(e)	(e)	(e)	(e)	P=0.500
<b>POLY 6</b>	(e)	(e)	(e)	(e)	P=0.500
<b>COCH-ARM / FISHERS</b>	P=0.438	(e)	(e)	(e)	P=0.500
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	(e)	P=0.274

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Larynx</b>					
<b>Inflammation Chronic</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (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	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.399	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.158

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Larynx: Squamous Epithelium</b>					
<b>Erosion</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (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	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.399	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.158

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Larynx: Squamous Epithelium Hyperplasia</b>					
<b>LESION RATES</b>					
OVERALL (a)	1/10 (10%)	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	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.399N	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.158N

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Liver</b>					
<b>Atrophy</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/1.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	100%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	93 (T)	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	P=0.091	(e)	(e)	(e)
POLY 1.5	(e)	P=0.091	(e)	(e)	(e)
POLY 6	(e)	P=0.091	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.466N	P=0.091	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	P<0.001**	(e)	(e)	(e)

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Liver</b>					
<b>Hepatodiaphragmatic Nodule</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/1.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)



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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Liver</b>					
<b>Necrosis</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/1.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Lung</b>					
<b>Infiltration Cellular Histiocyte</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/1.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.163	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.066

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Lung</b>					
<b>Inflammation Chronic</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/1.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Lung</b>					
<b>Metaplasia Osseous</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/1.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.388	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.158

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Lymph Node: Iliac Infiltration Cellular Mixed Cell</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/1.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Pancreas Atrophy</b>					
<b>LESION RATES</b>					
OVERALL (a)	1/10 (10%)	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	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	10%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	(e)	P=0.760
POLY 1.5	(e)	(e)	(e)	(e)	P=0.760
POLY 6	(e)	(e)	(e)	(e)	P=0.760
COCH-ARM / FISHERS	P=0.712	(e)	(e)	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=1.000

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Pancreas: Acinus Atrophy</b>					
<b>LESION RATES</b>					
OVERALL (a)	1/10 (10%)	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	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.399N	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.158N

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Pituitary Gland Cyst</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (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	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.399	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.158



TDMS No. 20724 - 03

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Acetoin

CAS Number: 513-86-0

Date Report Requested: 07/28/2011

Time Report Requested: 10:24:16

First Dose M/F: 06/29/09 / 06/30/09

Lab: BNW

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Preputial Gland Inflammation Chronic</b>					
<b>LESION RATES</b>					
OVERALL (a)	1/10 (10%)	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	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.399N	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.158N

TDMS No. 20724 - 03

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Acetoin

CAS Number: 513-86-0

Date Report Requested: 07/28/2011

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First Dose M/F: 06/29/09 / 06/30/09

Lab: BNW

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
Skin					
Ulcer					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (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	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Spleen</b>					
<b>Accessory Spleen</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (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	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>					
POLY 3	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.399	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.158

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Urinary Bladder</b>					
<b>Calculus Gross Observation</b>					
<b>LESION RATES</b>					
<b>OVERALL (a)</b>	0/10 (0%)	0/0 (0%)	1/1 (100%)	1/1 (100%)	0/10 (0%)
<b>POLY-3 RATE (b)</b>	0/10.00	0/0.00	1/1.00	1/1.00	0/10.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	100%	100%	0%
<b>TERMINAL (d)</b>	0/10 (0%)	0/0 (0%)	1/1 (100%)	1/1 (100%)	0/10 (0%)
<b>FIRST INCIDENCE</b>	---	---	93 (T)	93 (T)	---
<b>STATISTICAL TESTS</b>					
<b>POLY 3</b>	(e)	(e)	P=0.091	P=0.091	(e)
<b>POLY 1.5</b>	(e)	(e)	P=0.091	P=0.091	(e)
<b>POLY 6</b>	(e)	(e)	P=0.091	P=0.091	(e)
<b>COCH-ARM / FISHERS</b>	P=0.384N	(e)	P=0.091	P=0.091	(e)
<b>MAX-ISO-POLY-3</b>	(e)	(e)	P<0.001**	P<0.001**	(e)

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

DOSE	Males				
	CONTROL	50 ppm	100 ppm	200 ppm	800 ppm
<b>Urinary Bladder: Transitional Epithelium Hyperplasia</b>					
<b>LESION RATES</b>					
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/1.00	0/1.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/1 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---
<b>STATISTICAL TESTS</b>					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)

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

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Heart</b>				
<b>Cardiomyopathy</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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 RATS(Wistar Han)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Heart</b>				
<b>Necrosis Acute</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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 RATS(Wistar Han)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Kidney Nephropathy</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/10 (30%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	3/10.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	30%	0%	0%	20%
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	93 (T)	---	---	93 (T)
<b>STATISTICAL TESTS</b>				
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=0.474N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.310N



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

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Kidney: Cortex</b>				
<b>Cyst</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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 RATS(Wistar Han)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Kidney: Medulla Inflammation Chronic</b>				
<b>LESION RATES</b>				
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	93 (T)	---	---	93 (T)
<b>STATISTICAL TESTS</b>				
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=0.469N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.274N

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

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Kidney: Pelvis Dilatation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.449	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

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

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Kidney: Pelvis</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.449	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

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

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Kidney: Transitional Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.449	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

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

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Larynx</b>				
<b>Inflammation Acute</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.449	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

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

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Larynx</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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 RATS(Wistar Han)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Larynx: Squamous Epithelium</b>				
<b>Erosion</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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 RATS(Wistar Han)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Larynx: Squamous Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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 RATS(Wistar Han)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
Liver Atrophy				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	0/1 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/1.00	0/1.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/1 (0%)	0/1 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
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 RATS(Wistar Han)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Liver</b>				
<b>Hepatodiaphragmatic Nodule</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	0/1 (0%)	1/1 (100%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/1.00	1/1.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	100%	0%
TERMINAL (d)	0/10 (0%)	0/1 (0%)	1/1 (100%)	0/10 (0%)
FIRST INCIDENCE	---	---	93 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.582N	(e)	P=0.091	(e)
POLY 1.5	P=0.582N	(e)	P=0.091	(e)
POLY 6	P=0.582N	(e)	P=0.091	(e)
COCH-ARM / FISHERS	P=0.582N	(e)	P=0.091	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	P<0.001**	(e)

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

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Liver</b>				
<b>Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	1/1 (100%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/1.00	0/1.00	0/10.00
POLY-3 PERCENT (g)	0%	100%	0%	0%
TERMINAL (d)	0/10 (0%)	1/1 (100%)	0/1 (0%)	0/10 (0%)
FIRST INCIDENCE	---	93 (T)	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.531N	P=0.091	(e)	(e)
POLY 1.5	P=0.531N	P=0.091	(e)	(e)
POLY 6	P=0.531N	P=0.091	(e)	(e)
COCH-ARM / FISHERS	P=0.531N	P=0.091	(e)	(e)
MAX-ISO-POLY-3	P<0.001N**	P<0.001**	(e)	(e)

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

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Lung</b>				
<b>Infiltration Cellular Histiocyte</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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 RATS(Wistar Han)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Lung</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	93 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.449	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

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

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Lung</b>				
<b>Metaplasia Osseous</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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 RATS(Wistar Han)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Lymph Node: Iliac Infiltration Cellular Mixed Cell</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00	1/1.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	100%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)
FIRST INCIDENCE	---	---	93 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)



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

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Pancreas</b>				
<b>Atrophy</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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 RATS(Wistar Han)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Pancreas: Acinus Atrophy</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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 RATS(Wistar Han)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Pituitary Gland Cyst</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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 RATS(Wistar Han)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Skin</b>				
<b>Ulcer</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
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=0.449N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158N

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

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Spleen</b>				
<b>Accessory Spleen</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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 RATS(Wistar Han)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Urinary Bladder</b>				
<b>Calculus Gross Observation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	0/0 (0%)	1/1 (100%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	1/1.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	100%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	1/1 (100%)	0/10 (0%)
FIRST INCIDENCE	---	---	93 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	P=0.091	(e)
POLY 1.5	(e)	(e)	P=0.091	(e)
POLY 6	(e)	(e)	P=0.091	(e)
COCH-ARM / FISHERS	P=0.566N	(e)	P=0.091	(e)
MAX-ISO-POLY-3	(e)	(e)	P<0.001**	(e)

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

DOSE	Females			
	CONTROL	50 ppm	100 ppm	800 ppm
<b>Urinary Bladder: Transitional Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	0/0 (0%)	1/1 (100%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	1/1.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	100%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	1/1 (100%)	0/10 (0%)
FIRST INCIDENCE	---	---	93 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	P=0.091	(e)
POLY 1.5	(e)	(e)	P=0.091	(e)
POLY 6	(e)	(e)	P=0.091	(e)
COCH-ARM / FISHERS	P=0.566N	(e)	P=0.091	(e)
MAX-ISO-POLY-3	(e)	(e)	P<0.001**	(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.
  - (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 \*\*\*