

**TDMS No.** 98007 - 03  
**Test Type:** 90-DAY  
**Route:** SKIN APPLICATION  
**Species/Strain:** RATS/F 344

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

Sodium thioglycolate  
**CAS Number:** 367-51-1

**Date Report Requested:** 03/28/2008  
**Time Report Requested:** 10:56:29  
**First Dose M/F:** 12/16/02 / 12/17/02  
**Lab:** MBA

**C Number:** C98007  
**Lock Date:** 12/18/2003  
**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 Sodium thioglycolate**

**MALE RATS**

**Organ**

Skin: Sebaceous Gland, Site of Application - Dermis  
Skin: Site of Application - Epidermis

**Morphology**

Hypertrophy  
Hyperkeratosis  
Hyperplasia Diffuse

**FEMALE RATS**

**Organ**

Skin: Sebaceous Gland, Site of Application - Dermis  
Skin: Site of Application - Epidermis

**Morphology**

Hypertrophy  
Hyperkeratosis  
Hyperplasia Diffuse  
Parakeratosis Focal  
Ulcer Focal

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

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Adrenal Cortex: Zona Fasciculata  
 Vacuolization Cytoplasmic**

**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)

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

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Heart  
 Cardiomyopathy**

**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)

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

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 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)

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

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Kidney: Renal Tubule  
 Regeneration Focal**

**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)

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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Liver  
 Hepatodiaphragmatic Nodule

**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)

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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Liver  
 Inflammation Granulomatous

**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)



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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Lung: Alveolus  
 Inflammation Chronic Focal

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.138N	(e)	(e)	(e)	(e)	P=0.234N
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227N
LOGISTIC REGRESSION	P=0.138N	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.132N	(e)	(e)	(e)	(e)	P=0.237N
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Lymph Node: Thoracic  
 Hyperplasia Lymphoid

**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**

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)

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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Skin: Sebaceous Gland, Site of Application - Dermis  
 Hypertrophy

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	2/10 (20%)	4/10 (40%)	5/10 (50%)	6/10 (60%)
POLY-3 RATE (b)	0/10.00	0/10.00	2/10.00	4/10.00	5/10.00	6/10.00
POLY-3 PERCENT (g)	0%	0%	20%	40%	50%	60%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	2/10 (20%)	4/10 (40%)	5/10 (50%)	6/10 (60%)
FIRST INCIDENCE	---	---	93 (T)	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	(e)	P=0.234	P=0.051	P=0.022*	P=0.009**
POLY 3	P<0.001**	(e)	P=0.227	P=0.033*	P=0.008**	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.227	P=0.033*	P=0.008**	P<0.001**
POLY 6	P<0.001**	(e)	P=0.227	P=0.033*	P=0.008**	P<0.001**
LOGISTIC REGRESSION	(e)	(e)	P=0.234	P=0.051	P=0.022*	P=0.009**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.237	P=0.043*	P=0.016*	P=0.005**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Skin: Site of Application - Epidermis  
 Hyperkeratosis

**LESION RATES**

OVERALL (a)	0/10 (0%)	6/10 (60%)	9/10 (90%)	4/10 (40%)	4/10 (40%)	4/10 (40%)
POLY-3 RATE (b)	0/10.00	6/10.00	9/10.00	4/10.00	4/10.00	4/10.00
POLY-3 PERCENT (g)	0%	60%	90%	40%	40%	40%
TERMINAL (d)	0/10 (0%)	6/10 (60%)	9/10 (90%)	4/10 (40%)	4/10 (40%)	4/10 (40%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.509N	P=0.009**	P<0.001**	P=0.051	P=0.051	P=0.051
POLY 3	P=0.511N	P<0.001**	P<0.001**	P=0.033*	P=0.033*	P=0.033*
POLY 1.5	P=0.511N	P<0.001**	P<0.001**	P=0.033*	P=0.033*	P=0.033*
POLY 6	P=0.511N	P<0.001**	P<0.001**	P=0.033*	P=0.033*	P=0.033*
LOGISTIC REGRESSION	(e)	P=0.009**	P<0.001**	P=0.051	P=0.051	P=0.051
COCH-ARM / FISHERS	P=0.509N	P=0.005**	P<0.001**	P=0.043*	P=0.043*	P=0.043*
ORDER RESTRICTED	P=0.004**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.005**	(e)	(e)	(e)	(e)	(e)

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

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Skin: Site of Application - Epidermis  
 Hyperplasia Diffuse

**LESION RATES**

OVERALL (a)	0/10 (0%)	1/10 (10%)	2/10 (20%)	3/10 (30%)	5/10 (50%)	6/10 (60%)
POLY-3 RATE (b)	0/10.00	1/10.00	2/10.00	3/10.00	5/10.00	6/10.00
POLY-3 PERCENT (g)	0%	10%	20%	30%	50%	60%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	2/10 (20%)	3/10 (30%)	5/10 (50%)	6/10 (60%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.500	P=0.234	P=0.111	P=0.022*	P=0.009**
POLY 3	P<0.001**	P=0.500	P=0.227	P=0.095	P=0.008**	P<0.001**
POLY 1.5	P<0.001**	P=0.500	P=0.227	P=0.095	P=0.008**	P<0.001**
POLY 6	P<0.001**	P=0.500	P=0.227	P=0.095	P=0.008**	P<0.001**
LOGISTIC REGRESSION	(e)	P=0.500	P=0.234	P=0.111	P=0.022*	P=0.009**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.237	P=0.105	P=0.016*	P=0.005**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Skin: Site of Application - Epidermis  
 Parakeratosis Focal

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P=0.488N	P=0.500	(e)	(e)	(e)	(e)
POLY 3	P=0.488N	P=0.500	(e)	(e)	(e)	(e)
POLY 1.5	P=0.488N	P=0.500	(e)	(e)	(e)	(e)
POLY 6	P=0.488N	P=0.500	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	P=0.500	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.488N	P=0.500	(e)	(e)	(e)	(e)
ORDER RESTRICTED	P=0.353N	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.356N	(e)	(e)	(e)	(e)	(e)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Skin: Site of Application - Epidermis  
 Ulcer Focal

**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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Spleen  
 Congestion**

**LESION RATES**

OVERALL (a)	9/10 (90%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	10/10 (100%)
POLY-3 RATE (b)	9/10.00	0/0.00	0/0.00	0/0.00	0/0.00	10/10.00
POLY-3 PERCENT (g)	90%	0%	0%	0%	0%	100%
TERMINAL (d)	9/10 (90%)	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	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	P=0.309	(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)



TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Spleen  
 Hematopoietic Cell Proliferation**

**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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Spleen  
 Pigmentation**

**LESION RATES**

OVERALL (a)	9/10 (90%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	10/10 (100%)
POLY-3 RATE (b)	9/10.00	0/0.00	0/0.00	0/0.00	0/0.00	10/10.00
POLY-3 PERCENT (g)	90%	0%	0%	0%	0%	100%
TERMINAL (d)	9/10 (90%)	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	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	P=0.309	(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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Thymus: Thymocyte Atrophy

**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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Males				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Thyroid Gland  
 Ectopic Thymus

**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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Adrenal Cortex: Zona Fasciculata  
 Vacuolization Cytoplasmic**

**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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Heart  
 Cardiomyopathy**

**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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Kidney  
 Nephropathy**

**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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Kidney: Renal Tubule  
 Regeneration Focal**

**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)



TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Liver  
 Hepatodiaphragmatic Nodule

**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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Liver  
 Inflammation Granulomatous**

**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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Lung: Alveolus  
 Inflammation Chronic Focal

**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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Lymph Node: Thoracic  
 Hyperplasia Lymphoid

**LESION RATES**

OVERALL (a)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/3 (67%)
POLY-3 RATE (b)	0/1.00	0/0.00	0/0.00	0/0.00	0/0.00	2/3.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	66.7%
TERMINAL (d)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/3 (67%)
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=0.282	(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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Skin: Sebaceous Gland, Site of Application - Dermis  
 Hypertrophy

**LESION RATES**

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

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	(e)	(e)	P=0.234	P=0.009**	P=0.022*
POLY 3	P<0.001**	(e)	(e)	P=0.227	P<0.001**	P=0.008**
POLY 1.5	P<0.001**	(e)	(e)	P=0.227	P<0.001**	P=0.008**
POLY 6	P<0.001**	(e)	(e)	P=0.227	P<0.001**	P=0.008**
LOGISTIC REGRESSION	(e)	(e)	(e)	P=0.234	P=0.009**	P=0.022*
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.237	P=0.005**	P=0.016*
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Skin: Site of Application - Epidermis  
 Hyperkeratosis

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	7/10 (70%)	6/10 (60%)	5/10 (50%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	7/10.00	6/10.00	5/10.00
POLY-3 PERCENT (g)	0%	0%	10%	70%	60%	50%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	7/10 (70%)	6/10 (60%)	5/10 (50%)
FIRST INCIDENCE	---	---	93 (T)	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.003**	(e)	P=0.500	P=0.003**	P=0.009**	P=0.022*
POLY 3	P<0.001**	(e)	P=0.500	P<0.001**	P<0.001**	P=0.008**
POLY 1.5	P<0.001**	(e)	P=0.500	P<0.001**	P<0.001**	P=0.008**
POLY 6	P<0.001**	(e)	P=0.500	P<0.001**	P<0.001**	P=0.008**
LOGISTIC REGRESSION	(e)	(e)	P=0.500	P=0.003**	P=0.009**	P=0.022*
COCH-ARM / FISHERS	P=0.002**	(e)	P=0.500	P=0.002**	P=0.005**	P=0.016*
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Skin: Site of Application - Epidermis  
 Hyperplasia Diffuse

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	7/10 (70%)	8/10 (80%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	2/10.00	7/10.00	8/10.00
POLY-3 PERCENT (g)	0%	0%	0%	20%	70%	80%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	7/10 (70%)	8/10 (80%)
FIRST INCIDENCE	---	---	---	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	(e)	(e)	P=0.234	P=0.003**	P<0.001**
POLY 3	P<0.001**	(e)	(e)	P=0.227	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	P=0.227	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	(e)	P=0.227	P<0.001**	P<0.001**
LOGISTIC REGRESSION	(e)	(e)	(e)	P=0.234	P=0.003**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.237	P=0.002**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Skin: Site of Application - Epidermis  
 Parakeratosis Focal

**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**

LIFE TABLE	P<0.001**	(e)	(e)	(e)	(e)	P=0.111
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
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.111
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P=0.105
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)



TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Skin: Site of Application - Epidermis  
 Ulcer Focal

**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**

LIFE TABLE	P<0.001**	(e)	(e)	(e)	(e)	P=0.111
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
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.111
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P=0.105
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Spleen  
 Congestion**

**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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Spleen  
 Hematopoietic Cell Proliferation**

**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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Spleen  
 Pigmentation**

**LESION RATES**

OVERALL (a)	9/10 (90%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	10/10 (100%)
POLY-3 RATE (b)	9/10.00	0/0.00	0/0.00	0/0.00	0/0.00	10/10.00
POLY-3 PERCENT (g)	90%	0%	0%	0%	0%	100%
TERMINAL (d)	9/10 (90%)	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	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	P=0.309	(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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

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 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Thymus: Thymocyte Atrophy

**LESION RATES**

OVERALL (a)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	4/10.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	40%	0%	0%	0%	0%	30%
TERMINAL (d)	4/10 (40%)	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=0.410N	(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=0.410N	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.407N	(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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
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 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

Thyroid Gland  
 Ectopic Thymus

**LESION RATES**

OVERALL (a)	1/9 (11%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/9 (22%)
POLY-3 RATE (b)	1/9.00	0/0.00	0/0.00	0/0.00	0/0.00	2/9.00
POLY-3 PERCENT (g)	11.1%	0%	0%	0%	0%	22.2%
TERMINAL (d)	1/9 (11%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/9 (22%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.379	(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=0.379	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.376	(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)

TDMS No. 98007 - 03  
 Test Type: 90-DAY  
 Route: SKIN APPLICATION  
 Species/Strain: RATS/F 344

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

Sodium thioglycolate  
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008  
 Time Report Requested: 10:56:29  
 First Dose M/F: 12/16/02 / 12/17/02  
 Lab: MBA

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

DOSE	VEHICLE CONTROL	Females				
		11.25 MG/KG	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG

**Uterus  
 Dilatation**

**LESION RATES**

OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	4/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	40%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.238	(e)	(e)	(e)	(e)	P=0.317
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.318
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.318
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.318
LOGISTIC REGRESSION	P=0.238	(e)	(e)	(e)	(e)	P=0.317
COCH-ARM / FISHERS	P=0.232	(e)	(e)	(e)	(e)	P=0.314
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

TDMS No. 98007 - 03  
Test Type: 90-DAY  
Route: SKIN APPLICATION  
Species/Strain: RATS/F 344

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

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**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 \*\*\*