

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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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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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
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P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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**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
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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
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P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Sodium thioglycolate
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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

**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
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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 ***