

TDMS No. 98007 - 04
Test Type: 90-DAY
Route: SKIN APPLICATION
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Sodium thioglycolate
CAS Number: 367-51-1

Date Report Requested: 03/28/2008
Time Report Requested: 10:56:49
First Dose M/F: 12/19/02 / 12/20/02
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 MICE

Organ

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

Morphology

Hypertrophy
Hyperkeratosis
Hyperplasia Diffuse

FEMALE MICE

Organ

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

Morphology

Hypertrophy
Hyperkeratosis
Hyperplasia Diffuse

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Males				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

**Adrenal Cortex: Subcapsular
 Hyperplasia**

LESION RATES

OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	30%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	92 (T)	---	---	---	---	92 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.401	(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=0.401	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.398	(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				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

**Kidney: Renal Tubule
 Regeneration**

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	---	---	---	---	---	92 (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)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Males				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

**Liver
 Inflammation Chronic**

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	92 (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)

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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Males				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

Liver
 Necrosis 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)

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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Males				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

Skin: Sebaceous Gland, Site of Application - Dermis
 Hypertrophy

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	4/10 (40%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	2/10.00	4/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	20%	40%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	4/10 (40%)
FIRST INCIDENCE	---	---	---	---	92 (T)	92 (T)

STATISTICAL TESTS

LIFE TABLE	P<0.001**	(e)	(e)	(e)	P=0.234	P=0.051
POLY 3	P<0.001**	(e)	(e)	(e)	P=0.227	P=0.033*
POLY 1.5	P<0.001**	(e)	(e)	(e)	P=0.227	P=0.033*
POLY 6	P<0.001**	(e)	(e)	(e)	P=0.227	P=0.033*
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	P=0.234	P=0.051
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P=0.237	P=0.043*
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				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

Skin: Site of Application - Epidermis
 Hyperkeratosis

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	3/10.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	30%	30%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)	3/10 (30%)
FIRST INCIDENCE	---	---	---	---	92 (T)	92 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.002**	(e)	(e)	(e)	P=0.111	P=0.111
POLY 3	P<0.001**	(e)	(e)	(e)	P=0.095	P=0.095
POLY 1.5	P<0.001**	(e)	(e)	(e)	P=0.095	P=0.095
POLY 6	P<0.001**	(e)	(e)	(e)	P=0.095	P=0.095
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	P=0.111	P=0.111
COCH-ARM / FISHERS	P=0.002**	(e)	(e)	(e)	P=0.105	P=0.105
ORDER RESTRICTED	P=0.011*	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.002**	(e)	(e)	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Males				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

Skin: Site of Application - Epidermis
 Hyperplasia Diffuse

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)	6/10 (60%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	3/10.00	6/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	30%	60%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)	6/10 (60%)
FIRST INCIDENCE	---	---	---	---	92 (T)	92 (T)

STATISTICAL TESTS

LIFE TABLE	P<0.001**	(e)	(e)	(e)	P=0.111	P=0.009**
POLY 3	P<0.001**	(e)	(e)	(e)	P=0.095	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	(e)	P=0.095	P<0.001**
POLY 6	P<0.001**	(e)	(e)	(e)	P=0.095	P<0.001**
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	P=0.111	P=0.009**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P=0.105	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				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

Skin: Site of Application - Epidermis
 Hyperplasia Focal

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	2/10 (20%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	0/10.00	2/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%	0%	20%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	2/10 (20%)	1/10 (10%)
FIRST INCIDENCE	---	---	92 (T)	---	92 (T)	92 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.191	(e)	P=0.500	(e)	P=0.234	P=0.500
POLY 3	P=0.191	(e)	P=0.500	(e)	P=0.227	P=0.500
POLY 1.5	P=0.191	(e)	P=0.500	(e)	P=0.227	P=0.500
POLY 6	P=0.191	(e)	P=0.500	(e)	P=0.227	P=0.500
LOGISTIC REGRESSION	(e)	(e)	P=0.500	(e)	P=0.234	P=0.500
COCH-ARM / FISHERS	P=0.189	(e)	P=0.500	(e)	P=0.237	P=0.500
ORDER RESTRICTED	P=0.154	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.165	(e)	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Males				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 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	92 (T)	---	---	---	---	92 (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 MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Females				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

**Adrenal Cortex: Subcapsular
 Hyperplasia**

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	92 (T)	---	---	---	---	92 (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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 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	VEHICLE CONTROL	22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

**Kidney: Renal Tubule
 Regeneration**

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	---	---	---	---	---	92 (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 - 04
 Test Type: 90-DAY
 Route: SKIN APPLICATION
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Sodium thioglycolate
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008
 Time Report Requested: 10:56:49
 First Dose M/F: 12/19/02 / 12/20/02
 Lab: MBA

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Females				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

Liver
 Inflammation Chronic

LESION RATES

OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/10 (50%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	5/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	50%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/10 (50%)
FIRST INCIDENCE	92 (T)	---	---	---	---	92 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.127	(e)	(e)	(e)	(e)	P=0.180
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.174
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.174
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.174
LOGISTIC REGRESSION	P=0.127	(e)	(e)	(e)	(e)	P=0.180
COCH-ARM / FISHERS	P=0.121	(e)	(e)	(e)	(e)	P=0.175
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

TDMS No. 98007 - 04
 Test Type: 90-DAY
 Route: SKIN APPLICATION
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Sodium thioglycolate
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008
 Time Report Requested: 10:56:49
 First Dose M/F: 12/19/02 / 12/20/02
 Lab: MBA

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Females				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

Liver
 Necrosis Focal

LESION RATES

OVERALL (a)	0/10 (0%)	0/0 (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	0/0.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	30%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	---	---	---	---	---	92 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.064	(e)	(e)	(e)	(e)	P=0.111
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.095
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.095
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.095
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.111
COCH-ARM / FISHERS	P=0.059	(e)	(e)	(e)	(e)	P=0.105
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

TDMS No. 98007 - 04
 Test Type: 90-DAY
 Route: SKIN APPLICATION
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Sodium thioglycolate
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008
 Time Report Requested: 10:56:49
 First Dose M/F: 12/19/02 / 12/20/02
 Lab: MBA

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Females				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

Skin: Sebaceous Gland, Site of Application - Dermis
 Hypertrophy

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)	7/10 (70%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	6/10.00	7/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	60%	70%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)	7/10 (70%)
FIRST INCIDENCE	---	---	---	---	92 (T)	92 (T)

STATISTICAL TESTS

LIFE TABLE	P<0.001**	(e)	(e)	(e)	P=0.009**	P=0.003**
POLY 3	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	P=0.009**	P=0.003**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P=0.005**	P=0.002**
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 - 04
 Test Type: 90-DAY
 Route: SKIN APPLICATION
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Sodium thioglycolate
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008
 Time Report Requested: 10:56:49
 First Dose M/F: 12/19/02 / 12/20/02
 Lab: MBA

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Females				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

Skin: Site of Application - Epidermis
 Hyperkeratosis

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	4/10 (40%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	1/10.00	1/10.00	4/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	10%	40%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	4/10 (40%)
FIRST INCIDENCE	---	---	---	92 (T)	92 (T)	92 (T)

STATISTICAL TESTS

LIFE TABLE	P<0.001**	(e)	(e)	P=0.500	P=0.500	P=0.051
POLY 3	P<0.001**	(e)	(e)	P=0.500	P=0.500	P=0.033*
POLY 1.5	P<0.001**	(e)	(e)	P=0.500	P=0.500	P=0.033*
POLY 6	P<0.001**	(e)	(e)	P=0.500	P=0.500	P=0.033*
LOGISTIC REGRESSION	(e)	(e)	(e)	P=0.500	P=0.500	P=0.051
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.500	P=0.500	P=0.043*
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 - 04
 Test Type: 90-DAY
 Route: SKIN APPLICATION
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 03/28/2008
 Time Report Requested: 10:56:49
 First Dose M/F: 12/19/02 / 12/20/02
 Lab: MBA

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Females				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

Skin: Site of Application - Epidermis
 Hyperplasia Diffuse

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)	8/10 (80%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	6/10.00	8/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	60%	80%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)	8/10 (80%)
FIRST INCIDENCE	---	---	---	---	92 (T)	92 (T)

STATISTICAL TESTS

LIFE TABLE	P<0.001**	(e)	(e)	(e)	P=0.009**	P<0.001**
POLY 3	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	(e)	(e)	P<0.001**	P<0.001**
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	P=0.009**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P=0.005**	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 - 04
 Test Type: 90-DAY
 Route: SKIN APPLICATION
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 03/28/2008
 Time Report Requested: 10:56:49
 First Dose M/F: 12/19/02 / 12/20/02
 Lab: MBA

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Females				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

Skin: Site of Application - Epidermis
 Hyperplasia Focal

LESION RATES

OVERALL (a)	0/10 (0%)	1/10 (10%)	3/10 (30%)	1/10 (10%)	3/10 (30%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	1/10.00	3/10.00	1/10.00	3/10.00	2/10.00
POLY-3 PERCENT (g)	0%	10%	30%	10%	30%	20%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	3/10 (30%)	1/10 (10%)	3/10 (30%)	2/10 (20%)
FIRST INCIDENCE	---	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.239	P=0.500	P=0.111	P=0.500	P=0.111	P=0.234
POLY 3	P=0.239	P=0.500	P=0.095	P=0.500	P=0.095	P=0.227
POLY 1.5	P=0.239	P=0.500	P=0.095	P=0.500	P=0.095	P=0.227
POLY 6	P=0.239	P=0.500	P=0.095	P=0.500	P=0.095	P=0.227
LOGISTIC REGRESSION	(e)	P=0.500	P=0.111	P=0.500	P=0.111	P=0.234
COCH-ARM / FISHERS	P=0.237	P=0.500	P=0.105	P=0.500	P=0.105	P=0.237
ORDER RESTRICTED	P=0.113	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.123	(e)	(e)	(e)	(e)	(e)

TDMS No. 98007 - 04
 Test Type: 90-DAY
 Route: SKIN APPLICATION
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Sodium thioglycolate
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008
 Time Report Requested: 10:56:49
 First Dose M/F: 12/19/02 / 12/20/02
 Lab: MBA

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Females				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

**Spleen
 Hematopoietic Cell Proliferation**

LESION RATES

OVERALL (a)	8/10 (80%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	10/10 (100%)
POLY-3 RATE (b)	8/10.00	0/0.00	0/0.00	0/0.00	0/0.00	10/10.00
POLY-3 PERCENT (g)	80%	0%	0%	0%	0%	100%
TERMINAL (d)	8/10 (80%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	10/10 (100%)
FIRST INCIDENCE	92 (T)	---	---	---	---	92 (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	P=0.138	(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 - 04
 Test Type: 90-DAY
 Route: SKIN APPLICATION
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Sodium thioglycolate
 CAS Number: 367-51-1

Date Report Requested: 03/28/2008
 Time Report Requested: 10:56:49
 First Dose M/F: 12/19/02 / 12/20/02
 Lab: MBA

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	VEHICLE CONTROL	Females				
		22.5 MG/KG	45.0 MG/KG	90.0 MG/KG	180.0 MG/KG	360.0 MG/KG

Uterus: Endometrium
 Hyperplasia Cystic

LESION RATES

OVERALL (a)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
POLY-3 RATE (b)	4/10.00	0/0.00	0/0.00	0/0.00	0/0.00	4/10.00
POLY-3 PERCENT (g)	40%	0%	0%	0%	0%	40%
TERMINAL (d)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
FIRST INCIDENCE	92 (T)	---	---	---	---	92 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.588	(e)	(e)	(e)	(e)	P=0.672
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.667
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.667
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.667
LOGISTIC REGRESSION	P=0.588	(e)	(e)	(e)	(e)	P=0.672
COCH-ARM / FISHERS	P=0.590	(e)	(e)	(e)	(e)	P=0.675N
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

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 ***