

**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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**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

**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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 Lab: MBA

**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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**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  
 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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**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: 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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**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

**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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 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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 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

**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  
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 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  
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 Species/Strain: MICE/B6C3F1

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

Sodium thioglycolate  
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 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  
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 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Sodium thioglycolate  
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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

**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

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 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 \*\*\*