

**TDMS No.** 20701 - 99  
**Test Type:** 18-33 DAYS  
**Route:** GAVAGE  
**Species/Strain:** MICE/B6C3F1

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

Gum Guggul 2.5% granules  
**CAS Number:** GUMGUGGULEXT

**Date Report Requested:** 06/01/2011  
**Time Report Requested:** 11:24:32  
**First Dose M/F:** NA / 03/02/07  
**Lab:** VCU

F1\_M3

**C Number:** IM20701

**Lock Date:** 05/14/2009

**Cage Range:** ALL

**Date Range:** ALL

**Reasons For Removal:** ALL

**Removal Date Range:** ALL

**Treatment Groups:** Include 001 0 mg/kg

Include 002 31.25 mg/kg

Include 003 62.5 mg/kg

Include 004 125 mg/kg

Include 005 250 mg/kg

Include 006 500 mg/kg

**Study Gender:** Female

**TDMSE Version:** 2.4.1.0\_004

**PWG Approval Date:** NONE

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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF GUM GUGGUL 2.5% GRANULES**

**FEMALE MICE**

**Organ**

Spleen: Follicles, Germinal Center  
Spleen: Red Pulp

**Morphology**

Increased Number  
Increased Number Pigmented macrophages

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Adrenal Cortex: Unilateral Hyperplasia</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)
POLY-3 RATE (b)	0/8.00	0/8.00	0/8.00	0/8.00	1/8.00	0/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	12.5%	0%
TERMINAL (d)	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	29 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.584	(e)	(e)	(e)	P=0.500	(e)
POLY 1.5	P=0.584	(e)	(e)	(e)	P=0.500	(e)
POLY 6	P=0.584	(e)	(e)	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.585	(e)	(e)	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.356	(e)	(e)	(e)	P=0.158	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Bone Marrow</b>						
<b>Decreased Number Adipocyte</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)
<b>POLY-3 RATE (b)</b>	0/8.00	0/8.00	0/8.00	0/8.00	1/8.00	0/8.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	0%	0%	12.5%	0%
<b>TERMINAL (d)</b>	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)
<b>FIRST INCIDENCE</b>	---	---	---	---	29 (T)	---
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.584	(e)	(e)	(e)	P=0.500	(e)
<b>POLY 1.5</b>	P=0.584	(e)	(e)	(e)	P=0.500	(e)
<b>POLY 6</b>	P=0.584	(e)	(e)	(e)	P=0.500	(e)
<b>COCH-ARM / FISHERS</b>	P=0.585	(e)	(e)	(e)	P=0.500	(e)
<b>MAX-ISO-POLY-3</b>	P=0.356	(e)	(e)	(e)	P=0.158	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Bone Marrow</b>						
<b>Increased Number Adipocyte</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/8 (0%)	1/8 (13%)	1/8 (13%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
<b>POLY-3 RATE (b)</b>	0/8.00	1/8.00	1/8.00	0/8.00	0/8.00	0/8.00
<b>POLY-3 PERCENT (g)</b>	0%	12.5%	12.5%	0%	0%	0%
<b>TERMINAL (d)</b>	0/8 (0%)	1/8 (13%)	1/8 (13%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
<b>FIRST INCIDENCE</b>	---	29 (T)	29 (T)	---	---	---
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.334N	P=0.500	P=0.500	(e)	(e)	(e)
<b>POLY 1.5</b>	P=0.334N	P=0.500	P=0.500	(e)	(e)	(e)
<b>POLY 6</b>	P=0.334N	P=0.500	P=0.500	(e)	(e)	(e)
<b>COCH-ARM / FISHERS</b>	P=0.330N	P=0.500	P=0.500	(e)	(e)	(e)
<b>MAX-ISO-POLY-3</b>	P=0.382N	P=0.158	P=0.158	(e)	(e)	(e)

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**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

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 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Gut Associated Lymphoid Tissue: Follicles Increased Number Lymphocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/7 (0%)	0/7 (0%)	0/7 (0%)	1/7 (14%)	1/7 (14%)	0/6 (0%)
POLY-3 RATE (b)	0/7.00	0/7.00	0/7.00	1/7.00	1/7.00	0/6.00
POLY-3 PERCENT (g)	0%	0%	0%	14.3%	14.3%	0%
TERMINAL (d)	0/7 (0%)	0/7 (0%)	0/7 (0%)	1/7 (14%)	1/7 (14%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	29 (T)	29 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.595	(e)	(e)	P=0.500	P=0.500	(e)
POLY 1.5	P=0.595	(e)	(e)	P=0.500	P=0.500	(e)
POLY 6	P=0.595	(e)	(e)	P=0.500	P=0.500	(e)
COCH-ARM / FISHERS	P=0.598	(e)	(e)	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.400	(e)	(e)	P=0.158	P=0.158	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Gut Associated Lymphoid Tissue: Follicles Increased Size</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/7 (0%)	0/7 (0%)	0/7 (0%)	1/7 (14%)	1/7 (14%)	0/6 (0%)
POLY-3 RATE (b)	0/7.00	0/7.00	0/7.00	1/7.00	1/7.00	0/6.00
POLY-3 PERCENT (g)	0%	0%	0%	14.3%	14.3%	0%
TERMINAL (d)	0/7 (0%)	0/7 (0%)	0/7 (0%)	1/7 (14%)	1/7 (14%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	29 (T)	29 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.595	(e)	(e)	P=0.500	P=0.500	(e)
POLY 1.5	P=0.595	(e)	(e)	P=0.500	P=0.500	(e)
POLY 6	P=0.595	(e)	(e)	P=0.500	P=0.500	(e)
COCH-ARM / FISHERS	P=0.598	(e)	(e)	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.400	(e)	(e)	P=0.158	P=0.158	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Gut Associated Lymphoid Tissue: Follicles, Germinal Center Increased Size</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/7 (0%)	0/7 (0%)	0/7 (0%)	0/7 (0%)	1/7 (14%)	0/6 (0%)
POLY-3 RATE (b)	0/7.00	0/7.00	0/7.00	0/7.00	1/7.00	0/6.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	14.3%	0%
TERMINAL (d)	0/7 (0%)	0/7 (0%)	0/7 (0%)	0/7 (0%)	1/7 (14%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	29 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.568	(e)	(e)	(e)	P=0.500	(e)
POLY 1.5	P=0.568	(e)	(e)	(e)	P=0.500	(e)
POLY 6	P=0.568	(e)	(e)	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.569	(e)	(e)	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.363	(e)	(e)	(e)	P=0.158	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Gut Associated Lymphoid Tissue: Interfollicular area Increased Number Lymphocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/7 (0%)	0/7 (0%)	0/7 (0%)	1/7 (14%)	0/7 (0%)	0/6 (0%)
POLY-3 RATE (b)	0/7.00	0/7.00	0/7.00	1/7.00	0/7.00	0/6.00
POLY-3 PERCENT (g)	0%	0%	0%	14.3%	0%	0%
TERMINAL (d)	0/7 (0%)	0/7 (0%)	0/7 (0%)	1/7 (14%)	0/7 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	29 (T)	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.721N	(e)	(e)	P=0.500	(e)	(e)
POLY 1.5	P=0.721N	(e)	(e)	P=0.500	(e)	(e)
POLY 6	P=0.721N	(e)	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.724N	(e)	(e)	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.530	(e)	(e)	P=0.158	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Gut Associated Lymphoid Tissue: Interfollicular area Increased Number Neutrophil</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/7 (0%)	0/7 (0%)	1/7 (14%)	0/7 (0%)	0/7 (0%)	0/6 (0%)
POLY-3 RATE (b)	0/7.00	0/7.00	1/7.00	0/7.00	0/7.00	0/6.00
POLY-3 PERCENT (g)	0%	0%	14.3%	0%	0%	0%
TERMINAL (d)	0/7 (0%)	0/7 (0%)	1/7 (14%)	0/7 (0%)	0/7 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	29 (T)	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.582N	(e)	P=0.500	(e)	(e)	(e)
POLY 1.5	P=0.582N	(e)	P=0.500	(e)	(e)	(e)
POLY 6	P=0.582N	(e)	P=0.500	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.583N	(e)	P=0.500	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.545N	(e)	P=0.158	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Gut Associated Lymphoid Tissue: Interfollicular area Increased Size</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/7 (0%)	1/7 (14%)	0/7 (0%)	1/7 (14%)	0/7 (0%)	0/6 (0%)
POLY-3 RATE (b)	0/7.00	1/7.00	0/7.00	1/7.00	0/7.00	0/6.00
POLY-3 PERCENT (g)	0%	14.3%	0%	14.3%	0%	0%
TERMINAL (d)	0/7 (0%)	1/7 (14%)	0/7 (0%)	1/7 (14%)	0/7 (0%)	0/6 (0%)
FIRST INCIDENCE	---	29 (T)	---	29 (T)	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.457N	P=0.500	(e)	P=0.500	(e)	(e)
POLY 1.5	P=0.457N	P=0.500	(e)	P=0.500	(e)	(e)
POLY 6	P=0.457N	P=0.500	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.456N	P=0.500	(e)	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.527N	P=0.158	(e)	P=0.158	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Gut Associated Lymphoid Tissue: Interfollicular area Necrosis</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/7 (0%)	0/7 (0%)	1/7 (14%)	0/7 (0%)	0/7 (0%)	0/6 (0%)
POLY-3 RATE (b)	0/7.00	0/7.00	1/7.00	0/7.00	0/7.00	0/6.00
POLY-3 PERCENT (g)	0%	0%	14.3%	0%	0%	0%
TERMINAL (d)	0/7 (0%)	0/7 (0%)	1/7 (14%)	0/7 (0%)	0/7 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	29 (T)	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.582N	(e)	P=0.500	(e)	(e)	(e)
POLY 1.5	P=0.582N	(e)	P=0.500	(e)	(e)	(e)
POLY 6	P=0.582N	(e)	P=0.500	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.583N	(e)	P=0.500	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.545N	(e)	P=0.158	(e)	(e)	(e)

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 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Intestine Large, Colon Intussusception</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)	0/8 (0%)
POLY-3 RATE (b)	0/8.00	0/8.00	0/8.00	1/8.00	0/8.00	0/8.00
POLY-3 PERCENT (g)	0%	0%	0%	12.5%	0%	0%
TERMINAL (d)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	29 (T)	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
POLY 1.5	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
POLY 6	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.699N	(e)	(e)	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.516	(e)	(e)	P=0.158	(e)	(e)

TDMS No. 20701 - 99  
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 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Kidney</b>						
<b>Infiltration Cellular</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/8 (0%)	1/8 (13%)	0/8 (0%)	1/8 (13%)	2/8 (25%)	1/8 (13%)
POLY-3 RATE (b)	0/8.00	1/8.00	0/8.00	1/8.00	2/8.00	1/8.00
POLY-3 PERCENT (g)	0%	12.5%	0%	12.5%	25%	12.5%
TERMINAL (d)	0/8 (0%)	1/8 (13%)	0/8 (0%)	1/8 (13%)	2/8 (25%)	1/8 (13%)
FIRST INCIDENCE	---	29 (T)	---	29 (T)	29 (T)	29 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.274	P=0.500	(e)	P=0.500	P=0.223	P=0.500
POLY 1.5	P=0.274	P=0.500	(e)	P=0.500	P=0.223	P=0.500
POLY 6	P=0.274	P=0.500	(e)	P=0.500	P=0.223	P=0.500
COCH-ARM / FISHERS	P=0.269	P=0.500	(e)	P=0.500	P=0.233	P=0.500
MAX-ISO-POLY-3	P=0.211	P=0.158	(e)	P=0.158	P=0.063	P=0.158

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)**  
**TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Lung</b>						
<b>Foreign Body</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
<b>POLY-3 RATE (b)</b>	0/8.00	0/8.00	1/8.00	0/8.00	0/8.00	0/8.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	12.5%	0%	0%	0%
<b>TERMINAL (d)</b>	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
<b>FIRST INCIDENCE</b>	---	---	29 (T)	---	---	---
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.560N	(e)	P=0.500	(e)	(e)	(e)
<b>POLY 1.5</b>	P=0.560N	(e)	P=0.500	(e)	(e)	(e)
<b>POLY 6</b>	P=0.560N	(e)	P=0.500	(e)	(e)	(e)
<b>COCH-ARM / FISHERS</b>	P=0.561N	(e)	P=0.500	(e)	(e)	(e)
<b>MAX-ISO-POLY-3</b>	P=0.516N	(e)	P=0.158	(e)	(e)	(e)

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Lung</b>						
<b>Infiltration Cellular</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
<b>POLY-3 RATE (b)</b>	0/8.00	0/8.00	1/8.00	0/8.00	0/8.00	0/8.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	12.5%	0%	0%	0%
<b>TERMINAL (d)</b>	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
<b>FIRST INCIDENCE</b>	---	---	29 (T)	---	---	---
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.560N	(e)	P=0.500	(e)	(e)	(e)
<b>POLY 1.5</b>	P=0.560N	(e)	P=0.500	(e)	(e)	(e)
<b>POLY 6</b>	P=0.560N	(e)	P=0.500	(e)	(e)	(e)
<b>COCH-ARM / FISHERS</b>	P=0.561N	(e)	P=0.500	(e)	(e)	(e)
<b>MAX-ISO-POLY-3</b>	P=0.516N	(e)	P=0.158	(e)	(e)	(e)

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Lung: Perivascular Infiltration Cellular</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/8 (13%)	1/8 (13%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)
POLY-3 RATE (b)	1/8.00	1/8.00	0/8.00	0/8.00	0/8.00	1/8.00
POLY-3 PERCENT (g)	12.5%	12.5%	0%	0%	0%	12.5%
TERMINAL (d)	1/8 (13%)	1/8 (13%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)
FIRST INCIDENCE	29 (T)	29 (T)	---	---	---	29 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.604	P=0.760	P=0.500N	P=0.500N	P=0.500N	P=0.760
POLY 1.5	P=0.604	P=0.760	P=0.500N	P=0.500N	P=0.500N	P=0.760
POLY 6	P=0.604	P=0.760	P=0.500N	P=0.500N	P=0.500N	P=0.760
COCH-ARM / FISHERS	P=0.607	P=0.767N	P=0.500N	P=0.500N	P=0.500N	P=0.767N
MAX-ISO-POLY-3	P=0.417N	P=1.000	P=0.158N	P=0.158N	P=0.158N	P=1.000

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Lymph Node, Mesenteric: Cortex, Germinal Center Increased Area</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/8 (0%)	0/8 (0%)	0/7 (0%)	0/8 (0%)	2/7 (29%)	0/8 (0%)
POLY-3 RATE (b)	0/8.00	0/8.00	0/7.00	0/8.00	2/7.00	0/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	28.6%	0%
TERMINAL (d)	0/8 (0%)	0/8 (0%)	0/7 (0%)	0/8 (0%)	2/7 (29%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	29 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.409	(e)	(e)	(e)	P=0.188	(e)
POLY 1.5	P=0.409	(e)	(e)	(e)	P=0.188	(e)
POLY 6	P=0.409	(e)	(e)	(e)	P=0.188	(e)
COCH-ARM / FISHERS	P=0.415	(e)	(e)	(e)	P=0.200	(e)
MAX-ISO-POLY-3	P=0.143	(e)	(e)	(e)	P=0.054	(e)

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Lymph Node, Mesenteric: Cortex, Germinal Center Increased Number</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/8 (0%)	0/8 (0%)	0/7 (0%)	0/8 (0%)	2/7 (29%)	0/8 (0%)
POLY-3 RATE (b)	0/8.00	0/8.00	0/7.00	0/8.00	2/7.00	0/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	28.6%	0%
TERMINAL (d)	0/8 (0%)	0/8 (0%)	0/7 (0%)	0/8 (0%)	2/7 (29%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	29 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.409	(e)	(e)	(e)	P=0.188	(e)
POLY 1.5	P=0.409	(e)	(e)	(e)	P=0.188	(e)
POLY 6	P=0.409	(e)	(e)	(e)	P=0.188	(e)
COCH-ARM / FISHERS	P=0.415	(e)	(e)	(e)	P=0.200	(e)
MAX-ISO-POLY-3	P=0.143	(e)	(e)	(e)	P=0.054	(e)

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Popliteal Lymph Node</b>						
<b>Increased Number Neutrophil</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/4 (0%)	0/8 (0%)	0/5 (0%)	0/7 (0%)	1/6 (17%)	0/7 (0%)
<b>POLY-3 RATE (b)</b>	0/4.00	0/8.00	0/5.00	0/7.00	1/6.00	0/7.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	0%	0%	16.7%	0%
<b>TERMINAL (d)</b>	0/4 (0%)	0/8 (0%)	0/5 (0%)	0/7 (0%)	1/6 (17%)	0/7 (0%)
<b>FIRST INCIDENCE</b>	---	---	---	---	29 (T)	---
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.610	(e)	(e)	(e)	P=0.579	(e)
<b>POLY 1.5</b>	P=0.610	(e)	(e)	(e)	P=0.579	(e)
<b>POLY 6</b>	P=0.610	(e)	(e)	(e)	P=0.579	(e)
<b>COCH-ARM / FISHERS</b>	P=0.611	(e)	(e)	(e)	P=0.600	(e)
<b>MAX-ISO-POLY-3</b>	P=0.465	(e)	(e)	(e)	P=0.231	(e)

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Popliteal Lymph Node</b>						
<b>Increased Number Pigmented macrophages</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/4 (0%)	0/8 (0%)	0/5 (0%)	0/7 (0%)	1/6 (17%)	0/7 (0%)
<b>POLY-3 RATE (b)</b>	0/4.00	0/8.00	0/5.00	0/7.00	1/6.00	0/7.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	0%	0%	16.7%	0%
<b>TERMINAL (d)</b>	0/4 (0%)	0/8 (0%)	0/5 (0%)	0/7 (0%)	1/6 (17%)	0/7 (0%)
<b>FIRST INCIDENCE</b>	---	---	---	---	29 (T)	---
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.610	(e)	(e)	(e)	P=0.579	(e)
<b>POLY 1.5</b>	P=0.610	(e)	(e)	(e)	P=0.579	(e)
<b>POLY 6</b>	P=0.610	(e)	(e)	(e)	P=0.579	(e)
<b>COCH-ARM / FISHERS</b>	P=0.611	(e)	(e)	(e)	P=0.600	(e)
<b>MAX-ISO-POLY-3</b>	P=0.465	(e)	(e)	(e)	P=0.231	(e)

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Popliteal Lymph Node: Medullary Sinuses, Subcapsular Sinuses, Transverse Sinuses</b>						
<b>Increased Number Mast Cell</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/4 (0%)	0/8 (0%)	0/5 (0%)	0/7 (0%)	0/6 (0%)	1/7 (14%)
<b>POLY-3 RATE (b)</b>	0/4.00	0/8.00	0/5.00	0/7.00	0/6.00	1/7.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	0%	0%	0%	14.3%
<b>TERMINAL (d)</b>	0/4 (0%)	0/8 (0%)	0/5 (0%)	0/7 (0%)	0/6 (0%)	1/7 (14%)
<b>FIRST INCIDENCE</b>	---	---	---	---	---	29 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.129	(e)	(e)	(e)	(e)	P=0.609
<b>POLY 1.5</b>	P=0.129	(e)	(e)	(e)	(e)	P=0.609
<b>POLY 6</b>	P=0.129	(e)	(e)	(e)	(e)	P=0.609
<b>COCH-ARM / FISHERS</b>	P=0.123	(e)	(e)	(e)	(e)	P=0.636
<b>MAX-ISO-POLY-3</b>	P=0.204	(e)	(e)	(e)	(e)	P=0.255

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Popliteal Lymph Node: Medullary Sinuses, Subcapsular Sinuses, Transverse Sinuses</b>						
<b>Increased Number Neutrophil</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/4 (0%)	1/8 (13%)	0/5 (0%)	0/7 (0%)	0/6 (0%)	0/7 (0%)
POLY-3 RATE (b)	0/4.00	1/8.00	0/5.00	0/7.00	0/6.00	0/7.00
POLY-3 PERCENT (g)	0%	12.5%	0%	0%	0%	0%
TERMINAL (d)	0/4 (0%)	1/8 (13%)	0/5 (0%)	0/7 (0%)	0/6 (0%)	0/7 (0%)
FIRST INCIDENCE	---	29 (T)	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.461N	P=0.635	(e)	(e)	(e)	(e)
POLY 1.5	P=0.461N	P=0.635	(e)	(e)	(e)	(e)
POLY 6	P=0.461N	P=0.635	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.459N	P=0.667	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.444N	P=0.275	(e)	(e)	(e)	(e)

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Popliteal Lymph Node: Paracortex</b>						
<b>Prominent High Endothelial Venules</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/4 (0%)	0/8 (0%)	0/5 (0%)	1/7 (14%)	0/6 (0%)	0/7 (0%)
POLY-3 RATE (b)	0/4.00	0/8.00	0/5.00	1/7.00	0/6.00	0/7.00
POLY-3 PERCENT (g)	0%	0%	0%	14.3%	0%	0%
TERMINAL (d)	0/4 (0%)	0/8 (0%)	0/5 (0%)	1/7 (14%)	0/6 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	29 (T)	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.666N	(e)	(e)	P=0.609	(e)	(e)
POLY 1.5	P=0.666N	(e)	(e)	P=0.609	(e)	(e)
POLY 6	P=0.666N	(e)	(e)	P=0.609	(e)	(e)
COCH-ARM / FISHERS	P=0.670N	(e)	(e)	P=0.636	(e)	(e)
MAX-ISO-POLY-3	P=0.606	(e)	(e)	P=0.255	(e)	(e)

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Spleen: Follicles, Germinal Center Increased Number</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/8 (0%)	0/8 (0%)	0/8 (0%)	3/8 (38%)	1/8 (13%)	2/8 (25%)
POLY-3 RATE (b)	0/8.00	0/8.00	0/8.00	3/8.00	1/8.00	2/8.00
POLY-3 PERCENT (g)	0%	0%	0%	37.5%	12.5%	25%
TERMINAL (d)	0/8 (0%)	0/8 (0%)	0/8 (0%)	3/8 (38%)	1/8 (13%)	2/8 (25%)
FIRST INCIDENCE	---	---	---	29 (T)	29 (T)	29 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.080	(e)	(e)	P=0.086	P=0.500	P=0.223
POLY 1.5	P=0.080	(e)	(e)	P=0.086	P=0.500	P=0.223
POLY 6	P=0.080	(e)	(e)	P=0.086	P=0.500	P=0.223
COCH-ARM / FISHERS	P=0.088	(e)	(e)	P=0.100	P=0.500	P=0.233
MAX-ISO-POLY-3	P=0.104	(e)	(e)	P=0.020*	P=0.158	P=0.063

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Spleen: Marginal Zone Decreased Area</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)
POLY-3 RATE (b)	0/8.00	0/8.00	0/8.00	0/8.00	1/8.00	0/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	12.5%	0%
TERMINAL (d)	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	29 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.584	(e)	(e)	(e)	P=0.500	(e)
POLY 1.5	P=0.584	(e)	(e)	(e)	P=0.500	(e)
POLY 6	P=0.584	(e)	(e)	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.585	(e)	(e)	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.356	(e)	(e)	(e)	P=0.158	(e)

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Spleen: Marginal Zone Decreased Number Lymphocyte</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)
POLY-3 RATE (b)	0/8.00	0/8.00	0/8.00	0/8.00	1/8.00	0/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	12.5%	0%
TERMINAL (d)	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	29 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.584	(e)	(e)	(e)	P=0.500	(e)
POLY 1.5	P=0.584	(e)	(e)	(e)	P=0.500	(e)
POLY 6	P=0.584	(e)	(e)	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.585	(e)	(e)	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.356	(e)	(e)	(e)	P=0.158	(e)

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Spleen: Marginal Zone Decreased Number Macrophage</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)
POLY-3 RATE (b)	0/8.00	0/8.00	0/8.00	0/8.00	1/8.00	0/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	12.5%	0%
TERMINAL (d)	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	29 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.584	(e)	(e)	(e)	P=0.500	(e)
POLY 1.5	P=0.584	(e)	(e)	(e)	P=0.500	(e)
POLY 6	P=0.584	(e)	(e)	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.585	(e)	(e)	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.356	(e)	(e)	(e)	P=0.158	(e)

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Spleen: Red Pulp</b>						
<b>Increased Number Hematopoietic cells</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)
<b>POLY-3 RATE (b)</b>	0/8.00	0/8.00	0/8.00	0/8.00	1/8.00	0/8.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	0%	0%	12.5%	0%
<b>TERMINAL (d)</b>	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)
<b>FIRST INCIDENCE</b>	---	---	---	---	29 (T)	---
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.584	(e)	(e)	(e)	P=0.500	(e)
<b>POLY 1.5</b>	P=0.584	(e)	(e)	(e)	P=0.500	(e)
<b>POLY 6</b>	P=0.584	(e)	(e)	(e)	P=0.500	(e)
<b>COCH-ARM / FISHERS</b>	P=0.585	(e)	(e)	(e)	P=0.500	(e)
<b>MAX-ISO-POLY-3</b>	P=0.356	(e)	(e)	(e)	P=0.158	(e)

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Spleen: Red Pulp</b>						
<b>Increased Number Pigmented macrophages</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	2/8 (25%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
<b>POLY-3 RATE (b)</b>	2/8.00	0/8.00	0/8.00	0/8.00	0/8.00	0/8.00
<b>POLY-3 PERCENT (g)</b>	25%	0%	0%	0%	0%	0%
<b>TERMINAL (d)</b>	2/8 (25%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
<b>FIRST INCIDENCE</b>	29 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.189N	P=0.223N	P=0.223N	P=0.223N	P=0.223N	P=0.223N
<b>POLY 1.5</b>	P=0.189N	P=0.223N	P=0.223N	P=0.223N	P=0.223N	P=0.223N
<b>POLY 6</b>	P=0.189N	P=0.223N	P=0.223N	P=0.223N	P=0.223N	P=0.223N
<b>COCH-ARM / FISHERS</b>	P=0.202N	P=0.233N	P=0.233N	P=0.233N	P=0.233N	P=0.233N
<b>MAX-ISO-POLY-3</b>	P=0.007N**	P=0.063N	P=0.063N	P=0.063N	P=0.063N	P=0.063N

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Thymus Cyst</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/8 (0%)	2/8 (25%)	2/8 (25%)	0/8 (0%)	0/8 (0%)	0/7 (0%)
POLY-3 RATE (b)	0/8.00	2/8.00	2/8.00	0/8.00	0/8.00	0/7.00
POLY-3 PERCENT (g)	0%	25%	25%	0%	0%	0%
TERMINAL (d)	0/8 (0%)	2/8 (25%)	2/8 (25%)	0/8 (0%)	0/8 (0%)	0/7 (0%)
FIRST INCIDENCE	---	29 (T)	29 (T)	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.161N	P=0.223	P=0.223	(e)	(e)	(e)
POLY 1.5	P=0.161N	P=0.223	P=0.223	(e)	(e)	(e)
POLY 6	P=0.161N	P=0.223	P=0.223	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.169N	P=0.233	P=0.233	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.228N	P=0.063	P=0.063	(e)	(e)	(e)

TDMS No. 20701 - 99  
 Test Type: 18-33 DAYS  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Gum Guggul 2.5% granules  
 CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
 Time Report Requested: 11:24:32  
 First Dose M/F: NA / 03/02/07  
 Lab: VCU

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females					
	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
<b>Thymus: Cortex</b>						
<b>Decreased Area</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)	0/8 (0%)	0/7 (0%)
<b>POLY-3 RATE (b)</b>	0/8.00	0/8.00	1/8.00	0/8.00	0/8.00	0/7.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	12.5%	0%	0%	0%
<b>TERMINAL (d)</b>	0/8 (0%)	0/8 (0%)	1/8 (13%)	0/8 (0%)	0/8 (0%)	0/7 (0%)
<b>FIRST INCIDENCE</b>	---	---	29 (T)	---	---	---
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.579N	(e)	P=0.500	(e)	(e)	(e)
<b>POLY 1.5</b>	P=0.579N	(e)	P=0.500	(e)	(e)	(e)
<b>POLY 6</b>	P=0.579N	(e)	P=0.500	(e)	(e)	(e)
<b>COCH-ARM / FISHERS</b>	P=0.580N	(e)	P=0.500	(e)	(e)	(e)
<b>MAX-ISO-POLY-3</b>	P=0.542N	(e)	P=0.158	(e)	(e)	(e)

TDMS No. 20701 - 99  
Test Type: 18-33 DAYS  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

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

Gum Guggul 2.5% granules  
CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011  
Time Report Requested: 11:24:32  
First Dose M/F: NA / 03/02/07  
Lab: VCU

**LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (e) Value of statistic cannot be computed.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (n) No statistics are calculated if all dose groups have fewer than two tumors.
  - (I) Interim sacrifice
  - (T) Terminal sacrifice
  - # Tumor rates based on numbers of animals necropsied.
  - \* To the right of any statistical result, indicates significance at ( $P \leq 0.05$ ).
  - \*\* To the right of any statistical result, indicates significance at ( $P \leq 0.01$ ).
  - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

\*\*\* END OF REPORT \*\*\*