TDMS No. 20701 - 99 Test Type: 18-33 DAYS Route: GAVAGE

**Study Gender:** 

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Gum Guggul 2.5% granules

CAS Number: GUMGUGGULEXT

Date Report Requested: 06/01/2011 Time Report Requested: 11:24:31 First Dose M/F: NA / 03/02/07

Lab: VCU

Species/Strain: MICE/B6C3F1

F1\_M3

Include 002 31.25 mg/kg

Include 005 250 mg/kg

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 004 125 mg/kg

Female

**TDMSE Version:** 2.4.1.0\_004

**PWG Approval Date:** NONE

Include 003 62.5 mg/kg

Include 006 500 mg/kg

**TDMS No.** 20701 - 99 **Test Type:** 18-33 DAYS

Route: GAVAGE Species/Strain: MICE/B6C3F1

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B6C3F1 MICE FEMALE	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
Disposition Summary						
Animals Initially In Study Early Deaths Survivors	8	8	8	8	8	8
Terminal Sacrifice	8	8	8	8	8	8
Animals Examined Microscopically	8	8	8	8	8	8
ALIMENTARY SYSTEM						
Intestine Large, Cecum	(8)	(8)	(8)	(8)	(8)	(8)
Intestine Large, Colon	(8)	(8)	(8)	(8)	(8)	(8)
Intussusception				1 (13%)		
Intestine Large, Rectum	(3)	(6)	(3)	(3)	(4)	(4)
Intestine Small, Duodenum	(8)	(8)	(7)	(8)	(8)	(7)
Intestine Small, Ileum	(8)	(8)	(8)	(8)	(8)	(8)
Intestine Small, Jejunum	(8)	(8)	(8)	(8)	(8)	(8)
Liver	(8)	(8)	(8)	(8)	(8)	(8)
Stomach, Forestomach	(8)	(8)	(8)	(8)	(8)	(8)
Stomach, Glandular	(8)	(8)	(8)	(8)	(8)	(8)
CARDIOVASCULAR SYSTEM						
None						
ENDOCRINE SYSTEM						
Adrenal Cortex	(8)	(8)	(8)	(8)	(8)	(8)
Unilateral, Hyperplasia	(0)	(0)	(=)	(=)	1 (13%)	(=)
Adrenal Medulla	(8)	(8)	(8)	(8)	(8)	(8)

#### **GENERAL BODY SYSTEM**

None

a - Number of animals examined microscopically at site and number of animals with lesion

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B6C3F1 MICE FEMALE	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
GENITAL SYSTEM						
None						
HEMATOPOIETIC SYSTEM						
Bone Marrow	(8)	(8)	(8)	(8)	(8)	(8)
Decreased Number, Adipocyte					1 (13%)	
Increased Number, Adipocyte		1 (13%)	1 (13%)			
Gut Associated Lymphoid Tissue	(7)	(7)	(7)	(7)	(7)	(6)
Follicles, Increased Number, Lymphocyte				1 (14%)	1 (14%)	
Follicles, Increased Size				1 (14%)	1 (14%)	
Follicles, Germinal Center, Increased Size					1 (14%)	
Interfollicular Area, Increased Number, Neutrophil			1 (14%)			
Interfollicular Area, Increased Number, Lymphocyte				1 (14%)		
Interfollicular Area, Increased Size		1 (14%)		1 (14%)		
Interfollicular Area, Necrosis			1 (14%)			
Lymph Node, Mesenteric	(8)	(8)	(7)	(8)	(7)	(8)
Cortex, Germinal Center, Increased Area					2 (29%)	
Cortex, Germinal Center, Increased Number					2 (29%)	
Popliteal Lymph Node	(4)	(8)	(5)	(7)	(6)	(7)
Increased Number, Pigmented Macrophages					1 (17%)	
Increased Number, Neutrophil					1 (17%)	
Medullary Sinuses, Subcapsular Sinuses, Transverse Sinuses, Increased Number, Neutrophil		1 (13%)				
Medullary Sinuses, Subcapsular Sinuses, Transverse Sinuses, Increased Number, Mast Cell						1 (14%)
Paracortex, Prominent High Endothelial Venules				1 (14%)		
Spleen	(8)	(8)	(8)	(8)	(8)	(8)
Follicles, Germinal Center, Increased Number	. ,		• •	3 (38%)	1 (13%)	2 (25%)

a - Number of animals examined microscopically at site and number of animals with lesion

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Route: GAVAGE Species/Strain: MICE/B6C3F1 P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

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Marginal Zone, Decreased Area					1 (13%)	
Marginal Zone, Decreased Number, Lymphocyte					1 (13%)	
Marginal Zone, Decreased Number, Macrophage					1 (13%)	
Red Pulp, Increased Number, Hematopoietic Cells					1 (13%)	
Red Pulp, Increased Number, Pigmented Macrophages	2 (25%)					
Thymus	(8)	(8)	(8)	(8)	(8)	(7)
Cyst		2 (25%)	2 (25%)			
Cortex, Decreased Area			1 (13%)			
INTEGUMENTARY SYSTEM						
None						
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
Lung	(8)	(8)	(8)	(8)	(8)	(8)
Foreign Body			1 (13%)			
Infiltration Cellular			1 (13%)			
Perivascular, Infiltration Cellular	1 (13%)	1 (13%)				1 (13%)

# SPECIAL SENSES SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion

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B6C3F1 MICE FEMALE	0 mg/kg	31.25 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg
None						
URINARY SYSTEM						
Kidney Infiltration Cellular	(8)	(8) 1 (13%)	(8)	(8) 1 (13%)	(8) 2 (25%)	(8) 1 (13%)

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