

**Experiment Number:** 20605 - 01

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH  
AVERAGE SEVERITY GRADES[b]**

**Date Report Requested:** 08/08/2012

**Test Type:** 14-WEEK

Gum guggul extract

**Time Report Requested:** 13:56:16

**Route:** GAVAGE

**CAS Number:** GUMGUGGULEXT

**First Dose M/F:** 07/23/09 / 07/24/09

**Species/Strain:** RATS/HSD

**Lab:** BAT

F1\_Rev.1\_HSD

**NTP Study Number:** C20605  
**Lock Date:** 11/04/2010  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.6.0.0\_007  
**PWG Approval Date:** 05/11/2012

Test Type: 14-WEEK

Gum guggul extract

Time Report Requested: 13:56:16

Route: GAVAGE

CAS Number: GUMGUGGULEXT

First Dose M/F: 07/23/09 / 07/24/09

Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS MALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
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**Disposition Summary**

Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10

## ALIMENTARY SYSTEM

Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(0)	(0)	(0)	(10)	(10)
Clear Cell Focus	2					1
Hematopoietic Cell Proliferation						1 [1.0]
Hepatodiaphragmatic Nodule	1					
Infiltration Cellular, Mixed Cell	8 [1.0]				9 [1.0]	8 [1.1]
Centrilobular, Necrosis, Acute						1 [2.0]
Hepatocyte, Hypertrophy, Diffuse					1 [2.0]	
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)

## CARDIOVASCULAR SYSTEM

Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy	4 [1.0]					2 [1.0]

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

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

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Lab: BAT

Harlan Sprague Dawley RATS MALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(10)	(10)	(10)	(10)	(10)
Hypertrophy, Focal	1 [1.0]					1 [2.0]
Vacuolization Cytoplasmic, Diffuse				1 [1.0]		
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pars Distalis, Hypertrophy, Diffuse						1 [1.0]
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
Cyst	1	1	2	2	3	2

**GENERAL BODY SYSTEM**

None

**GENITAL SYSTEM**

Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	1 [2.0]					3 [1.3]
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(0)	(0)	(0)	(0)	(10)

**HEMATOPOIETIC SYSTEM**

Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mandibular	(10)	(0)	(1)	(0)	(0)	(10)
Hyperplasia, Lymphoid			1 [3.0]			
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Hyperplasia, Lymphoid						1 [2.0]
Spleen	(10)	(0)	(0)	(0)	(0)	(10)

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Harlan Sprague Dawley RATS MALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Hematopoietic Cell Proliferation Thymus	(10)	(0)	(0)	(0)	(0)	1 [1.0] (10)
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(1)	(10)
Cerebrum, Hydrocephalus					1 [3.0]	
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic	1 [1.0]					
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Infarct	1 [2.0]					

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

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Harlan Sprague Dawley RATS MALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Nephropathy	6 [1.0]					10 [1.0]
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

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\*\*\* END OF MALE \*\*\*

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

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Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
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**Disposition Summary**

Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Dosing Accident					1	
Moribund Sacrifice			1			
Natural Death	1					
Survivors						
Terminal Sacrifice	9	10	9	10	9	10
Animals Examined Microscopically	10	10	10	10	10	10

## ALIMENTARY SYSTEM

Esophagus	(10)	(0)	(1)	(0)	(1)	(10)
Intestine Large, Cecum	(10)	(0)	(1)	(0)	(1)	(10)
Intestine Large, Colon	(10)	(0)	(1)	(0)	(1)	(10)
Parasite Metazoan	1					
Intestine Large, Rectum	(10)	(0)	(1)	(0)	(1)	(10)
Intestine Small, Duodenum	(10)	(0)	(1)	(0)	(1)	(10)
Intestine Small, Ileum	(10)	(0)	(1)	(0)	(1)	(10)
Intestine Small, Jejunum	(10)	(0)	(1)	(0)	(1)	(10)
Liver	(10)	(0)	(1)	(10)	(10)	(10)
Infiltration Cellular, Mixed Cell	8 [1.0]			9 [1.0]	8 [1.0]	6 [1.0]
Vacuolization Cytoplasmic					1 [1.0]	
Hepatocyte, Atrophy	1 [2.0]					
Pancreas	(10)	(0)	(1)	(0)	(1)	(10)
Salivary Glands	(10)	(0)	(1)	(0)	(1)	(10)
Stomach, Forestomach	(10)	(0)	(1)	(0)	(1)	(10)
Stomach, Glandular	(10)	(0)	(1)	(0)	(1)	(10)

## CARDIOVASCULAR SYSTEM

Blood Vessel	(10)	(0)	(1)	(0)	(1)	(10)
Heart	(10)	(0)	(1)	(0)	(1)	(10)
Epicardium, Inflammation, Suppurative	1 [3.0]					

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## ENDOCRINE SYSTEM

Adrenal Cortex	(10)	(0)	(1)	(0)	(1)	(10)
Hypertrophy, Focal						1 [1.0]
Adrenal Medulla	(10)	(0)	(1)	(0)	(1)	(10)
Islets, Pancreatic	(10)	(0)	(1)	(0)	(1)	(10)
Parathyroid Gland	(9)	(0)	(1)	(0)	(0)	(10)
Pituitary Gland	(10)	(0)	(1)	(0)	(1)	(10)
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
Cyst	1	4	2	3	2	5

## GENERAL BODY SYSTEM

None

## GENITAL SYSTEM

Clitoral Gland	(10)	(0)	(1)	(0)	(1)	(10)
Inflammation, Chronic Active	3 [1.3]					1 [1.0]
Ovary	(10)	(0)	(1)	(0)	(1)	(10)
Uterus	(10)	(0)	(1)	(0)	(1)	(10)

## HEMATOPOIETIC SYSTEM

Bone Marrow	(10)	(0)	(1)	(0)	(1)	(10)
Hyperplasia	1 [3.0]					
Lymph Node	(0)	(0)	(1)	(0)	(0)	(0)
Renal, Hyperplasia			1 [2.0]			
Renal, Pigmentation			1 [1.0]			
Lymph Node, Mandibular	(10)	(0)	(1)	(0)	(1)	(10)
Atrophy	1 [2.0]					
Lymph Node, Mesenteric	(10)	(0)	(1)	(0)	(1)	(10)

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Harlan Sprague Dawley RATS FEMALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Atrophy	1 [3.0]					
Spleen	(10)	(0)	(1)	(0)	(1)	(10)
Atrophy	1 [2.0]					
Hyperplasia, Lymphoid			1 [2.0]			
Thymus	(10)	(0)	(1)	(0)	(1)	(10)
Atrophy, Diffuse	1 [4.0]		1 [2.0]		1 [3.0]	
Pigmentation, Hemosiderin						1 [2.0]
Mediastinum, Inflammation, Suppurative	1 [3.0]				1 [2.0]	
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(1)	(0)	(1)	(10)
Skin	(10)	(0)	(1)	(0)	(1)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(1)	(0)	(1)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(1)	(0)	(1)	(10)
Brain, Cerebrum	(0)	(0)	(1)	(0)	(0)	(0)
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(0)	(1)	(0)	(1)	(10)
Congestion, Diffuse	1 [3.0]					
Mediastinum, Inflammation, Suppurative	1 [3.0]					
Pleura, Inflammation, Suppurative	1 [3.0]		1 [4.0]		1 [3.0]	
Nose	(10)	(0)	(1)	(0)	(1)	(10)
Trachea	(10)	(0)	(1)	(0)	(1)	(10)

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

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Harlan Sprague Dawley RATS FEMALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<hr/>						
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(1)	(0)	(1)	(10)
<hr/>						
URINARY SYSTEM						
Kidney	(10)	(0)	(1)	(0)	(1)	(10)
Nephropathy	2 [1.0]					3 [1.0]
Renal Tubule, Cyst	1 [1.0]					
Urinary Bladder	(10)	(0)	(1)	(0)	(1)	(10)

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

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

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)