

**Experiment Number:** 20605 - 01  
**Test Type:** 14-WEEK  
**Route:** GAVAGE  
**Species/Strain:** RATS/HSD

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

Gum guggul extract  
**CAS Number:** GUMGUGGULEXT

**Date Report Requested:** 08/08/2012  
**Time Report Requested:** 13:56:15  
**First Dose M/F:** 07/23/09 / 07/24/09  
**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

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

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

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:15

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

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
---------------------------------	---------	------------	-----------	-----------	-----------	------------

**Disposition Summary**

<b>Animals Initially In Study</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>
<b>Early Deaths</b>						
<b>Survivors</b>						
<b>Terminal Sacrifice</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>
<b>Animals Examined Microscopically</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>

## 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 (20%)					1 (10%)
Hematopoietic Cell Proliferation						1 (10%)
Hepatodiaphragmatic Nodule	1 (10%)					
Infiltration Cellular, Mixed Cell	8 (80%)				9 (90%)	8 (80%)
Centrilobular, Necrosis, Acute						1 (10%)
Hepatocyte, Hypertrophy, Diffuse					1 (10%)	
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 (40%)					2 (20%)

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

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

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

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:15

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

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 (10%)					1 (10%)
Vacuolization Cytoplasmic, Diffuse				1 (10%)		
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 (10%)
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
Cyst	1 (10%)	1 (10%)	2 (20%)	2 (20%)	3 (30%)	2 (20%)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	1 (10%)					3 (30%)
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(0)	(0)	(0)	(0)	(10)
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mandibular	(10)	(0)	(1)	(0)	(0)	(10)
Hyperplasia, Lymphoid			1 (100%)			
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Hyperplasia, Lymphoid						1 (10%)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)

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

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

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

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:15

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

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
Hematopoietic Cell Proliferation Thymus	(10)	(0)	(0)	(0)	(0)	1 (10%) (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 (100%)	
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic	1 (10%)					
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 (10%)					

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

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

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

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:15

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

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
Nephropathy	6 (60%)					10 (100%)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

---

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

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

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

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

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:15

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

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
-----------------------------------	---------	------------	-----------	-----------	-----------	------------

**Disposition Summary**

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

## 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 (10%)					
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 (80%)			9 (90%)	8 (80%)	6 (60%)
Vacuolization Cytoplasmic					1 (10%)	
Hepatocyte, Atrophy	1 (10%)					
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 (10%)					

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

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

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

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:15

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

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
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(1)	(0)	(1)	(10)
Hypertrophy, Focal						1 (10%)
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 (10%)	4 (40%)	2 (20%)	3 (30%)	2 (20%)	5 (50%)

**GENERAL BODY SYSTEM**

None

**GENITAL SYSTEM**

Clitoral Gland	(10)	(0)	(1)	(0)	(1)	(10)
Inflammation, Chronic Active	3 (30%)					1 (10%)
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 (10%)					
Lymph Node	(0)	(0)	(1)	(0)	(0)	(0)
Renal, Hyperplasia			1 (100%)			
Renal, Pigmentation			1 (100%)			
Lymph Node, Mandibular	(10)	(0)	(1)	(0)	(1)	(10)
Atrophy	1 (10%)					
Lymph Node, Mesenteric	(10)	(0)	(1)	(0)	(1)	(10)

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

Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

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

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:15

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

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
Atrophy	1 (10%)					
Spleen	(10)	(0)	(1)	(0)	(1)	(10)
Atrophy	1 (10%)					
Hyperplasia, Lymphoid			1 (100%)			
Thymus	(10)	(0)	(1)	(0)	(1)	(10)
Atrophy, Diffuse	1 (10%)		1 (100%)		1 (100%)	
Pigmentation, Hemosiderin						1 (10%)
Mediastinum, Inflammation, Suppurative	1 (10%)				1 (100%)	
<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 (10%)					
Mediastinum, Inflammation, Suppurative	1 (10%)					
Pleura, Inflammation, Suppurative	1 (10%)		1 (100%)		1 (100%)	
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



Experiment Number: 20605 - 01

Test Type: 14-WEEK

Route: GAVAGE

Species/Strain: RATS/HSD

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

Gum guggul extract

CAS Number: GUMGUGGULEXT

Date Report Requested: 08/08/2012

Time Report Requested: 13:56:15

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

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
<hr/>						
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(1)	(0)	(1)	(10)
<hr/>						
URINARY SYSTEM						
Kidney	(10)	(0)	(1)	(0)	(1)	(10)
Nephropathy	2 (20%)					3 (30%)
Renal Tubule, Cyst	1 (10%)					
Urinary Bladder	(10)	(0)	(1)	(0)	(1)	(10)

---

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

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