

Experiment Number: 20605 - 01

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS
ABRIDGED) (a)**

Date Report Requested: 08/08/2012

Test Type: 14-WEEK

Gum guggul extract

Time Report Requested: 13:56:15

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

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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)
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)

ENDOCRINE SYSTEM

Adrenal Cortex	(10)	(10)	(10)	(10)	(10)	(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)

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

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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
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
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)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)

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

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P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

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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
<hr/>						
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(1)	(10)
<hr/>						
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
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SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
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URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

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

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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

Tumor Summary for Males

Total Animals with Primary Neoplasms (b)

Total Primary Neoplasms

Total Animals with Benign Neoplasms

Total Benign Neoplasms

Total Animals with Malignant Neoplasms

Total Malignant Neoplasms

Total Animals with Metastatic Neoplasms

Total Metastatic Neoplasms

Total Animals with Malignant Neoplasms

Uncertain Primary Site

Total Animals with Neoplasms Uncertain-

Benign or Malignant

Total Uncertain Neoplasms

*** END OF MALE ***

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

b - Primary tumors: all tumors except metastatic tumors

Test Type: 14-WEEK

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CAS Number: GUMGUGGULEXT

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Species/Strain: RATS/HSD

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)
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)
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)

ENDOCRINE SYSTEM

Adrenal Cortex	(10)	(0)	(1)	(0)	(1)	(10)
Adrenal Medulla	(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
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)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(10)	(0)	(1)	(0)	(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)
Lymph Node	(0)	(0)	(1)	(0)	(0)	(0)
Lymph Node, Mandibular	(10)	(0)	(1)	(0)	(1)	(10)
Lymph Node, Mesenteric	(10)	(0)	(1)	(0)	(1)	(10)
Spleen	(10)	(0)	(1)	(0)	(1)	(10)
Thymus	(10)	(0)	(1)	(0)	(1)	(10)

INTEGUMENTARY SYSTEM

Mammary Gland	(10)	(0)	(1)	(0)	(1)	(10)
Carcinoma			1 (100%)			
Skin	(10)	(0)	(1)	(0)	(1)	(10)

MUSCULOSKELETAL SYSTEM

Bone	(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
NERVOUS SYSTEM						
Brain	(10)	(0)	(1)	(0)	(1)	(10)
Brain, Cerebrum	(0)	(0)	(1)	(0)	(0)	(0)
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(1)	(0)	(1)	(10)
Nose	(10)	(0)	(1)	(0)	(1)	(10)
Trachea	(10)	(0)	(1)	(0)	(1)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(1)	(0)	(1)	(10)
URINARY SYSTEM						
Kidney	(10)	(0)	(1)	(0)	(1)	(10)
Urinary Bladder	(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
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	1
Total Primary Neoplasms	1

Total Animals with Benign Neoplasms	
Total Benign Neoplasms	

Total Animals with Malignant Neoplasms	1
Total Malignant Neoplasms	1

Total Animals with Metastatic Neoplasms	
Total Metastatic Neoplasms	

Total Animals with Malignant Neoplasms Uncertain Primary Site	
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Total Animals with Neoplasms Uncertain- Benign or Malignant	
Total Uncertain Neoplasms	

*** END OF REPORT ***

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

b - Primary tumors: all tumors except metastatic tumors