

**Experiment Number:** 20203 - 04

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

**Date Report Requested:** 01/18/2013

**Test Type:** CHRONIC

Green tea extract

**Time Report Requested:** 13:10:01

**Route:** GAVAGE

**CAS Number:** GREENTEAEXTR

**First Dose M/F:** 07/10/07 / 07/09/07

**Species/Strain:** MICE/B6C3F1

**Lab:** BAT

F1\_M3

**NTP Study Number:** C20203  
**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:** 3.0.1.0\_004  
**PWG Approval Date:** NONE

Test Type: CHRONIC

Green tea extract

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CAS Number: GREENTEAEXTR

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg
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**Disposition Summary**

<b>Animals Initially In Study</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Early Deaths</b>				
<b>Dosing Accident</b>				<b>2</b>
<b>Moribund Sacrifice</b>	<b>6</b>	<b>8</b>	<b>7</b>	<b>10</b>
<b>Natural Death</b>	<b>11</b>	<b>6</b>	<b>10</b>	<b>1</b>
<b>Survivors</b>				
<b>Dosing Accident</b>			<b>1</b>	
<b>Terminal Sacrifice</b>	<b>33</b>	<b>36</b>	<b>32</b>	<b>37</b>
<b>Animals Examined Microscopically</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>

## ALIMENTARY SYSTEM

Esophagus	(50)	(49)	(50)	(50)
Gallbladder	(50)	(48)	(49)	(49)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Leiomyoma			1 (2%)	
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(43)	(50)	(47)	(49)
Adenoma			1 (2%)	
Intestine Small, Ileum	(47)	(50)	(48)	(50)
Intestine Small, Jejunum	(45)	(50)	(49)	(50)
Adenocarcinoma			1 (2%)	1 (2%)
Adenoma				1 (2%)
Carcinoma	2 (4%)	1 (2%)		
Liver	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung		1 (2%)		
Hemangioma	2 (4%)		2 (4%)	
Hemangiosarcoma	3 (6%)	3 (6%)	3 (6%)	
Hepatoblastoma	2 (4%)			1 (2%)
Hepatocellular Adenoma	19 (38%)	14 (28%)	19 (38%)	14 (28%)
Hepatocellular Adenoma, Multiple	16 (32%)	15 (30%)	6 (12%)	2 (4%)
Hepatocellular Carcinoma	13 (26%)	11 (22%)	8 (16%)	7 (14%)

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

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CAS Number: GREENTEAEXTR

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg
Hepatocellular Carcinoma, Multiple	2 (4%)	7 (14%)	5 (10%)	1 (2%)
Hepatocholangiocarcinoma		3 (6%)		
Squamous Cell Carcinoma, Metastatic, Stomach, Forestomach		1 (2%)		
Mesentery	(1)	(4)	(2)	(1)
Pancreas	(50)	(50)	(50)	(50)
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Carcinoma		1 (2%)		
Squamous Cell Papilloma				1 (2%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Tooth	(0)	(1)	(0)	(1)
Odontoma		1 (100%)		

## CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Aorta, Hepatoblastoma, Metastatic, Liver				1 (2%)
Heart	(50)	(50)	(50)	(50)
Hepatoblastoma, Metastatic, Liver				1 (2%)
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)		

## ENDOCRINE SYSTEM

Adrenal Cortex	(49)	(50)	(50)	(50)
Adenoma			1 (2%)	
Hepatoblastoma, Metastatic, Liver				1 (2%)
Subcapsular, Adenoma	1 (2%)		1 (2%)	
Adrenal Medulla	(49)	(50)	(50)	(50)
Pheochromocytoma Benign		1 (2%)	1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	3 (6%)		
Carcinoma	1 (2%)			
Parathyroid Gland	(41)	(30)	(46)	(44)

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

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg
Pituitary Gland	(49)	(50)	(49)	(50)
Pars Distalis, Adenoma	1 (2%)			
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Carcinoma				1 (2%)
Follicular Cell, Adenoma	1 (2%)	2 (4%)		

## GENERAL BODY SYSTEM

None

## GENITAL SYSTEM

Coagulating Gland	(1)	(0)	(0)	(0)
Sarcoma	1 (100%)			
Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(50)	(50)	(50)
Prostate	(50)	(50)	(50)	(50)
Seminal Vesicle	(50)	(50)	(50)	(50)
Testes	(50)	(50)	(50)	(50)
Interstitial Cell, Adenoma	1 (2%)	3 (6%)		1 (2%)

## HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)			
Lymph Node	(2)	(3)	(1)	(0)
Renal, Hemangiosarcoma			1 (100%)	
Lymph Node, Mandibular	(50)	(50)	(50)	(50)
Lymph Node, Mesenteric	(50)	(49)	(48)	(50)
Hemangiosarcoma	1 (2%)			
Spleen	(50)	(50)	(50)	(50)
Hemangiosarcoma	2 (4%)	1 (2%)		
Thymus	(44)	(49)	(46)	(48)

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg
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Alveolar/Bronchiolar Carcinoma, Metastatic, Lung		1 (2%)		
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## INTEGUMENTARY SYSTEM

Mammary Gland	(0)	(2)	(0)	(1)
Skin	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Kidney	1 (2%)			

## MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(1)	(1)	(0)

## NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)		

## RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	12 (24%)	7 (14%)	8 (16%)	4 (8%)
Alveolar/Bronchiolar Adenoma, Multiple		1 (2%)	2 (4%)	1 (2%)
Alveolar/Bronchiolar Carcinoma		3 (6%)	2 (4%)	
Alveolar/Bronchiolar Carcinoma, Multiple	2 (4%)	4 (8%)	1 (2%)	
Carcinoma, Metastatic, Harderian Gland		1 (2%)		
Carcinoma, Metastatic, Kidney	1 (2%)			
Hepatoblastoma, Metastatic, Liver				1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver	4 (8%)	5 (10%)	2 (4%)	
Hepatocholangiocarcinoma, Metastatic, Liver		3 (6%)		
Mediastinum, Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)			
Nose	(50)	(49)	(50)	(50)

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg
Trachea	(50)	(50)	(50)	(50)

## SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma	7 (14%)	1 (2%)	6 (12%)	4 (8%)
Carcinoma	1 (2%)	1 (2%)	1 (2%)	1 (2%)

## URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Hemangioma				1 (2%)
Hepatoblastoma, Metastatic, Liver				1 (2%)
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)		
Bilateral, Renal Tubule, Carcinoma	2 (4%)			
Renal Tubule, Adenoma	1 (2%)			1 (2%)
Urinary Bladder	(50)	(50)	(50)	(50)

## SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		1 (2%)		
Lymphoma Malignant	4 (8%)	6 (12%)	2 (4%)	

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

\* Number of animals with any tissue examined microscopically

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First Dose M/F: 07/10/07 / 07/09/07

Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg
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**Tumor Summary for Males**

Total Animals with Primary Neoplasms (b)	49	48	42	30
Total Primary Neoplasms	99	91	72	42
Total Animals with Benign Neoplasms	43	37	31	26
Total Benign Neoplasms	62	49	48	30
Total Animals with Malignant Neoplasms	28	34	23	12
Total Malignant Neoplasms	37	42	24	12
Total Animals with Metastatic Neoplasms	5	12	2	1
Total Metastatic Neoplasms	7	15	2	5
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: CHRONIC

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CAS Number: GREENTEAEXTR

First Dose M/F: 07/10/07 / 07/09/07

Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg
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**Disposition Summary**

<b>Animals Initially In Study</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Early Deaths</b>				
<b>Dosing Accident</b>	<b>3</b>	<b>6</b>	<b>1</b>	
<b>Moribund Sacrifice</b>	<b>10</b>	<b>2</b>	<b>2</b>	<b>6</b>
<b>Natural Death</b>	<b>3</b>	<b>9</b>	<b>3</b>	<b>5</b>
<b>Survivors</b>				
<b>Moribund Sacrifice</b>		<b>1</b>		
<b>Terminal Sacrifice</b>	<b>34</b>	<b>32</b>	<b>44</b>	<b>39</b>
<b>Animals Examined Microscopically</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>

## ALIMENTARY SYSTEM

Esophagus	(50)	(49)	(49)	(50)
Gallbladder	(49)	(48)	(50)	(49)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(48)	(40)	(49)	(48)
Adenoma		1 (3%)		
Epithelium, Adenocarcinoma			1 (2%)	
Intestine Small, Ileum	(49)	(46)	(49)	(48)
Intestine Small, Jejunum	(48)	(43)	(49)	(48)
Leiomyosarcoma	1 (2%)			
Liver	(50)	(50)	(50)	(50)
Cystadenocarcinoma, Metastatic, Ovary	1 (2%)			
Hemangiosarcoma	1 (2%)			
Hepatocellular Adenoma	7 (14%)	8 (16%)	3 (6%)	
Hepatocellular Adenoma, Multiple	5 (10%)	1 (2%)		
Hepatocellular Carcinoma	5 (10%)	6 (12%)	4 (8%)	1 (2%)
Hepatocellular Carcinoma, Multiple		1 (2%)		
Hepatocholangiocarcinoma, Multiple			1 (2%)	
Mesentery	(6)	(0)	(3)	(2)
Hemangiosarcoma			1 (33%)	

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



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Lab: BAT

B6C3F1 MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg
Leiomyosarcoma, Metastatic, Intestine Small, Jejunum	1 (17%)			
Pancreas	(50)	(49)	(50)	(50)
Hepatocellular Carcinoma, Metastatic, Liver			1 (2%)	
Salivary Glands	(50)	(48)	(49)	(48)
Stomach, Forestomach	(49)	(49)	(50)	(49)
Squamous Cell Carcinoma	1 (2%)			
Squamous Cell Papilloma	1 (2%)			
Stomach, Glandular	(49)	(48)	(49)	(49)
Tongue	(0)	(0)	(0)	(2)
Squamous Cell Carcinoma				1 (50%)
Squamous Cell Papilloma				1 (50%)

## CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(49)	(50)	(50)

## ENDOCRINE SYSTEM

Adrenal Cortex	(49)	(50)	(50)	(50)
Hepatocellular Carcinoma, Metastatic, Liver		1 (2%)		
Subcapsular, Adenoma		1 (2%)		
Adrenal Medulla	(49)	(50)	(50)	(50)
Pheochromocytoma Benign		1 (2%)	1 (2%)	
Islets, Pancreatic	(50)	(49)	(50)	(50)
Adenoma	1 (2%)			1 (2%)
Parathyroid Gland	(35)	(40)	(41)	(35)
Pituitary Gland	(50)	(48)	(49)	(50)
Thyroid Gland	(50)	(48)	(49)	(49)
C-cell, Carcinoma		1 (2%)		
Follicular Cell, Adenoma		1 (2%)		

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

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg
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## GENERAL BODY SYSTEM

None

## GENITAL SYSTEM

Clitoral Gland	(49)	(49)	(50)	(50)
Ovary	(50)	(50)	(50)	(49)
Cystadenocarcinoma	1 (2%)	1 (2%)		
Cystadenoma	2 (4%)	1 (2%)	5 (10%)	4 (8%)
Sarcoma	1 (2%)			
Bilateral, Cystadenoma	1 (2%)			
Uterus	(50)	(50)	(50)	(50)
Polyp Stromal	2 (4%)		3 (6%)	1 (2%)

## HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)			
Lymph Node	(5)	(5)	(3)	(2)
Lymph Node, Mandibular	(50)	(48)	(49)	(48)
Lymph Node, Mesenteric	(50)	(49)	(50)	(50)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Spleen	(50)	(49)	(50)	(50)
Thymus	(47)	(49)	(49)	(50)

## INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(50)
Skin	(50)	(50)	(50)	(50)
Fibrosarcoma				1 (2%)
Subcutaneous Tissue, Fibrosarcoma		1 (2%)		
Subcutaneous Tissue, Hemangiosarcoma			1 (2%)	
Subcutaneous Tissue, Sarcoma				1 (2%)

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Subcutaneous Tissue, Schwannoma Malignant		1 (2%)		
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## MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(4)	(0)	(0)	(3)
Leiomyosarcoma, Metastatic, Intestine Small, Jejunum	1 (25%)			
Rhabdomyosarcoma	2 (50%)			2 (67%)

## NERVOUS SYSTEM

Brain	(50)	(49)	(50)	(50)
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## RESPIRATORY SYSTEM

Lung	(50)	(49)	(50)	(50)
Alveolar/Bronchiolar Adenoma	5 (10%)	2 (4%)	1 (2%)	3 (6%)
Alveolar/Bronchiolar Carcinoma		1 (2%)	1 (2%)	1 (2%)
Alveolar/Bronchiolar Carcinoma, Multiple	1 (2%)			
Carcinoma, Metastatic, Harderian Gland	1 (2%)			
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)	3 (6%)		
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Rhabdomyosarcoma, Metastatic, Skeletal Muscle	1 (2%)			
Mediastinum, Rhabdomyosarcoma, Metastatic, Skeletal Muscle				1 (2%)
Nose	(48)	(48)	(50)	(50)
Glands, Adenoma	1 (2%)			
Trachea	(50)	(48)	(49)	(49)

## SPECIAL SENSES SYSTEM

Eye	(50)	(48)	(49)	(50)
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Lab: BAT

B6C3F1 MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg
Harderian Gland	(50)	(46)	(49)	(50)
Adenoma	2 (4%)	1 (2%)	3 (6%)	3 (6%)
Carcinoma	2 (4%)			1 (2%)
Zymbal's Gland	(0)	(0)	(0)	(1)
Carcinoma				1 (100%)
<b>URINARY SYSTEM</b>				
Kidney	(50)	(50)	(50)	(50)
Bilateral, Renal Tubule, Carcinoma			1 (2%)	
Renal Tubule, Carcinoma			1 (2%)	
Urinary Bladder	(50)	(50)	(50)	(50)
Leiomyosarcoma, Metastatic, Intestine Small, Jejunum	1 (2%)			
<b>SYSTEMIC LESIONS</b>				
Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		2 (4%)	1 (2%)	1 (2%)
Lymphoma Malignant	7 (14%)	9 (18%)	6 (12%)	4 (8%)

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

\* Number of animals with any tissue examined microscopically

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Lab: BAT

B6C3F1 MICE FEMALE	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg
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**Tumor Summary for Females**

Total Animals with Primary Neoplasms (b)	29	30	23	22
Total Primary Neoplasms	50	40	34	27
Total Animals with Benign Neoplasms	20	17	13	13
Total Benign Neoplasms	27	17	16	13
Total Animals with Malignant Neoplasms	18	18	16	12
Total Malignant Neoplasms	23	23	18	14
Total Animals with Metastatic Neoplasms	5	3	1	1
Total Metastatic Neoplasms	7	4	3	1
Total Animals with Malignant Neoplasms Uncertain Primary Site				
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