

TDMS No. 99031 - 04

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

Date Report Requested: 04/13/2011

Test Type: CHRONIC

Ginkgo biloba extract

Time Report Requested: 14:43:06

Route: GAVAGE

CAS Number: 90045-36-6

First Dose M/F: 03/17/05 / 03/18/05

Species/Strain: MICE/B6C3F1

Lab: BAT

F1_M3

C Number: C99031
Lock Date: 05/05/2008
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.3.1
PWG Approval Date: NONE

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 mg/kg	200 mg/kg	600 mg/kg	2000 mg/kg
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Accidentally Killed			1	
Moribund Sacrifice	8	16	23	13
Natural Death	8	7	5	14
Survivors				
Terminal Sacrifice	34	27	21	23
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Gallbladder	(46)	(48)	(44)	(46)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Carcinoma			1 (2%)	
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Carcinoma	1 (2%)		1 (2%)	2 (4%)
Serosa, Hepatoblastoma		1 (2%)		
Liver	(50)	(50)	(50)	(50)
Hemangiosarcoma	9 (18%)	2 (4%)		3 (6%)
Hemangiosarcoma, Multiple		1 (2%)		
Hepatoblastoma	2 (4%)	16 (32%)	10 (20%)	17 (34%)
Hepatoblastoma, Metastatic, Liver				1 (2%)
Hepatoblastoma, Multiple	1 (2%)	12 (24%)	26 (52%)	21 (42%)
Hepatocellular Adenoma	13 (26%)	6 (12%)	7 (14%)	6 (12%)
Hepatocellular Adenoma, Multiple	18 (36%)	40 (80%)	26 (52%)	27 (54%)
Hepatocellular Carcinoma	11 (22%)	8 (16%)	9 (18%)	4 (8%)
Hepatocellular Carcinoma, Multiple	11 (22%)	23 (46%)	32 (64%)	43 (86%)
Hepatocholangiocarcinoma		1 (2%)		
Hepatocholangiocarcinoma, Multiple		1 (2%)		1 (2%)

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

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B6C3F1 MICE MALE	0 mg/kg	200 mg/kg	600 mg/kg	2000 mg/kg
Ito Cell Tumor Benign		1 (2%)		
Ito Cell Tumor Benign, Multiple	1 (2%)			
Mesentery	(5)	(6)	(3)	(4)
Hepatoblastoma, Metastatic, Liver		2 (33%)	1 (33%)	1 (25%)
Hepatocholangiocarcinoma, Metastatic, Liver				1 (25%)
Pancreas	(50)	(50)	(50)	(50)
Hepatoblastoma, Metastatic, Liver		1 (2%)	1 (2%)	
Salivary Glands	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)		
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma		2 (4%)	1 (2%)	
Squamous Cell Papilloma, Multiple				1 (2%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Tooth	(50)	(50)	(50)	(50)

CARDIOVASCULAR SYSTEM

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

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Hepatoblastoma, Metastatic, Liver			1 (2%)	
Subcapsular, Adenoma	1 (2%)	3 (6%)	1 (2%)	
Adrenal Medulla	(50)	(50)	(50)	(49)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Parathyroid Gland	(36)	(46)	(46)	(44)
Pituitary Gland	(49)	(50)	(50)	(49)
Thyroid Gland	(49)	(49)	(50)	(50)
C-cell, Carcinoma			1 (2%)	1 (2%)

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B6C3F1 MICE MALE	0 mg/kg	200 mg/kg	600 mg/kg	2000 mg/kg
Follicular Cell, Adenoma			2 (4%)	2 (4%)
GENERAL BODY SYSTEM				
Peritoneum	(0)	(1)	(2)	(2)
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Hepatoblastoma, Metastatic, Liver		1 (2%)		
Bilateral, Hepatoblastoma, Metastatic, Liver				1 (2%)
Preputial Gland	(50)	(50)	(50)	(50)
Hemangiosarcoma				1 (2%)
Prostate	(50)	(50)	(49)	(50)
Adenoma				1 (2%)
Carcinoma		1 (2%)		
Hemangiosarcoma		1 (2%)		
Seminal Vesicle	(50)	(50)	(50)	(50)
Hepatoblastoma, Metastatic, Liver			1 (2%)	
Testes	(50)	(50)	(50)	(50)
Interstitial Cell, Adenoma	1 (2%)		1 (2%)	1 (2%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Hemangioma			1 (2%)	
Lymph Node	(11)	(15)	(18)	(14)
Bronchial, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung		1 (7%)		
Bronchial, Hepatoblastoma, Metastatic, Liver		1 (7%)		
Bronchial, Hepatocholangiocarcinoma, Metastatic, Liver				1 (7%)
Lymph Node, Mandibular	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Harderian Gland			1 (2%)	
Lymph Node, Mesenteric	(50)	(49)	(49)	(50)

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B6C3F1 MICE MALE	0 mg/kg	200 mg/kg	600 mg/kg	2000 mg/kg
Hepatoblastoma, Metastatic, Liver			1 (2%)	1 (2%)
Spleen	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)		1 (2%)
Thymus	(50)	(47)	(50)	(45)
Thymoma Malignant		1 (2%)		
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(50)
Hepatoblastoma, Metastatic, Liver				1 (2%)
Pinna, Amelanotic Melanoma, Malignant				1 (2%)
Pinna, Melanoma Malignant	1 (2%)			
Tail, Schwannoma Nos				1 (2%)
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Turbinates, Carcinoma, Metastatic, Harderian Gland			1 (2%)	
Skeletal Muscle	(1)	(1)	(1)	(1)
Hepatoblastoma, Metastatic, Liver		1 (100%)		
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Neuroblastoma			1 (2%)	
Peripheral Nerve	(0)	(0)	(1)	(0)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	8 (16%)	6 (12%)	5 (10%)	1 (2%)
Alveolar/Bronchiolar Carcinoma	11 (22%)	7 (14%)	4 (8%)	3 (6%)

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Lab: BAT

B6C3F1 MICE MALE	0 mg/kg	200 mg/kg	600 mg/kg	2000 mg/kg
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	2 (4%)			
Alveolar/Bronchiolar Carcinoma, Multiple Carcinoma, Metastatic, Harderian Gland		1 (2%)	1 (2%)	
Hemangiosarcoma	1 (2%)		1 (2%)	
Hepatoblastoma, Metastatic, Liver		7 (14%)	14 (28%)	14 (28%)
Hepatocellular Carcinoma, Metastatic, Liver	10 (20%)	8 (16%)	8 (16%)	18 (36%)
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)		1 (2%)
Nose	(50)	(50)	(50)	(50)
Trachea	(50)	(50)	(50)	(50)

SPECIAL SENSES SYSTEM

Ear	(1)	(0)	(0)	(1)
Neural Crest Tumor				1 (100%)
Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma	4 (8%)	3 (6%)	2 (4%)	3 (6%)
Carcinoma	3 (6%)	5 (10%)	4 (8%)	2 (4%)
Hepatoblastoma, Metastatic, Liver			1 (2%)	

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Hepatoblastoma, Metastatic, Liver		1 (2%)		1 (2%)
Urethra	(0)	(1)	(0)	(0)
Urinary Bladder	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)		

SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Lymphoma Malignant	1 (2%)	3 (6%)	1 (2%)	

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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B6C3F1 MICE MALE	0 mg/kg	200 mg/kg	600 mg/kg	2000 mg/kg
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	44	48	48	49
Total Primary Neoplasms	99	148	137	144
Total Animals with Benign Neoplasms	38	47	36	35
Total Benign Neoplasms	47	61	46	42
Total Animals with Malignant Neoplasms	35	46	46	48
Total Malignant Neoplasms	52	87	91	100
Total Animals with Metastatic Neoplasms	13	17	23	26
Total Metastatic Neoplasms	13	26	31	42
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant				2
Total Uncertain Neoplasms				2

*** 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

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Lab: BAT

B6C3F1 MICE FEMALE	0 mg/kg	200 mg/kg	600 mg/kg	2000 mg/kg
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Accidentally Killed		2		
Dosing Accident	5		1	
Moribund Sacrifice	8	8	3	3
Natural Death	6	4	3	11
Survivors				
Terminal Sacrifice	31	36	43	36
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Gallbladder	(50)	(50)	(48)	(48)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Fibrous Histiocytoma				1 (2%)
Hemangiosarcoma		1 (2%)	1 (2%)	
Hepatoblastoma	1 (2%)	1 (2%)	7 (14%)	7 (14%)
Hepatoblastoma, Multiple			1 (2%)	4 (8%)
Hepatocellular Adenoma	7 (14%)	7 (14%)	4 (8%)	5 (10%)
Hepatocellular Adenoma, Multiple	10 (20%)	30 (60%)	37 (74%)	43 (86%)
Hepatocellular Carcinoma	7 (14%)	8 (16%)	10 (20%)	13 (26%)
Hepatocellular Carcinoma, Multiple	2 (4%)	2 (4%)	5 (10%)	31 (62%)
Osteosarcoma, Metastatic, Bone				1 (2%)
Mesentery	(3)	(5)	(3)	(4)
Oral Mucosa	(1)	(0)	(0)	(0)
Gingival, Squamous Cell Carcinoma	1 (100%)			
Pancreas	(50)	(49)	(50)	(50)

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B6C3F1 MICE FEMALE	0 mg/kg	200 mg/kg	600 mg/kg	2000 mg/kg
Fibrous Histiocytoma				1 (2%)
Salivary Glands	(50)	(50)	(49)	(50)
Sarcoma, Metastatic, Skin		1 (2%)		
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma	2 (4%)	1 (2%)		
Stomach, Glandular	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	
Tooth	(50)	(50)	(50)	(50)

CARDIOVASCULAR SYSTEM

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

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Fibrous Histiocytoma				1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign		1 (2%)		
Pheochromocytoma Malignant		1 (2%)		
Islets, Pancreatic	(50)	(50)	(50)	(50)
Parathyroid Gland	(47)	(46)	(45)	(45)
Pituitary Gland	(50)	(50)	(49)	(50)
Pars Distalis, Adenoma	4 (8%)	2 (4%)	1 (2%)	
Pars Intermedia, Adenoma	1 (2%)			1 (2%)
Thyroid Gland	(49)	(48)	(49)	(48)

GENERAL BODY SYSTEM

None

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Lab: BAT

B6C3F1 MICE FEMALE	0 mg/kg	200 mg/kg	600 mg/kg	2000 mg/kg
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(49)
Ovary	(50)	(50)	(49)	(50)
Choriocarcinoma	1 (2%)			
Cystadenoma	2 (4%)	3 (6%)	1 (2%)	1 (2%)
Fibrous Histiocytoma				1 (2%)
Hemangioma				1 (2%)
Hemangiosarcoma	1 (2%)			
Teratoma Benign			1 (2%)	
Uterus	(50)	(50)	(50)	(50)
Polyp Stromal	1 (2%)			
Sarcoma Stromal	1 (2%)			
Endometrium, Polyp Stromal			1 (2%)	
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(16)	(11)	(11)	(6)
Lymph Node, Bronchial	(0)	(0)	(0)	(1)
Lymph Node, Mandibular	(49)	(50)	(49)	(50)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)			
Thymus	(50)	(49)	(49)	(50)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Carcinoma		1 (2%)	1 (2%)	
Skin	(50)	(50)	(50)	(50)
Basal Cell Carcinoma	1 (2%)			
Keratoacanthoma				1 (2%)
Melanoma Malignant	1 (2%)			

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Sarcoma	1 (2%)	1 (2%)		
Subcutaneous Tissue, Sarcoma	2 (4%)	2 (4%)		
Tail, Fibrous Histiocytoma			1 (2%)	
Tail, Melanoma Malignant		1 (2%)		

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Osteosarcoma				1 (2%)
Skeletal Muscle	(1)	(1)	(0)	(0)
Hemangiosarcoma	1 (100%)			
Sarcoma		1 (100%)		

NERVOUS SYSTEM

Brain	(50)	(50)	(49)	(50)
Peripheral Nerve	(1)	(1)	(1)	(0)
Spinal Cord	(0)	(1)	(1)	(0)

RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma				1 (2%)
Alveolar/Bronchiolar Carcinoma	1 (2%)	2 (4%)	2 (4%)	3 (6%)
Hepatoblastoma, Metastatic, Liver			1 (2%)	
Hepatocellular Carcinoma, Metastatic, Liver	3 (6%)	3 (6%)	2 (4%)	5 (10%)
Osteosarcoma, Metastatic, Bone				1 (2%)
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla		1 (2%)		
Sarcoma, Metastatic, Skin	1 (2%)			
Nose	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Trachea	(50)	(50)	(50)	(50)

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B6C3F1 MICE FEMALE	0 mg/kg	200 mg/kg	600 mg/kg	2000 mg/kg
SPECIAL SENSES SYSTEM				
Ear	(1)	(0)	(0)	(0)
Eye	(50)	(50)	(49)	(50)
Harderian Gland	(50)	(50)	(49)	(50)
Adenoma	5 (10%)	3 (6%)	2 (4%)	10 (20%)
Carcinoma	1 (2%)		4 (8%)	1 (2%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Fibrous Histiocytoma				1 (2%)
Urinary Bladder	(50)	(50)	(50)	(50)
Fibrous Histiocytoma				1 (2%)
SYSTEMIC LESIONS				
Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)	1 (2%)	3 (6%)	3 (6%)
Leukemia Myeloid				1 (2%)
Lymphoma Malignant	11 (22%)	9 (18%)	7 (14%)	2 (4%)

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* Number of animals with any tissue examined microscopically

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Lab: BAT

B6C3F1 MICE FEMALE

0 mg/kg

200 mg/kg

600 mg/kg

2000 mg/kg

Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	35	46	46	49
Total Primary Neoplasms	67	79	90	135
Total Animals with Benign Neoplasms	25	39	41	48
Total Benign Neoplasms	32	48	48	63
Total Animals with Malignant Neoplasms	28	26	30	47
Total Malignant Neoplasms	35	31	42	72
Total Animals with Metastatic Neoplasms	4	5	3	6
Total Metastatic Neoplasms	4	5	3	7
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