

TDMS No. 20005 - 06

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

Date Report Requested: 08/27/2008

Test Type: CHRONIC

Ginseng

Time Report Requested: 15:02:16

Route: GAVAGE

CAS Number: 50647-08-0

First Dose M/F: 02/10/04 / 02/09/04

Species/Strain: MICE/B6C3F1

Lab: BAT

F1_M3

C Number: C20005
Lock Date: 10/10/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.0.0

Test Type: CHRONIC

Ginseng

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First Dose M/F: 02/10/04 / 02/09/04

Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Accidently Killed				1
Moribund Sacrifice	12	10	8	8
Natural Death	6	7	4	8
Survivors				
Moribund Sacrifice		1		
Natural Death				1
Terminal Sacrifice	32	32	38	32
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Gallbladder	(49)	(50)	(49)	(50)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Adenoma				1 (2%)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Adenoma		1 (2%)	1 (2%)	
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Adenoma				1 (2%)
Carcinoma		1 (2%)		2 (4%)
Hemangiosarcoma				1 (2%)
Liver	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Uncertain Primary Site				1 (2%)
Cholangiocarcinoma		1 (2%)	1 (2%)	
Hemangioma			1 (2%)	
Hemangiosarcoma	2 (4%)	4 (8%)	1 (2%)	3 (6%)
Hepatoblastoma	1 (2%)	1 (2%)		1 (2%)
Hepatocellular Adenoma	19 (38%)	11 (22%)	11 (22%)	12 (24%)
Hepatocellular Adenoma, Multiple	15 (30%)	18 (36%)	22 (44%)	22 (44%)
Hepatocellular Carcinoma	7 (14%)	9 (18%)	10 (20%)	10 (20%)
Hepatocellular Carcinoma, Multiple	7 (14%)	5 (10%)	5 (10%)	2 (4%)

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

Test Type: CHRONIC

Ginseng

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Hepatocarcinoma			1 (2%)	
Schwannoma Malignant, Metastatic, Skin	1 (2%)			
Mesentery	(3)	(4)	(6)	(0)
Cholangiocarcinoma, Metastatic, Liver			1 (17%)	
Hemangiosarcoma, Metastatic, Epididymis			1 (17%)	
Hepatocellular Carcinoma, Metastatic, Liver	1 (33%)	1 (25%)		
Pancreas	(50)	(50)	(50)	(50)
Salivary Glands	(50)	(50)	(50)	(50)
Mast Cell Tumor Malignant	1 (2%)			
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma	1 (2%)	1 (2%)	1 (2%)	
Stomach, Glandular	(50)	(50)	(50)	(50)
Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Tooth	(13)	(15)	(9)	(13)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(48)	(50)	(50)
Aorta, Carcinoma, Metastatic, Uncertain Primary Site				1 (2%)
Heart	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Uncertain Primary Site				1 (2%)
Cholangiocarcinoma, Metastatic, Liver		1 (2%)	1 (2%)	
Hemangioma				1 (2%)
Hemangiosarcoma	1 (2%)	1 (2%)		
Sarcoma, Metastatic, Skeletal Muscle	1 (2%)			
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Subcapsular, Adenoma	1 (2%)	2 (4%)	4 (8%)	2 (4%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign		1 (2%)		1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Carcinoma	1 (2%)			

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

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Parathyroid Gland	(49)	(48)	(45)	(48)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	1 (2%)			
Pars Intermedia, Adenoma				1 (2%)
Thyroid Gland	(50)	(50)	(50)	(50)
Follicular Cell, Adenoma	1 (2%)			
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Hemangiosarcoma			1 (2%)	
Hepatocellular Carcinoma, Metastatic, Liver		1 (2%)		
Preputial Gland	(50)	(50)	(50)	(50)
Prostate	(50)	(50)	(50)	(50)
Carcinoma				1 (2%)
Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Seminal Vesicle	(50)	(50)	(50)	(50)
Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Testes	(50)	(50)	(50)	(50)
Interstitial Cell, Adenoma		1 (2%)	1 (2%)	
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)		
Hemangiosarcoma, Metastatic, Spleen	1 (2%)			
Lymph Node	(2)	(2)	(2)	(1)
Inguinal, Hepatocellular Carcinoma, Metastatic, Liver		1 (50%)		
Mediastinal, Cholangiocarcinoma, Metastatic, Liver			1 (50%)	
Renal, Hepatocellular Carcinoma, Metastatic, Liver		1 (50%)		

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Lymph Node, Mandibular	(50)	(50)	(50)	(50)
Mast Cell Tumor Malignant	1 (2%)			
Lymph Node, Mesenteric	(50)	(49)	(50)	(50)
Cholangiocarcinoma, Metastatic, Liver		1 (2%)		
Spleen	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)	1 (2%)		1 (2%)
Thymus	(47)	(50)	(50)	(49)
Carcinoma, Metastatic, Uncertain				1 (2%)
Primary Site				
Cholangiocarcinoma, Metastatic, Liver		1 (2%)	1 (2%)	
Sarcoma, Metastatic, Skeletal Muscle	1 (2%)			
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(50)
Squamous Cell Papilloma			2 (4%)	
Subcutaneous Tissue, Fibrosarcoma	1 (2%)			
Subcutaneous Tissue, Hemangioma	1 (2%)	1 (2%)		
Subcutaneous Tissue, Schwannoma	1 (2%)			
Malignant				
MUSCULOSKELETAL SYSTEM				
Skeletal Muscle	(1)	(1)	(0)	(0)
Cholangiocarcinoma, Metastatic, Liver		1 (100%)		
Sarcoma	1 (100%)			
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	7 (14%)	2 (4%)	5 (10%)	15 (30%)
Alveolar/Bronchiolar Adenoma, Multiple	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Alveolar/Bronchiolar Carcinoma	3 (6%)	3 (6%)	4 (8%)	3 (6%)
Alveolar/Bronchiolar Carcinoma, Multiple			1 (2%)	

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Carcinoma, Metastatic, Harderian Gland	1 (2%)			
Carcinoma, Metastatic, Uncertain Primary Site				1 (2%)
Cholangiocarcinoma, Metastatic, Liver		1 (2%)	1 (2%)	
Hemangiosarcoma, Metastatic, Liver	1 (2%)	1 (2%)		1 (2%)
Hepatoblastoma, Metastatic, Liver			1 (2%)	
Hepatocellular Carcinoma, Metastatic, Liver	2 (4%)	8 (16%)	6 (12%)	4 (8%)
Sarcoma, Metastatic, Skeletal Muscle	1 (2%)			
Serosa, Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Nose	(50)	(49)	(49)	(50)
Trachea	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Uncertain Primary Site				1 (2%)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma	10 (20%)	7 (14%)	11 (22%)	14 (28%)
Carcinoma	1 (2%)			
Bilateral, Adenoma	1 (2%)			1 (2%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Adenoma				1 (2%)
Adenoma, Multiple				1 (2%)
Carcinoma	1 (2%)			
Urinary Bladder	(50)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)		1 (2%)	
Lymphoma Malignant	4 (8%)	1 (2%)	2 (4%)	

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* Number of animals with any tissue examined microscopically

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Tumor Summary for Males				
Total Animals with Primary Neoplasms (b)	46	44	46	47
Total Primary Neoplasms	95	75	88	99
Total Animals with Benign Neoplasms	38	34	40	44
Total Benign Neoplasms	60	47	61	75
Total Animals with Malignant Neoplasms	26	22	24	22
Total Malignant Neoplasms	35	28	27	24
Total Animals with Metastatic Neoplasms	7	10	8	6
Total Metastatic Neoplasms	10	18	18	11
Total Animals with Malignant Neoplasms Uncertain Primary Site				1
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

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident			1	4
Moribund Sacrifice	7	11	10	8
Natural Death	5	8	5	6
Survivors				
Terminal Sacrifice	38	31	34	32
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Gallbladder	(49)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(49)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Hemangioma		1 (2%)		
Hemangiosarcoma		1 (2%)	2 (4%)	
Hepatocellular Adenoma	14 (28%)	10 (20%)	11 (22%)	6 (12%)
Hepatocellular Adenoma, Multiple	7 (14%)	10 (20%)	6 (12%)	9 (18%)
Hepatocellular Carcinoma	2 (4%)	4 (8%)	4 (8%)	1 (2%)
Hepatocellular Carcinoma, Multiple		1 (2%)		
Osteosarcoma, Metastatic, Bone		1 (2%)		
Mesentery	(8)	(9)	(7)	(4)
Osteosarcoma, Metastatic, Bone		1 (11%)		
Pancreas	(50)	(50)	(50)	(50)
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma			1 (2%)	
Stomach, Glandular	(50)	(50)	(50)	(50)
CARDIOVASCULAR SYSTEM				

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Pericardium, Osteosarcoma, Metastatic, Bone		1 (2%)		
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	1 (2%)			
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	1 (2%)		1 (2%)	
Parathyroid Gland	(41)	(44)	(39)	(43)
Pituitary Gland	(50)	(50)	(50)	(49)
Pars Distalis, Adenoma	1 (2%)	4 (8%)	5 (10%)	3 (6%)
Pars Intermedia, Adenoma	1 (2%)	1 (2%)		
Thyroid Gland	(49)	(50)	(50)	(50)
C-cell, Carcinoma			1 (2%)	
Follicular Cell, Carcinoma			1 (2%)	
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(49)	(50)
Ovary	(50)	(50)	(50)	(50)
Cystadenoma	7 (14%)	2 (4%)	3 (6%)	
Hemangioma			1 (2%)	
Luteoma			1 (2%)	
Periovarian Tissue, Fibrous	1 (2%)			
Histiocytoma, Metastatic, Skin				
Uterus	(50)	(50)	(50)	(50)
Carcinoma				1 (2%)
Hemangioma			1 (2%)	
Hemangiosarcoma			1 (2%)	
Polyp Stromal			2 (4%)	
Sarcoma Stromal				1 (2%)

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(49)	(50)
Hemangiosarcoma, Metastatic, Spleen				1 (2%)
Lymph Node	(4)	(4)	(6)	(6)
Fibrosarcoma, Metastatic, Skin	1 (25%)			
Lymph Node, Mandibular	(50)	(49)	(50)	(50)
Lymph Node, Mesenteric	(49)	(50)	(50)	(50)
Spleen	(50)	(50)	(49)	(50)
Hemangioma	1 (2%)			
Hemangiosarcoma				1 (2%)
Thymus	(48)	(49)	(49)	(49)
Osteosarcoma, Metastatic, Bone		1 (2%)		
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Skin	(50)	(50)	(50)	(50)
Sarcoma		1 (2%)		
Trichoepithelioma				1 (2%)
Subcutaneous Tissue, Fibrosarcoma	3 (6%)			2 (4%)
Subcutaneous Tissue, Fibrous	1 (2%)			3 (6%)
Histiocytoma				
Subcutaneous Tissue, Hemangioma				1 (2%)
Subcutaneous Tissue, Hemangiosarcoma		1 (2%)		
Subcutaneous Tissue, Sarcoma		2 (4%)	1 (2%)	
Subcutaneous Tissue, Schwannoma	2 (4%)		1 (2%)	2 (4%)
Malignant				
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Osteosarcoma		2 (4%)		
NERVOUS SYSTEM				

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Brain	(50)	(50)	(50)	(50)
Spinal Cord	(0)	(1)	(1)	(1)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	5 (10%)	2 (4%)	2 (4%)	4 (8%)
Alveolar/Bronchiolar Adenoma, Multiple	1 (2%)	1 (2%)		
Alveolar/Bronchiolar Carcinoma	1 (2%)	2 (4%)		
Alveolar/Bronchiolar Carcinoma, Multiple		1 (2%)	1 (2%)	
Carcinoma, Metastatic, Thyroid Gland			1 (2%)	
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)			
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)	3 (6%)	2 (4%)	
Osteosarcoma, Metastatic, Bone		2 (4%)		
Osteosarcoma, Metastatic, Uncertain Primary Site			1 (2%)	
Sarcoma, Metastatic, Skin		1 (2%)		
Nose	(50)	(50)	(50)	(49)
Adenoma		1 (2%)		
SPECIAL SENSES SYSTEM				
Eye	(49)	(50)	(50)	(50)
Harderian Gland	(49)	(50)	(50)	(50)
Adenoma	5 (10%)	7 (14%)	8 (16%)	7 (14%)
Bilateral, Adenoma	2 (4%)		1 (2%)	1 (2%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Urinary Bladder	(49)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		1 (2%)	1 (2%)	2 (4%)
Lymphoma Malignant	9 (18%)	12 (24%)	6 (12%)	8 (16%)

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

TDMS No. 20005 - 06

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

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B6C3F1 MICE FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
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* Number of animals with any tissue examined microscopically

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Tumor Summary for Females				
Total Animals with Primary Neoplasms (b)	42	38	34	36
Total Primary Neoplasms	65	67	62	53
Total Animals with Benign Neoplasms	33	30	29	25
Total Benign Neoplasms	47	39	43	32
Total Animals with Malignant Neoplasms	15	27	16	20
Total Malignant Neoplasms	18	28	19	21
Total Animals with Metastatic Neoplasms	3	6	4	1
Total Metastatic Neoplasms	4	10	4	1
Total Animals with Malignant Neoplasms Uncertain Primary Site			1	
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