

TDMS No. 20107 - 04

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

Date Report Requested: 03/10/2011

Test Type: CHRONIC

N,N-Dimethyl-p-toluidine

Time Report Requested: 11:42:39

Route: GAVAGE

CAS Number: 99-97-8

First Dose M/F: 10/26/04 / 10/25/04

Species/Strain: MICE/B6C3F1

Lab: BAT

F1_M3

C Number: C20107
Lock Date: 02/26/2008
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.3.0
PWG Approval Date: NONE

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Dosing Accident	2			
Moribund Sacrifice	5	4	11	14
Natural Death	9	10	8	
Survivors				
Natural Death	1			
Terminal Sacrifice	33	36	31	36
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Gallbladder	(49)	(50)	(47)	(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	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		1 (2%)
Carcinoma, Multiple				1 (2%)
Liver	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Islets, Pancreatic	1 (2%)			
Fibrous Histiocytoma, Metastatic, Skin		1 (2%)		
Hemangioma			1 (2%)	
Hemangiosarcoma	6 (12%)	2 (4%)	9 (18%)	3 (6%)
Hepatoblastoma	1 (2%)	5 (10%)	8 (16%)	8 (16%)
Hepatoblastoma, Multiple			2 (4%)	
Hepatocellular Adenoma	12 (24%)	15 (30%)	10 (20%)	10 (20%)
Hepatocellular Adenoma, Multiple	17 (34%)	19 (38%)	27 (54%)	26 (52%)
Hepatocellular Carcinoma	15 (30%)	18 (36%)	14 (28%)	14 (28%)
Hepatocellular Carcinoma, Multiple	7 (14%)	7 (14%)	16 (32%)	22 (44%)
Hepatocholangiocarcinoma			1 (2%)	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	6 MG/KG	20 MG/KG	60 MG/KG
Mesentery	(4)	(3)	(5)	(2)
Fat, Hepatocholangiocarcinoma, Metastatic, Liver			1 (20%)	
Pancreas	(50)	(50)	(50)	(50)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Salivary Glands	(50)	(50)	(50)	(50)
Hepatocellular Carcinoma, Metastatic, Liver		1 (2%)		
Stomach, Forestomach	(50)	(50)	(50)	(50)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Squamous Cell Papilloma	1 (2%)	1 (2%)		3 (6%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Tongue	(2)	(0)	(0)	(0)
Tooth	(37)	(38)	(34)	(30)
Odontoma	3 (8%)	1 (3%)	1 (3%)	
Odontoma, Multiple	2 (5%)			

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Zymbal'S Gland	1 (2%)			
Hemangiosarcoma	1 (2%)			

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma				1 (2%)
Bilateral, Subcapsular, Adenoma		1 (2%)		
Subcapsular, Adenoma	3 (6%)	4 (8%)	1 (2%)	1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign				1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	1 (2%)		
Adenoma, Multiple		1 (2%)		

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Carcinoma	1 (2%)			
Parathyroid Gland	(40)	(43)	(45)	(42)
Pituitary Gland	(50)	(50)	(49)	(50)
Thyroid Gland	(50)	(50)	(50)	(50)
Follicular Cell, Adenoma	1 (2%)			

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Coagulating Gland	(0)	(1)	(0)	(0)
Epididymis	(50)	(50)	(50)	(50)
Hemangiosarcoma			1 (2%)	
Preputial Gland	(50)	(50)	(50)	(50)
Prostate	(50)	(50)	(50)	(50)
Hepatocarcinoma, Metastatic, Liver			1 (2%)	
Seminal Vesicle	(50)	(50)	(50)	(50)
Testes	(50)	(50)	(50)	(50)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Hemangiosarcoma				1 (2%)
Lymph Node	(2)	(3)	(4)	(0)
Mediastinal, Hepatocarcinoma, Metastatic, Liver			1 (25%)	
Pancreatic, Hemangiosarcoma			1 (25%)	
Lymph Node, Mandibular	(50)	(50)	(49)	(50)
Lymph Node, Mesenteric	(50)	(50)	(49)	(50)
Hemangiosarcoma	1 (2%)			
Hepatocarcinoma, Metastatic, Liver			1 (2%)	
Spleen	(48)	(50)	(49)	(50)

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B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Hemangiosarcoma	3 (6%)	1 (2%)	3 (6%)	1 (2%)
Hemangiosarcoma, Multiple			1 (2%)	
Thymus	(48)	(48)	(48)	(49)
Carcinoma, Metastatic, Zymbal'S Gland	1 (2%)			

INTEGUMENTARY SYSTEM

Skin	(50)	(50)	(50)	(50)
Subcutaneous Tissue, Fibrosarcoma				1 (2%)
Subcutaneous Tissue, Fibrous Histiocytoma		1 (2%)		
Subcutaneous Tissue, Lipoma	1 (2%)	1 (2%)		
Subcutaneous Tissue, Melanoma Malignant		1 (2%)		

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(1)	(2)	(2)
Hemangiosarcoma			1 (50%)	
Hepatocholangiocarcinoma, Metastatic, Liver			1 (50%)	
Sarcoma				1 (50%)

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
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RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	11 (22%)	11 (22%)	17 (34%)	10 (20%)
Alveolar/Bronchiolar Adenoma, Multiple		5 (10%)	1 (2%)	
Alveolar/Bronchiolar Carcinoma	2 (4%)	2 (4%)		4 (8%)
Alveolar/Bronchiolar Carcinoma, Multiple		1 (2%)		
Carcinoma, Metastatic, Harderian Gland			1 (2%)	

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Carcinoma, Metastatic, Zymbal'S Gland	1 (2%)			
Hemangiosarcoma	1 (2%)			
Hepatoblastoma, Metastatic, Liver		2 (4%)	4 (8%)	5 (10%)
Hepatocellular Carcinoma, Metastatic, Liver	6 (12%)	5 (10%)	7 (14%)	3 (6%)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Osteosarcoma, Metastatic, Uncertain Primary Site		1 (2%)		
Bronchus, Adenoma		1 (2%)		
Nose	(49)	(50)	(50)	(50)
Respiratory Epithelium, Adenoma		1 (2%)		
Trachea	(50)	(50)	(50)	(50)

SPECIAL SENSES SYSTEM

Ear	(1)	(0)	(0)	(0)
Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma	10 (20%)	7 (14%)	4 (8%)	2 (4%)
Carcinoma		1 (2%)	1 (2%)	
Bilateral, Adenoma	1 (2%)			
Zymbal's Gland	(1)	(0)	(0)	(0)
Carcinoma	1 (100%)			

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Hepatocellular Carcinoma, Metastatic, Liver		1 (2%)		
Renal Tubule, Adenoma	1 (2%)			
Ureter	(1)	(0)	(0)	(0)
Urethra	(0)	(1)	(0)	(0)
Urinary Bladder	(50)	(50)	(50)	(50)
Hemangioma				1 (2%)

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* Number of animals with any tissue examined microscopically

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B6C3F1 MICE MALE

0 MG/KG

6 MG/KG

20 MG/KG

60 MG/KG

SYSTEMIC LESIONS

	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma			1 (2%)	
Lymphoma Malignant	4 (8%)	6 (12%)	1 (2%)	1 (2%)

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* Number of animals with any tissue examined microscopically

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Lab: BAT

B6C3F1 MICE MALE

0 MG/KG

6 MG/KG

20 MG/KG

60 MG/KG

Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	45	47	50	49
Total Primary Neoplasms	107	115	122	114
Total Animals with Benign Neoplasms	36	40	41	39
Total Benign Neoplasms	64	70	62	56
Total Animals with Malignant Neoplasms	29	32	41	40
Total Malignant Neoplasms	43	45	60	58
Total Animals with Metastatic Neoplasms	8	9	12	8
Total Metastatic Neoplasms	10	11	21	8
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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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Dosing Accident		1	1	2
Moribund Sacrifice	3	1	7	10
Natural Death	4	8	3	6
Survivors				
Terminal Sacrifice	43	40	39	32
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Gallbladder	(50)	(50)	(49)	(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	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Hemangioma	1 (2%)	1 (2%)	1 (2%)	
Hemangiosarcoma		1 (2%)	1 (2%)	
Hepatoblastoma		1 (2%)		4 (8%)
Hepatocellular Adenoma	15 (30%)	13 (26%)	8 (16%)	9 (18%)
Hepatocellular Adenoma, Multiple	2 (4%)	6 (12%)	29 (58%)	35 (70%)
Hepatocellular Carcinoma	5 (10%)	10 (20%)	13 (26%)	12 (24%)
Hepatocellular Carcinoma, Multiple	1 (2%)	3 (6%)	5 (10%)	19 (38%)
Sarcoma, Metastatic, Skeletal Muscle		1 (2%)		
Mesentery	(3)	(8)	(9)	(6)
Sarcoma		1 (13%)		
Sarcoma, Metastatic, Skeletal Muscle		1 (13%)		
Pancreas	(50)	(50)	(50)	(50)
Sarcoma, Metastatic, Skeletal Muscle		1 (2%)		
Salivary Glands	(50)	(50)	(50)	(48)

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adenoma	1 (2%)			
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Carcinoma		1 (2%)		
Squamous Cell Papilloma	1 (2%)	4 (8%)	5 (10%)	7 (14%)
Squamous Cell Papilloma, Multiple		1 (2%)	1 (2%)	
Stomach, Glandular	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Tongue	(0)	(0)	(0)	(1)
Tooth	(13)	(10)	(7)	(4)

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(49)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Sarcoma, Metastatic, Skeletal Muscle		1 (2%)		

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	2 (4%)			2 (4%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Parathyroid Gland	(48)	(38)	(38)	(34)
Pituitary Gland	(48)	(50)	(50)	(49)
Pars Distalis, Adenoma		2 (4%)	1 (2%)	
Pars Intermedia, Adenoma		3 (6%)		
Thyroid Gland	(50)	(50)	(50)	(50)
Follicular Cell, Adenoma				1 (2%)

GENERAL BODY SYSTEM

None

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(49)
Ovary	(50)	(49)	(50)	(50)
Cystadenoma	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Luteoma		1 (2%)		
Thecoma Benign		1 (2%)		
Tubulostromal Adenoma	1 (2%)			
Oviduct	(0)	(1)	(0)	(0)
Sarcoma, Metastatic, Skeletal Muscle		1 (100%)		
Uterus	(50)	(50)	(50)	(50)
Carcinoma			1 (2%)	
Fibrous Histiocytoma			1 (2%)	
Polyp Stromal		2 (4%)	2 (4%)	
Sarcoma Stromal			1 (2%)	
Squamous Cell Carcinoma			1 (2%)	

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(49)
Lymph Node	(7)	(3)	(5)	(4)
Mediastinal, Osteosarcoma, Metastatic, Bone				1 (25%)
Lymph Node, Mandibular	(50)	(50)	(50)	(48)
Hemangioma				1 (2%)
Lymph Node, Mesenteric	(49)	(49)	(49)	(50)
Sarcoma, Metastatic, Skeletal Muscle		1 (2%)		
Spleen	(49)	(49)	(49)	(50)
Hemangiosarcoma		1 (2%)		
Sarcoma, Metastatic, Skeletal Muscle		1 (2%)		
Thymus	(50)	(50)	(48)	(48)
Sarcoma, Metastatic, Skeletal Muscle		1 (2%)		

INTEGUMENTARY SYSTEM

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Mammary Gland	(50)	(50)	(50)	(50)
Carcinoma	1 (2%)		1 (2%)	
Skin	(50)	(50)	(50)	(50)
Keratoacanthoma	1 (2%)			
Dermis, Fibrous Histiocytoma		1 (2%)		
Subcutaneous Tissue, Fibrosarcoma	1 (2%)		1 (2%)	
Subcutaneous Tissue, Fibrosarcoma, Multiple	1 (2%)			
Subcutaneous Tissue, Liposarcoma		1 (2%)		
Subcutaneous Tissue, Melanoma Malignant			1 (2%)	
Subcutaneous Tissue, Neurofibrosarcoma			1 (2%)	
Subcutaneous Tissue, Sarcoma			1 (2%)	
Subcutaneous Tissue, Schwannoma Malignant			1 (2%)	

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Osteosarcoma				1 (2%)
Skeletal Muscle	(0)	(2)	(1)	(2)
Rhabdomyosarcoma				2 (100%)
Rhabdomyosarcoma, Multiple			1 (100%)	
Sarcoma		1 (50%)		

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(49)
Meningioma Benign				1 (2%)
Peripheral Nerve	(0)	(0)	(1)	(0)
Spinal Cord	(0)	(0)	(1)	(0)

RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma		3 (6%)	7 (14%)	12 (24%)
Alveolar/Bronchiolar Adenoma, Multiple	2 (4%)	1 (2%)	1 (2%)	

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B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Alveolar/Bronchiolar Carcinoma		1 (2%)	2 (4%)	1 (2%)
Carcinoma, Metastatic, Harderian Gland		1 (2%)	2 (4%)	
Fibrous Histiocytoma			1 (2%)	
Hepatoblastoma, Metastatic, Liver				1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver	2 (4%)	3 (6%)		2 (4%)
Osteosarcoma, Metastatic, Bone				1 (2%)
Sarcoma, Metastatic, Skeletal Muscle		1 (2%)		
Nose	(50)	(49)	(50)	(50)
Trachea	(50)	(50)	(50)	(50)

SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(49)
Harderian Gland	(50)	(50)	(50)	(49)
Adenoma	1 (2%)	6 (12%)	1 (2%)	3 (6%)
Carcinoma		1 (2%)	2 (4%)	

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Sarcoma		1 (2%)		
Urinary Bladder	(50)	(50)	(50)	(50)
Fibrous Histiocytoma			1 (2%)	

SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		2 (4%)	3 (6%)	1 (2%)
Lymphoma Malignant	15 (30%)	9 (18%)	11 (22%)	8 (16%)

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 FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	35	41	47	46
Total Primary Neoplasms	52	82	107	120
Total Animals with Benign Neoplasms	24	31	40	44
Total Benign Neoplasms	28	47	57	72
Total Animals with Malignant Neoplasms	21	25	34	36
Total Malignant Neoplasms	24	35	50	48
Total Animals with Metastatic Neoplasms	2	4	2	4
Total Metastatic Neoplasms	2	13	2	5
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