

**TDMS No.** 99020 - 06

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

**Date Report Requested:** 07/23/2008

**Test Type:** CHRONIC

Pulegone

**Time Report Requested:** 09:18:35

**Route:** GAVAGE

**CAS Number:** 89-82-7

**First Dose M/F:** 04/15/03 / 04/14/03

**Species/Strain:** MICE/B6C3F1

**Lab:** BAT

F1\_\_M3

**C Number:** C99020

**Lock Date:** 12/21/2005

**Cage Range:** ALL

**Date Range:** ALL

**Reasons For Removal:** 25022 ACCK 25021 TSAC 25020 NATD

25019 MSAC 25018 DACC

**Removal Date Range:** ALL

**Treatment Groups:** Include ALL

**Study Gender:** Both

**TDMSE Version:** 2.0.0

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Disposition Summary</b>				
Animals Initially in Study	50	50	50	50
Early Deaths				
Accidently Killed		1		
Dosing Accident		1		
Moribund Sacrifice	7	8	7	8
Natural Death	5	4	1	1
Survivors				
Terminal Sacrifice	38	36	42	41
Animals Examined Microscopically	50	50	50	50
<b>ALIMENTARY SYSTEM</b>				
Esophagus	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Carcinoma, Metastatic, Liver				1 (2%)
Gallbladder	(49)	(49)	(50)	(50)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)			
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Carcinoma				1 (2%)
Sarcoma, Metastatic, Mesentery		1 (2%)		
Liver	(50)	(50)	(50)	(50)
Hemangioma			2 (4%)	
Hemangiosarcoma		1 (2%)		
Hepatoblastoma	1 (2%)	3 (6%)	5 (10%)	2 (4%)
Hepatoblastoma, Multiple			2 (4%)	
Hepatocellular Adenoma	16 (32%)	12 (24%)	8 (16%)	10 (20%)
Hepatocellular Adenoma, Multiple	6 (12%)	19 (38%)	27 (54%)	18 (36%)
Hepatocellular Carcinoma	11 (22%)	9 (18%)	16 (32%)	12 (24%)
Hepatocellular Carcinoma, Multiple	2 (4%)	2 (4%)	2 (4%)	3 (6%)
Hepatocholangiocarcinoma				1 (2%)
Hepatocholangiocarcinoma, Multiple				1 (2%)
Hepatocholangioma				1 (2%)
Sarcoma, Metastatic, Mesentery		1 (2%)		
Mesentery	(4)	(2)	(3)	(0)

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	37.5 MG/KG	75 MG/KG	150 MG/KG
Hepatoblastoma, Metastatic, Liver			1 (33%)	
Rhabdomyosarcoma, Metastatic, Skeletal Muscle	1 (25%)			
Sarcoma		1 (50%)		
Pancreas	(50)	(50)	(50)	(50)
Hepatoblastoma, Metastatic, Liver			1 (2%)	
Rhabdomyosarcoma, Metastatic, Skeletal Muscle	1 (2%)			
Sarcoma, Metastatic, Mesentery		1 (2%)		
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Carcinoma	1 (2%)			
Squamous Cell Papilloma		2 (4%)		1 (2%)
Squamous Cell Papilloma, Multiple				1 (2%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Tooth	(37)	(37)	(35)	(20)
<b>CARDIOVASCULAR SYSTEM</b>				
Blood Vessel	(50)	(50)	(50)	(50)
Aorta, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung				1 (2%)
Heart	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Carcinoma, Metastatic, Heart				1 (2%)
Hemangiosarcoma, Metastatic, Spleen			1 (2%)	
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(50)	(50)	(50)	(50)
Hepatoblastoma, Metastatic, Liver			1 (2%)	
Sarcoma, Metastatic, Mesentery		1 (2%)		
Subcapsular, Adenoma	1 (2%)	3 (6%)	3 (6%)	
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	1 (2%)	1 (2%)	1 (2%)	
Pheochromocytoma Malignant				1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Pituitary Gland	(50)	(50)	(50)	(50)
Thyroid Gland	(50)	(50)	(50)	(50)

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B6C3F1 MICE MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Follicular Cell, Carcinoma		1 (2%)	2 (4%)	
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
Coagulating Gland	(1)	(1)	(0)	(1)
Sarcoma, Metastatic, Mesentery		1 (100%)		
Epididymis	(50)	(50)	(50)	(50)
Hemangiosarcoma, Metastatic, Spleen				1 (2%)
Rhabdomyosarcoma, Metastatic, Skeletal Muscle	1 (2%)			
Sarcoma, Metastatic, Mesentery		1 (2%)		
Preputial Gland	(50)	(50)	(50)	(50)
Prostate	(50)	(50)	(50)	(50)
Sarcoma, Metastatic, Mesentery		1 (2%)		
Seminal Vesicle	(50)	(50)	(50)	(50)
Sarcoma, Metastatic, Mesentery		1 (2%)		
Testes	(50)	(50)	(50)	(50)
Interstitial Cell, Adenoma			1 (2%)	1 (2%)
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(50)	(50)	(50)
Hemangiosarcoma			1 (2%)	
Hemangiosarcoma, Metastatic, Spleen	1 (2%)			1 (2%)
Hemangiosarcoma, Metastatic, Uncertain Primary Site	1 (2%)			
Lymph Node	(1)	(3)	(0)	(2)
Mediastinal, Hepatocholangiocarcinoma, Metastatic, Liver				1 (50%)
Mediastinal, Sarcoma, Metastatic, Mesentery		1 (33%)		
Lymph Node, Mandibular	(50)	(50)	(50)	(50)
Lymph Node, Mesenteric	(47)	(49)	(45)	(44)
Spleen	(50)	(50)	(50)	(50)
Hemangiosarcoma	2 (4%)	2 (4%)	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	37.5 MG/KG	75 MG/KG	150 MG/KG
Thymus Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	(49)	(46)	(45)	(42) 1 (2%)
INTEGUMENTARY SYSTEM				
Skin Hemangiosarcoma Sarcoma	(50)	(50) 1 (2%) 1 (2%)	(50)	(50)
MUSCULOSKELETAL SYSTEM				
Bone Skeletal Muscle Rhabdomyosarcoma	(50) (1) 1 (100%)	(50) (0)	(50) (0)	(50) (0)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
RESPIRATORY SYSTEM				
Lung Alveolar/Bronchiolar Adenoma Alveolar/Bronchiolar Carcinoma Alveolar/Bronchiolar Carcinoma, Multiple Carcinoma, Metastatic, Thyroid Gland Hemangiosarcoma, Metastatic, Skin Hepatoblastoma, Metastatic, Liver Hepatocellular Carcinoma, Metastatic, Liver Hepatocholangiocarcinoma, Metastatic, Liver Rhabdomyosarcoma, Metastatic, Skeletal Muscle Sarcoma, Metastatic, Skin Serosa, Hepatocholangiocarcinoma, Metastatic, Liver	(50) 6 (12%) 3 (6%)	(50) 5 (10%) 3 (6%) 1 (2%)	(50) 6 (12%) 4 (8%) 1 (2%) 1 (2%) 2 (4%)	(50) 5 (10%) 3 (6%)  5 (10%) 1 (2%)  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 MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Nose Osteoma	(50)	(50)	(50)	(50) 1 (2%)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma	6 (12%)	4 (8%)	7 (14%)	7 (14%)
Adenoma, Multiple			1 (2%)	
Carcinoma	1 (2%)			
<b>URINARY SYSTEM</b>				
Kidney	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Thyroid Gland			1 (2%)	
Hepatoblastoma, Metastatic, Liver			1 (2%)	
Renal Tubule, Adenoma		1 (2%)		
Urethra	(0)	(0)	(1)	(0)
Transitional Epithelium, Carcinoma			1 (100%)	
Urinary Bladder	(50)	(50)	(50)	(50)
<b>SYSTEMIC LESIONS</b>				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		2 (4%)	1 (2%)	
Lymphoma Malignant	1 (2%)	1 (2%)		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: 04/15/03 / 04/14/03

Species/Strain: MICE/B6C3F1

Lab: BAT

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B6C3F1 MICE MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
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**Tumor Summary for Males**

<b>Total Animals with Primary Neoplasms (b)</b>	38	43	44	43
<b>Total Primary Neoplasms</b>	60	75	91	72
<b>Total Animals with Benign Neoplasms</b>	30	35	37	37
<b>Total Benign Neoplasms</b>	36	47	56	45
<b>Total Animals with Malignant Neoplasms</b>	19	24	28	22
<b>Total Malignant Neoplasms</b>	24	28	35	27
<b>Total Animals with Metastatic Neoplasms</b>	4	7	4	7
<b>Total Metastatic Neoplasms</b>	7	15	10	14
<b>Total Animals with Malignant Neoplasms Uncertain Primary Site</b>	1			
<b>Total Animals with Neoplasms Uncertain-Benign or Malignant</b>				
<b>Total Uncertain Neoplasms</b>				

\*\*\* 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	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Disposition Summary</b>				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident				1
Moribund Sacrifice	9	3	5	9
Natural Death	5	6	7	3
Survivors				
Terminal Sacrifice	35	41	38	37
Animals Examined Microscopically	49	50	50	50
<b>ALIMENTARY SYSTEM</b>				
Esophagus	(49)	(50)	(50)	(50)
Gallbladder	(48)	(50)	(50)	(50)
Osteosarcoma, Metastatic, Bone			1 (2%)	
Intestine Large, Cecum	(49)	(50)	(50)	(50)
Leiomyoma		1 (2%)		
Intestine Large, Colon	(49)	(50)	(50)	(50)
Sarcoma, Metastatic, Skeletal Muscle				1 (2%)
Intestine Large, Rectum	(49)	(50)	(50)	(50)
Sarcoma, Metastatic, Skeletal Muscle				1 (2%)
Intestine Small, Duodenum	(49)	(50)	(50)	(50)
Osteosarcoma, Metastatic, Bone			1 (2%)	
Intestine Small, Ileum	(49)	(50)	(50)	(50)
Intestine Small, Jejunum	(49)	(50)	(50)	(50)
Liver	(49)	(50)	(50)	(50)
Hepatoblastoma		1 (2%)	2 (4%)	1 (2%)
Hepatoblastoma, Multiple				1 (2%)
Hepatocellular Adenoma	7 (14%)	7 (14%)	10 (20%)	15 (30%)
Hepatocellular Adenoma, Multiple	6 (12%)	8 (16%)	3 (6%)	12 (24%)
Hepatocellular Carcinoma	5 (10%)	1 (2%)	3 (6%)	8 (16%)
Hepatocellular Carcinoma, Multiple			1 (2%)	
Hepatocholangiocarcinoma				1 (2%)
Osteosarcoma, Metastatic, Bone			1 (2%)	
Sarcoma, Metastatic, Skin		1 (2%)		
Mesentery	(6)	(12)	(11)	(2)
Osteosarcoma, Metastatic, Bone			1 (9%)	

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Sarcoma, Metastatic, Skeletal Muscle				1 (50%)
Sarcoma, Metastatic, Skin		1 (8%)		
Pancreas	(49)	(50)	(50)	(50)
Sarcoma, Metastatic, Skeletal Muscle				1 (2%)
Sarcoma, Metastatic, Skin		1 (2%)		
Salivary Glands	(49)	(50)	(49)	(50)
Stomach, Forestomach	(49)	(50)	(50)	(50)
Squamous Cell Papilloma	2 (4%)	4 (8%)	1 (2%)	1 (2%)
Squamous Cell Papilloma, Multiple			1 (2%)	
Stomach, Glandular	(49)	(50)	(50)	(50)
Sarcoma, Metastatic, Skeletal Muscle				1 (2%)
Tongue	(0)	(0)	(0)	(1)
Squamous Cell Carcinoma				1 (100%)
Tooth	(3)	(1)	(2)	(1)
<b>CARDIOVASCULAR SYSTEM</b>				
Blood Vessel	(49)	(50)	(50)	(50)
Heart	(49)	(50)	(50)	(50)
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(49)	(50)	(50)	(50)
Sarcoma, Metastatic, Skeletal Muscle				1 (2%)
Subcapsular, Adenoma	1 (2%)			
Adrenal Medulla	(49)	(50)	(50)	(50)
Pheochromocytoma Benign	1 (2%)	2 (4%)		1 (2%)
Islets, Pancreatic	(49)	(50)	(50)	(50)
Parathyroid Gland	(45)	(47)	(39)	(39)
Pituitary Gland	(49)	(50)	(49)	(49)
Pars Distalis, Adenoma	2 (4%)	2 (4%)		
Thyroid Gland	(49)	(50)	(49)	(50)
Follicular Cell, Adenoma	1 (2%)	1 (2%)		
Follicular Cell, Carcinoma	1 (2%)			
<b>GENERAL BODY SYSTEM</b>				
None				

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>GENITAL SYSTEM</b>				
Clitoral Gland	(47)	(50)	(49)	(49)
Ovary	(49)	(49)	(50)	(50)
Cystadenocarcinoma		1 (2%)		
Cystadenoma	1 (2%)	2 (4%)		2 (4%)
Granulosa Cell Tumor Benign	1 (2%)			
Granulosa Cell Tumor Malignant				1 (2%)
Hemangioma	1 (2%)		1 (2%)	
Hemangiosarcoma	1 (2%)			
Luteoma		1 (2%)		
Osteosarcoma, Metastatic, Bone			1 (2%)	
Teratoma Benign			1 (2%)	
Uterus	(49)	(49)	(50)	(50)
Polyp Stromal			3 (6%)	
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(49)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)		1 (2%)	1 (2%)
Lymph Node	(1)	(2)	(5)	(2)
Inguinal, Sarcoma, Metastatic, Skin			1 (20%)	
Mediastinal, Osteosarcoma, Metastatic, Bone			1 (20%)	
Mediastinal, Schwannoma Malignant, Metastatic, Skin	1 (100%)			
Lymph Node, Mandibular	(49)	(50)	(49)	(50)
Lymph Node, Mesenteric	(47)	(49)	(50)	(49)
Sarcoma, Metastatic, Skeletal Muscle				1 (2%)
Spleen	(49)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)			1 (2%)
Thymus	(48)	(49)	(49)	(46)
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(49)	(50)	(50)	(50)
Adenoacanthoma	1 (2%)			
Carcinoma	1 (2%)	1 (2%)		

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Skin	(49)	(50)	(50)	(50)
Fibrosarcoma	1 (2%)			1 (2%)
Fibrous Histiocytoma	1 (2%)			
Sarcoma		2 (4%)	1 (2%)	1 (2%)
Schwannoma Malignant	1 (2%)		1 (2%)	
Schwannoma Malignant, Multiple	1 (2%)	1 (2%)		
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(49)	(50)	(50)	(50)
Osteoma			1 (2%)	
Osteosarcoma			1 (2%)	1 (2%)
Skeletal Muscle	(0)	(0)	(1)	(1)
Rhabdomyosarcoma			1 (100%)	
Sarcoma				1 (100%)
<b>NERVOUS SYSTEM</b>				
Brain	(49)	(50)	(50)	(50)
<b>RESPIRATORY SYSTEM</b>				
Lung	(49)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)	5 (10%)	2 (4%)	3 (6%)
Alveolar/Bronchiolar Carcinoma	2 (4%)	1 (2%)	1 (2%)	3 (6%)
Alveolar/Bronchiolar Carcinoma, Multiple			1 (2%)	
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)			2 (4%)
Osteosarcoma, Metastatic, Bone			1 (2%)	
Sarcoma, Metastatic, Skin		1 (2%)	1 (2%)	1 (2%)
Schwannoma Malignant, Metastatic, Skin	1 (2%)		1 (2%)	
Nose	(49)	(50)	(50)	(50)
Osteoma			1 (2%)	
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(49)	(50)	(49)	(50)
Harderian Gland	(49)	(50)	(49)	(50)

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B6C3F1 MICE FEMALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Adenoma	7 (14%)	6 (12%)	4 (8%)	6 (12%)
Carcinoma	1 (2%)		2 (4%)	2 (4%)
<b>URINARY SYSTEM</b>				
Kidney	(49)	(50)	(50)	(50)
Osteosarcoma, Metastatic, Bone			1 (2%)	
Sarcoma, Metastatic, Skeletal Muscle				1 (2%)
Renal Tubule, Adenoma	1 (2%)			
Urinary Bladder	(49)	(49)	(50)	(50)
<b>SYSTEMIC LESIONS</b>				
Multiple Organs	*(49)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	3 (6%)	1 (2%)		3 (6%)
Leukemia Granulocytic			1 (2%)	
Lymphoma Malignant	6 (12%)	2 (4%)	4 (8%)	6 (12%)

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\* Number of animals with any tissue examined microscopically

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B6C3F1 MICE FEMALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
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**Tumor Summary for Females**

<b>Total Animals with Primary Neoplasms (b)</b>	40	26	34	41
<b>Total Primary Neoplasms</b>	59	50	48	73
<b>Total Animals with Benign Neoplasms</b>	27	22	24	32
<b>Total Benign Neoplasms</b>	32	39	28	40
<b>Total Animals with Malignant Neoplasms</b>	20	11	17	23
<b>Total Malignant Neoplasms</b>	27	11	20	33
<b>Total Animals with Metastatic Neoplasms</b>	2	1	3	3
<b>Total Metastatic Neoplasms</b>	3	4	11	11
<b>Total Animals with Malignant Neoplasms Uncertain Primary Site</b>				
<b>Total Animals with Neoplasms Uncertain-Benign or Malignant</b>				
<b>Total Uncertain Neoplasms</b>				

\*\*\* 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