

**TDMS No.** 99024 - 08

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

**Date Report Requested:** 05/09/2008

**Test Type:** CHRONIC

Androstenedione

**Time Report Requested:** 12:55:58

**Route:** GAVAGE

**CAS Number:** 63-05-8

**First Dose M/F:** 12/16/02 / 12/16/02

**Species/Strain:** MICE/B6C3F1

**Lab:** SRI

F1\_M3

**C Number:** C99024C  
**Lock Date:** 06/29/2006  
**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

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Species/Strain: MICE/B6C3F1

Lab: SRI

B6C3F1 MICE MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Disposition Summary</b>				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	5	2	5	3
Natural Death	9	4	11	10
Survivors				
Terminal Sacrifice	36	44	34	37
Animals Examined Microscopically	50	50	50	50
<b>ALIMENTARY SYSTEM</b>				
Gallbladder	(45)	(46)	(42)	(44)
Intestine Large, Cecum	(50)	(49)	(50)	(49)
Intestine Small, Duodenum	(47)	(49)	(46)	(49)
Carcinoma	1 (2%)			
Intestine Small, Ileum	(49)	(50)	(49)	(49)
Carcinoma	1 (2%)			
Intestine Small, Jejunum	(47)	(49)	(47)	(49)
Carcinoma	1 (2%)		2 (4%)	1 (2%)
Liver	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Lung		1 (2%)		
Hemangioma	1 (2%)			1 (2%)
Hemangiosarcoma	3 (6%)	1 (2%)	5 (10%)	3 (6%)
Hepatoblastoma	3 (6%)	7 (14%)	6 (12%)	5 (10%)
Hepatoblastoma, Multiple		1 (2%)	1 (2%)	3 (6%)
Hepatocellular Adenoma	16 (32%)	11 (22%)	6 (12%)	9 (18%)
Hepatocellular Adenoma, Multiple	16 (32%)	27 (54%)	23 (46%)	34 (68%)
Hepatocellular Carcinoma	19 (38%)	21 (42%)	18 (36%)	15 (30%)
Hepatocellular Carcinoma, Multiple	7 (14%)	12 (24%)	10 (20%)	17 (34%)
Sarcoma, Metastatic, Skeletal Muscle	1 (2%)			
Mesentery	(5)	(8)	(4)	(5)
Hepatoblastoma, Metastatic, Liver		2 (25%)	1 (25%)	
Hepatocellular Carcinoma, Metastatic, Liver			1 (25%)	
Pancreas	(50)	(50)	(50)	(49)
Acinus, Carcinoma			1 (2%)	
Salivary Glands	(50)	(50)	(50)	(50)

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

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Species/Strain: MICE/B6C3F1

Lab: SRI

B6C3F1 MICE MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Stomach, Forestomach	(49)	(50)	(50)	(50)
Carcinoma, Metastatic, Pancreas			1 (2%)	
Squamous Cell Carcinoma			1 (2%)	
Squamous Cell Papilloma	2 (4%)		1 (2%)	1 (2%)
Stomach, Glandular	(49)	(50)	(50)	(50)
Carcinoma			1 (2%)	
Carcinoma, Metastatic, Pancreas			1 (2%)	
Tooth	(0)	(1)	(0)	(0)
Odontoma		1 (100%)		
<b>CARDIOVASCULAR SYSTEM</b>				
Heart	(50)	(50)	(50)	(50)
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(50)	(49)	(50)	(50)
Adenoma		1 (2%)		
Capsule, Adenoma	1 (2%)	4 (8%)	1 (2%)	
Capsule, Adenoma, Multiple				1 (2%)
Adrenal Medulla	(49)	(49)	(50)	(50)
Pheochromocytoma Benign		1 (2%)		
Islets, Pancreatic	(50)	(50)	(50)	(49)
Adenoma	2 (4%)	2 (4%)	2 (4%)	4 (8%)
Adenoma, Multiple				1 (2%)
Parathyroid Gland	(48)	(48)	(47)	(46)
Pituitary Gland	(50)	(49)	(49)	(50)
Thyroid Gland	(50)	(50)	(50)	(50)
Follicular Cell, Adenoma			1 (2%)	
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(50)	(50)	(50)

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Lab: SRI

B6C3F1 MICE MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Prostate	(50)	(50)	(50)	(50)
Seminal Vesicle	(50)	(50)	(50)	(50)
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%)		1 (2%)
Lymph Node	(2)	(1)	(1)	(4)
Lymph Node, Mandibular	(47)	(47)	(47)	(47)
Basal Cell Carcinoma, Metastatic, Skin			1 (2%)	
Lymph Node, Mesenteric	(49)	(49)	(49)	(45)
Spleen	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)	1 (2%)	5 (10%)	1 (2%)
Thymus	(45)	(46)	(42)	(45)
<b>INTEGUMENTARY SYSTEM</b>				
Skin	(50)	(50)	(50)	(50)
Basal Cell Carcinoma			1 (2%)	
Subcutaneous Tissue, Fibroma		1 (2%)		
Subcutaneous Tissue, Fibrosarcoma			1 (2%)	
Subcutaneous Tissue, Fibrous	1 (2%)		1 (2%)	
Histiocytoma				
Subcutaneous Tissue, Hemangiosarcoma	1 (2%)	2 (4%)	1 (2%)	
Subcutaneous Tissue, Melanoma		1 (2%)		
Malignant				
Subcutaneous Tissue, Sarcoma			1 (2%)	
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(1)	(1)	(2)	(1)
Hemangiosarcoma		1 (100%)		
Sarcoma	1 (100%)			

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Lab: SRI

B6C3F1 MICE MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(49)	(50)
Peripheral Nerve	(1)	(1)	(4)	(3)
Spinal Cord	(1)	(1)	(4)	(3)
<b>RESPIRATORY SYSTEM</b>				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	7 (14%)	6 (12%)	6 (12%)	5 (10%)
Alveolar/Bronchiolar Adenoma, Multiple		1 (2%)	1 (2%)	
Alveolar/Bronchiolar Carcinoma	8 (16%)	6 (12%)	3 (6%)	8 (16%)
Alveolar/Bronchiolar Carcinoma, Multiple	3 (6%)	2 (4%)	1 (2%)	5 (10%)
Basal Cell Carcinoma, Metastatic, Skin			1 (2%)	
Carcinoma, Metastatic, Harderian Gland		1 (2%)		1 (2%)
Hepatoblastoma, Metastatic, Liver		1 (2%)	1 (2%)	1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver	6 (12%)	6 (12%)	11 (22%)	5 (10%)
Sarcoma, Metastatic, Skeletal Muscle	1 (2%)			
Nose	(50)	(49)	(49)	(50)
Carcinoma, Metastatic, Harderian Gland				1 (2%)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Harderian Gland				1 (2%)
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma	7 (14%)	9 (18%)	6 (12%)	4 (8%)
Adenoma, Multiple			1 (2%)	
Carcinoma	2 (4%)			3 (6%)
Lacrimal Gland	(0)	(1)	(0)	(0)
<b>URINARY SYSTEM</b>				
Kidney	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Lung		1 (2%)		
Urinary Bladder	(50)	(50)	(50)	(50)
Hemangioma			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: SRI

B6C3F1 MICE MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma			1 (2%)	
Lymphoma Malignant	4 (8%)	6 (12%)	3 (6%)	6 (12%)

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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Route: GAVAGE

CAS Number: 63-05-8

First Dose M/F: 12/16/02 / 12/16/02

Species/Strain: MICE/B6C3F1

Lab: SRI

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B6C3F1 MICE MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
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**Tumor Summary for Males**

<b>Total Animals with Primary Neoplasms (b)</b>	47	50	44	50
<b>Total Primary Neoplasms</b>	108	128	112	129
<b>Total Animals with Benign Neoplasms</b>	38	43	35	46
<b>Total Benign Neoplasms</b>	52	65	49	61
<b>Total Animals with Malignant Neoplasms</b>	37	41	38	44
<b>Total Malignant Neoplasms</b>	56	63	63	68
<b>Total Animals with Metastatic Neoplasms</b>	7	9	14	7
<b>Total Metastatic Neoplasms</b>	8	11	18	9
<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 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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First Dose M/F: 12/16/02 / 12/16/02

Species/Strain: MICE/B6C3F1

Lab: SRI

B6C3F1 MICE FEMALE	0 MG/KG	2 MG/KG	10 MG/KG	50 MG/KG
<b>Disposition Summary</b>				
Animals Initially in Study	50	50	50	50
Early Deaths				
Accidently Killed	2		1	1
Moribund Sacrifice	6	2	3	3
Natural Death	7	8	6	6
Survivors				
Natural Death	1		1	
Terminal Sacrifice	34	40	39	40
Animals Examined Microscopically	50	50	50	50

## ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(49)	(50)
Sarcoma, Metastatic, Skeletal Muscle			1 (2%)	
Gallbladder	(44)	(45)	(42)	(48)
Adenoma				1 (2%)
Intestine Large, Cecum	(49)	(50)	(50)	(49)
Leiomyoma				1 (2%)
Intestine Small, Duodenum	(47)	(46)	(46)	(49)
Intestine Small, Ileum	(46)	(48)	(49)	(50)
Intestine Small, Jejunum	(46)	(48)	(49)	(50)
Liver	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)	1 (2%)	1 (2%)
Hepatocellular Adenoma	10 (20%)	9 (18%)	11 (22%)	11 (22%)
Hepatocellular Adenoma, Multiple	4 (8%)	7 (14%)	7 (14%)	17 (34%)
Hepatocellular Carcinoma	4 (8%)	11 (22%)	10 (20%)	11 (22%)
Hepatocellular Carcinoma, Multiple	1 (2%)	2 (4%)	5 (10%)	4 (8%)
Mesentery	(7)	(9)	(14)	(8)
Hepatocellular Carcinoma, Metastatic, Liver		1 (11%)		
Oral Mucosa	(0)	(0)	(0)	(1)
Squamous Cell Carcinoma				1 (100%)
Pancreas	(49)	(50)	(50)	(49)
Salivary Glands	(49)	(49)	(49)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma	1 (2%)		1 (2%)	

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Species/Strain: MICE/B6C3F1

Lab: SRI

B6C3F1 MICE FEMALE	0 MG/KG	2 MG/KG	10 MG/KG	50 MG/KG
Stomach, Glandular	(50)	(50)	(50)	(50)
<b>CARDIOVASCULAR SYSTEM</b>				
Heart	(50)	(50)	(50)	(50)
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)			
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(50)	(50)	(50)	(50)
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)			
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign			1 (2%)	
Islets, Pancreatic	(49)	(50)	(49)	(48)
Adenoma		2 (4%)	4 (8%)	4 (8%)
Parathyroid Gland	(48)	(49)	(45)	(50)
Pituitary Gland	(49)	(47)	(50)	(50)
Pars Distalis, Adenoma	1 (2%)	2 (4%)	4 (8%)	4 (8%)
Pars Intermedia, Adenoma		1 (2%)		
Thyroid Gland	(50)	(50)	(48)	(50)
Sarcoma, Metastatic, Skeletal Muscle			1 (2%)	
C-cell, Carcinoma			1 (2%)	
Follicular Cell, Adenoma	1 (2%)			
Follicular Cell, Carcinoma	1 (2%)			
<b>GENERAL BODY SYSTEM</b>				
Tissue NOS	(1)	(0)	(0)	(1)
Hemangioma				1 (100%)
Sarcoma, Metastatic, Skin	1 (100%)			
<b>GENITAL SYSTEM</b>				
Clitoral Gland	(47)	(47)	(49)	(50)
Ovary	(49)	(50)	(49)	(48)
Cystadenoma	4 (8%)	3 (6%)	1 (2%)	2 (4%)

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Lab: SRI

B6C3F1 MICE FEMALE	0 MG/KG	2 MG/KG	10 MG/KG	50 MG/KG
Cystadenoma, Multiple			1 (2%)	
Hemangioma		1 (2%)		1 (2%)
Uterus	(50)	(50)	(50)	(50)
Hemangiosarcoma			1 (2%)	
Leiomyosarcoma				1 (2%)
Polyp Stromal	2 (4%)	1 (2%)		4 (8%)
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(49)	(50)	(50)
Hemangiosarcoma				1 (2%)
Lymph Node	(10)	(5)	(4)	(1)
Hepatocellular Carcinoma, Metastatic, Liver	1 (10%)			
Iliac, Rhabdomyosarcoma, Metastatic, Skeletal Muscle				1 (100%)
Mediastinal, Hemangioma	1 (10%)			
Renal, Rhabdomyosarcoma, Metastatic, Skeletal Muscle				1 (100%)
Lymph Node, Mandibular	(46)	(49)	(47)	(49)
Hemangiosarcoma		1 (2%)		
Lymph Node, Mesenteric	(50)	(50)	(46)	(48)
Spleen	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)		1 (2%)
Thymus	(47)	(46)	(46)	(46)
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)			
Sarcoma, Metastatic, Skin	1 (2%)			
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Carcinoma	1 (2%)	2 (4%)		
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma		1 (2%)		
Squamous Cell Papilloma			1 (2%)	
Subcutaneous Tissue, Fibrosarcoma	3 (6%)		2 (4%)	1 (2%)
Subcutaneous Tissue, Fibrous				1 (2%)

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Species/Strain: MICE/B6C3F1

Lab: SRI

B6C3F1 MICE FEMALE	0 MG/KG	2 MG/KG	10 MG/KG	50 MG/KG
Histiocytoma				
Subcutaneous Tissue, Hemangioma		1 (2%)		
Subcutaneous Tissue, Hemangiosarcoma	1 (2%)		1 (2%)	
Subcutaneous Tissue, Liposarcoma		2 (4%)		
Subcutaneous Tissue, Myxosarcoma	1 (2%)			
Subcutaneous Tissue, Sarcoma	1 (2%)	1 (2%)	1 (2%)	
Subcutaneous Tissue, Schwannoma			1 (2%)	
Malignant				
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Osteosarcoma	1 (2%)		1 (2%)	
Skeletal Muscle	(4)	(0)	(4)	(2)
Fibrosarcoma	1 (25%)			
Hepatocellular Carcinoma, Metastatic, Liver	1 (25%)			
Myxosarcoma	1 (25%)			
Rhabdomyosarcoma				1 (50%)
Sarcoma			2 (50%)	
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(49)	(50)	(50)
Peripheral Nerve	(2)	(1)	(3)	(1)
Spinal Cord	(2)	(1)	(4)	(1)
Osteosarcoma, Metastatic, Bone	1 (50%)			
<b>RESPIRATORY SYSTEM</b>				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma		2 (4%)	3 (6%)	
Alveolar/Bronchiolar Carcinoma	4 (8%)	3 (6%)		4 (8%)
Alveolar/Bronchiolar Carcinoma, Multiple				1 (2%)
Carcinoma, Metastatic, Thyroid Gland			1 (2%)	
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)	3 (6%)	1 (2%)	1 (2%)
Liposarcoma, Metastatic, Skin		1 (2%)		

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Lab: SRI

B6C3F1 MICE FEMALE	0 MG/KG	2 MG/KG	10 MG/KG	50 MG/KG
Osteosarcoma, Metastatic, Bone	1 (2%)			
Rhabdomyosarcoma, Metastatic, Skeletal Muscle				1 (2%)
Sarcoma, Metastatic, Skin	1 (2%)			
Nose	(50)	(49)	(50)	(50)
Carcinoma, Metastatic, Harderian Gland	1 (2%)			
Trachea	(50)	(50)	(48)	(50)
Sarcoma, Metastatic, Skeletal Muscle			1 (2%)	
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Harderian Gland	1 (2%)			1 (2%)
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma	9 (18%)	4 (8%)	11 (22%)	4 (8%)
Adenoma, Multiple		1 (2%)		
Carcinoma	1 (2%)	1 (2%)	1 (2%)	2 (4%)
<b>URINARY SYSTEM</b>				
Kidney	(50)	(50)	(50)	(50)
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)			
Renal Tubule, Carcinoma		1 (2%)		
Urinary Bladder	(50)	(50)	(50)	(50)
<b>SYSTEMIC LESIONS</b>				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	2 (4%)	4 (8%)		1 (2%)
Lymphoma Malignant	14 (28%)	15 (30%)	11 (22%)	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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Lab: SRI

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B6C3F1 MICE FEMALE	0 MG/KG	2 MG/KG	10 MG/KG	50 MG/KG
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**Tumor Summary for Females**

<b>Total Animals with Primary Neoplasms (b)</b>	40	43	43	38
<b>Total Primary Neoplasms</b>	70	81	83	83
<b>Total Animals with Benign Neoplasms</b>	27	27	31	32
<b>Total Benign Neoplasms</b>	33	36	45	50
<b>Total Animals with Malignant Neoplasms</b>	27	36	31	25
<b>Total Malignant Neoplasms</b>	37	45	38	33
<b>Total Animals with Metastatic Neoplasms</b>	4	4	3	3
<b>Total Metastatic Neoplasms</b>	14	5	5	5
<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