

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
Disposition Summary				
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
ALIMENTARY SYSTEM				
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%)		
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
ENDOCRINE SYSTEM				
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%)	
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
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%)
HEMATOPOIETIC SYSTEM				
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)
INTEGUMENTARY SYSTEM				
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%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(1)	(1)	(2)	(1)
Hemangiosarcoma		1 (100%)		
Sarcoma	1 (100%)			

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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
NERVOUS SYSTEM				
Brain	(50)	(50)	(49)	(50)
Peripheral Nerve	(1)	(1)	(4)	(3)
Spinal Cord	(1)	(1)	(4)	(3)
RESPIRATORY SYSTEM				
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%)
SPECIAL SENSES SYSTEM				
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)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Lung		1 (2%)		
Urinary Bladder	(50)	(50)	(50)	(50)
Hemangioma			1 (2%)	

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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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Species/Strain: MICE/B6C3F1

Lab: SRI

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

Total Animals with Primary Neoplasms (b)	47	50	44	50
Total Primary Neoplasms	108	128	112	129
Total Animals with Benign Neoplasms	38	43	35	46
Total Benign Neoplasms	52	65	49	61
Total Animals with Malignant Neoplasms	37	41	38	44
Total Malignant Neoplasms	56	63	63	68
Total Animals with Metastatic Neoplasms	7	9	14	7
Total Metastatic Neoplasms	8	11	18	9
Total Animals with Malignant Neoplasms Uncertain Primary Site				
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: SRI

B6C3F1 MICE FEMALE	0 MG/KG	2 MG/KG	10 MG/KG	50 MG/KG
Disposition Summary				
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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Lab: SRI

B6C3F1 MICE FEMALE	0 MG/KG	2 MG/KG	10 MG/KG	50 MG/KG
Stomach, Glandular	(50)	(50)	(50)	(50)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)			
ENDOCRINE SYSTEM				
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%)			
GENERAL BODY SYSTEM				
Tissue NOS	(1)	(0)	(0)	(1)
Hemangioma				1 (100%)
Sarcoma, Metastatic, Skin	1 (100%)			
GENITAL SYSTEM				
Clitoral Gland	(47)	(47)	(49)	(50)
Ovary	(49)	(50)	(49)	(48)
Cystadenoma	4 (8%)	3 (6%)	1 (2%)	2 (4%)

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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
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%)
HEMATOPOIETIC SYSTEM				
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%)			
INTEGUMENTARY SYSTEM				
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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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				
MUSCULOSKELETAL SYSTEM				
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%)	
NERVOUS SYSTEM				
Brain	(50)	(49)	(50)	(50)
Peripheral Nerve	(2)	(1)	(3)	(1)
Spinal Cord	(2)	(1)	(4)	(1)
Osteosarcoma, Metastatic, Bone	1 (50%)			
RESPIRATORY SYSTEM				
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%)	
SPECIAL SENSES SYSTEM				
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%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)			
Renal Tubule, Carcinoma		1 (2%)		
Urinary Bladder	(50)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	2 (4%)	4 (8%)		1 (2%)
Lymphoma Malignant	14 (28%)	15 (30%)	11 (22%)	2 (4%)

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* Number of animals with any tissue examined microscopically

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Lab: SRI

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

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