

TDMS No. 99024 - 07

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

Date Report Requested: 07/18/2008

Test Type: CHRONIC

Androstenedione

Time Report Requested: 13:49:10

Route: GAVAGE

CAS Number: 63-05-8

First Dose M/F: 02/03/03 / 02/03/03

Species/Strain: RATS/F 344

Lab: SRI

F1_R2

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

Test Type: CHRONIC

Androstenedione

Time Report Requested: 13:49:10

Route: GAVAGE

CAS Number: 63-05-8

First Dose M/F: 02/03/03 / 02/03/03

Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS 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	22	9	17	13
Natural Death	7	8	4	10
Survivors				
Natural Death	1			
Terminal Sacrifice	20	33	29	27
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(47)	(46)	(47)	(48)
Intestine Large, Colon	(44)	(43)	(47)	(44)
Adenocarcinoma, Metastatic, Uncertain Primary Site			1 (2%)	
Intestine Large, Rectum	(46)	(46)	(47)	(47)
Intestine Small, Duodenum	(48)	(47)	(49)	(47)
Intestine Small, Ileum	(44)	(46)	(47)	(44)
Osteosarcoma			1 (2%)	
Intestine Small, Jejunum	(44)	(44)	(47)	(42)
Liver	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uncertain Primary Site			1 (2%)	
Carcinoma, Metastatic, Islets, Pancreatic		1 (2%)		
Hepatocellular Adenoma	2 (4%)		1 (2%)	3 (6%)
Hepatocellular Carcinoma		1 (2%)		1 (2%)
Osteosarcoma, Metastatic, Uncertain Primary Site				1 (2%)
Sarcoma, Metastatic, Skeletal Muscle				1 (2%)
Mesentery	(18)	(13)	(12)	(18)
Adenocarcinoma, Metastatic, Uncertain Primary Site			1 (8%)	
Pancreas	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uncertain Primary Site			1 (2%)	

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

Test Type: CHRONIC

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First Dose M/F: 02/03/03 / 02/03/03

Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Mixed Tumor Benign Acinus, Adenoma	3 (6%)		2 (4%)	1 (2%)
Salivary Glands	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Thyroid Gland		1 (2%)		
Sarcoma	1 (2%)			
Schwannoma Malignant			1 (2%)	
Stomach, Forestomach	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uncertain Primary Site			1 (2%)	
Stomach, Glandular	(50)	(50)	(50)	(50)
Adenoma, Multiple				1 (2%)
Tongue	(1)	(0)	(0)	(2)
Squamous Cell Papilloma	1 (100%)			
Tooth	(0)	(0)	(1)	(0)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(2)	(3)	(1)	(0)
Carcinoma, Metastatic, Thyroid Gland		1 (33%)		
Heart	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uncertain Primary Site			1 (2%)	
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung				1 (2%)
Carcinoma, Metastatic, Uncertain Primary Site			1 (2%)	
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uncertain Primary Site			1 (2%)	
Adenoma	3 (6%)			1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	5 (10%)	10 (20%)	3 (6%)	3 (6%)
Pheochromocytoma Complex	1 (2%)			
Pheochromocytoma Malignant			1 (2%)	
Bilateral, Pheochromocytoma Benign	2 (4%)	2 (4%)	1 (2%)	2 (4%)
Islets, Pancreatic	(50)	(50)	(50)	(50)

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

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First Dose M/F: 02/03/03 / 02/03/03

Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Adenoma	4 (8%)	3 (6%)	9 (18%)	1 (2%)
Carcinoma		1 (2%)		1 (2%)
Parathyroid Gland	(48)	(50)	(50)	(48)
Pituitary Gland	(50)	(50)	(49)	(50)
Pars Distalis, Adenoma	19 (38%)	21 (42%)	15 (31%)	24 (48%)
Pars Intermedia, Carcinoma		1 (2%)		
Thyroid Gland	(50)	(50)	(50)	(50)
Schwannoma Malignant			1 (2%)	
C-cell, Adenoma	3 (6%)	3 (6%)	4 (8%)	4 (8%)
C-cell, Carcinoma	1 (2%)	2 (4%)	2 (4%)	2 (4%)
Follicular Cell, Adenoma	3 (6%)		1 (2%)	
GENERAL BODY SYSTEM				
Tissue NOS	(0)	(0)	(1)	(0)
Paraganglioma			1 (100%)	
GENITAL SYSTEM				
Coagulating Gland	(0)	(3)	(2)	(0)
Adenocarcinoma, Metastatic, Uncertain			1 (50%)	
Primary Site				
Epididymis	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uncertain			1 (2%)	
Primary Site				
Penis	(0)	(1)	(0)	(0)
Preputial Gland	(50)	(50)	(50)	(50)
Adenoma	3 (6%)	2 (4%)		4 (8%)
Carcinoma			1 (2%)	1 (2%)
Prostate	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uncertain			1 (2%)	
Primary Site				
Seminal Vesicle	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uncertain			1 (2%)	
Primary Site				
Testes	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uncertain			1 (2%)	
Primary Site				
Bilateral, Interstitial Cell, Adenoma	29 (58%)	29 (58%)	28 (56%)	10 (20%)

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Route: GAVAGE

First Dose M/F: 02/03/03 / 02/03/03

Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Interstitial Cell, Adenoma	13 (26%)	10 (20%)	8 (16%)	16 (32%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(25)	(18)	(16)	(13)
Adenocarcinoma, Metastatic, Uncertain Primary Site			1 (6%)	
Hemangiosarcoma	1 (4%)			
Deep Cervical, Carcinoma, Metastatic, Thyroid Gland		1 (6%)		
Lymph Node, Mandibular	(1)	(0)	(1)	(2)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uncertain Primary Site			1 (2%)	
Basal Cell Carcinoma, Metastatic, Skin Sarcoma			1 (2%) 1 (2%)	
Thymus	(50)	(50)	(50)	(49)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung				1 (2%)
Carcinoma, Metastatic, Thyroid Gland		1 (2%)		
Thymoma Malignant			1 (2%)	
INTEGUMENTARY SYSTEM				
Mammary Gland	(48)	(50)	(50)	(50)
Carcinoma		1 (2%)		
Fibroadenoma	2 (4%)	5 (10%)		6 (12%)
Fibroma	1 (2%)	1 (2%)		
Skin	(50)	(50)	(50)	(50)
Basal Cell Carcinoma	1 (2%)	2 (4%)	4 (8%)	
Keratoacanthoma	3 (6%)	3 (6%)	3 (6%)	1 (2%)
Keratoacanthoma, Multiple		1 (2%)		
Squamous Cell Carcinoma			1 (2%)	
Squamous Cell Papilloma	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Pinna, Schwannoma Malignant		1 (2%)		
Sebaceous Gland, Adenoma			2 (4%)	
Sebaceous Gland, Carcinoma				1 (2%)

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Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Subcutaneous Tissue, Fibroma	5 (10%)	7 (14%)	9 (18%)	5 (10%)
Subcutaneous Tissue, Fibrosarcoma	1 (2%)			2 (4%)
Subcutaneous Tissue, Fibrous Histiocytoma				1 (2%)
Subcutaneous Tissue, Lipoma	1 (2%)			
Subcutaneous Tissue, Sarcoma		1 (2%)		
Subcutaneous Tissue, Schwannoma Malignant		1 (2%)		1 (2%)
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Preputial Gland				1 (2%)
Carcinoma, Metastatic, Thyroid Gland		1 (2%)		
Chordoma	1 (2%)			
Schwannoma Malignant			1 (2%)	
Humerus, Osteosarcoma			1 (2%)	
Vertebra, Osteosarcoma	1 (2%)			
Skeletal Muscle	(8)	(1)	(3)	(5)
Adenocarcinoma, Metastatic, Uncertain Primary Site			1 (33%)	
Carcinoma, Metastatic, Thyroid Gland		1 (100%)		
Fibrous Histiocytoma, Metastatic, Skin				1 (20%)
Sarcoma				1 (20%)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Astrocytoma Malignant	1 (2%)			
Spinal Cord	(6)	(1)	(0)	(5)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uncertain Primary Site			1 (2%)	
Alveolar/Bronchiolar Adenoma			5 (10%)	2 (4%)
Alveolar/Bronchiolar Carcinoma				1 (2%)
Carcinoma, Metastatic, Thyroid Gland		1 (2%)		

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

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Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Carcinoma, Metastatic, Uncertain Primary Site			1 (2%)	
Chordoma, Metastatic, Bone	1 (2%)			
Chordoma, Metastatic, Uncertain Primary Site			1 (2%)	
Osteosarcoma, Metastatic, Bone	1 (2%)			
Osteosarcoma, Metastatic, Uncertain Primary Site				1 (2%)
Squamous Cell Carcinoma Mediastinum, Alveolar/Bronchiolar Carcinoma		1 (2%)		1 (2%)
Mediastinum, Carcinoma, Metastatic, Uncertain Primary Site			1 (2%)	
Mediastinum, Osteosarcoma, Metastatic, Uncertain Primary Site				1 (2%)
Serosa, Hemangiosarcoma	1 (2%)			
Nose	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Preputial Gland				1 (2%)
SPECIAL SENSES SYSTEM				
Eye	(48)	(46)	(50)	(49)
Harderian Gland	(50)	(50)	(50)	(50)
Zymbal's Gland	(0)	(0)	(1)	(0)
Adenoma			1 (100%)	
URINARY SYSTEM				
Kidney	(49)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uncertain Primary Site			1 (2%)	
Renal Tubule, Adenoma			2 (4%)	1 (2%)
Urinary Bladder	(50)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)	1 (2%)		
Leukemia Mononuclear	26 (52%)	22 (44%)	18 (36%)	18 (36%)

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

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First Dose M/F: 02/03/03 / 02/03/03

Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Mesothelioma Benign			1 (2%)	
Mesothelioma Malignant	1 (2%)	1 (2%)	2 (4%)	2 (4%)
Mesothelioma Nos		1 (2%)		

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

* Number of animals with any tissue examined microscopically

Test Type: CHRONIC

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First Dose M/F: 02/03/03 / 02/03/03

Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Tumor Summary for Males				
Total Animals with Primary Neoplasms (b)	49	48	48	49
Total Primary Neoplasms	141	135	133	120
Total Animals with Benign Neoplasms	47	47	46	46
Total Benign Neoplasms	103	98	96	87
Total Animals with Malignant Neoplasms	34	29	25	28
Total Malignant Neoplasms	38	36	36	33
Total Animals with Metastatic Neoplasms	3	3	5	5
Total Metastatic Neoplasms	4	9	23	9
Total Animals with Malignant Neoplasms Uncertain Primary Site		1	4	1
Total Animals with Neoplasms Uncertain-Benign or Malignant		1		
Total Uncertain Neoplasms		1		

*** 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

Test Type: CHRONIC

Androstenedione

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Route: GAVAGE

CAS Number: 63-05-8

First Dose M/F: 02/03/03 / 02/03/03

Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS FEMALE	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	10	7	12	9
Natural Death	2	6	5	4
Survivors				
Natural Death		1		
Terminal Sacrifice	38	36	33	37
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Intestine Large, Rectum	(49)	(47)	(47)	(48)
Intestine Small, Ileum	(48)	(46)	(45)	(48)
Liver	(50)	(50)	(50)	(50)
Mesentery	(13)	(14)	(15)	(15)
Oral Mucosa	(0)	(1)	(0)	(0)
Squamous Cell Papilloma		1 (100%)		
Pancreas	(50)	(50)	(50)	(50)
Acinus, Adenoma				1 (2%)
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
Tongue	(1)	(0)	(1)	(1)
Squamous Cell Papilloma			1 (100%)	
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma		1 (2%)	1 (2%)	1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	3 (6%)	1 (2%)	3 (6%)	1 (2%)

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Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS FEMALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Pheochromocytoma Complex	1 (2%)			1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Carcinoma	1 (2%)			
Parathyroid Gland	(49)	(48)	(48)	(45)
Pituitary Gland	(50)	(50)	(49)	(50)
Pars Distalis, Adenoma	19 (38%)	19 (38%)	17 (35%)	12 (24%)
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Adenoma	4 (8%)	4 (8%)	5 (10%)	5 (10%)
C-cell, Carcinoma			1 (2%)	
Follicular Cell, Adenoma		1 (2%)		1 (2%)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(50)
Adenoma	12 (24%)	11 (22%)	11 (22%)	9 (18%)
Adenoma, Multiple			1 (2%)	
Carcinoma	1 (2%)	2 (4%)	5 (10%)	2 (4%)
Sarcoma	1 (2%)			
Ovary	(50)	(50)	(50)	(50)
Tubulostromal Adenoma	1 (2%)			
Uterus	(50)	(50)	(50)	(50)
Polyp Stromal	9 (18%)	12 (24%)	10 (20%)	5 (10%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(5)	(10)	(16)	(10)
Lymph Node, Mandibular	(0)	(0)	(0)	(1)
Lymph Node, Mesenteric	(50)	(50)	(49)	(50)
Spleen	(50)	(49)	(50)	(50)
Thymus	(50)	(50)	(49)	(50)
Thymoma Benign		1 (2%)		1 (2%)

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First Dose M/F: 02/03/03 / 02/03/03

Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS FEMALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Carcinoma	2 (4%)	1 (2%)		
Fibroadenoma	18 (36%)	18 (36%)	16 (32%)	9 (18%)
Fibroadenoma, Multiple	17 (34%)	13 (26%)	6 (12%)	3 (6%)
Skin	(50)	(50)	(50)	(50)
Neural Crest Tumor		1 (2%)		
Squamous Cell Papilloma			1 (2%)	
Sebaceous Gland, Carcinoma			1 (2%)	
Subcutaneous Tissue, Fibroma	3 (6%)	2 (4%)	1 (2%)	
Subcutaneous Tissue, Fibroma, Multiple				1 (2%)
Subcutaneous Tissue, Fibrosarcoma			2 (4%)	
Subcutaneous Tissue, Fibrous Histiocytoma		1 (2%)		
Subcutaneous Tissue, Hemangiosarcoma				1 (2%)
Subcutaneous Tissue, Sarcoma		1 (2%)		
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Osteosarcoma			1 (2%)	
Cranium, Osteosarcoma		1 (2%)		
Skeletal Muscle	(0)	(1)	(0)	(0)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Zymbal'S Gland			1 (2%)	
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma			2 (4%)	1 (2%)
Nose	(50)	(50)	(50)	(50)

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Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS FEMALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
SPECIAL SENSES SYSTEM				
Ear	(0)	(1)	(0)	(0)
Eye	(49)	(48)	(47)	(49)
Harderian Gland	(50)	(50)	(50)	(50)
Zymbal's Gland	(0)	(0)	(1)	(0)
Carcinoma			1 (100%)	
URINARY SYSTEM				
Kidney	(50)	(49)	(50)	(50)
Urinary Bladder	(50)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Leukemia Mononuclear	5 (10%)	11 (22%)	18 (36%)	15 (30%)

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

* Number of animals with any tissue examined microscopically

Test Type: CHRONIC

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First Dose M/F: 02/03/03 / 02/03/03

Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS FEMALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Tumor Summary for Females				
Total Animals with Primary Neoplasms (b)	46	46	46	40
Total Primary Neoplasms	99	104	105	70
Total Animals with Benign Neoplasms	44	44	40	32
Total Benign Neoplasms	88	86	76	51
Total Animals with Malignant Neoplasms	10	16	25	19
Total Malignant Neoplasms	11	17	29	19
Total Animals with Metastatic Neoplasms			1	
Total Metastatic Neoplasms			1	
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain-Benign or Malignant		1		
Total Uncertain Neoplasms		1		

*** 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