

TDMS No. 20005 - 05

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

Date Report Requested: 07/23/2008

Test Type: CHRONIC

Ginseng

Time Report Requested: 11:57:36

Route: GAVAGE

CAS Number: 50647-08-0

First Dose M/F: 01/21/04 / 01/22/04

Species/Strain: RATS/F 344

Lab: BAT

F1_R2

C Number: C20005
Lock Date: 09/07/2006
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

Ginseng

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Route: GAVAGE

CAS Number: 50647-08-0

First Dose M/F: 01/21/04 / 01/22/04

Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident	2			
Moribund Sacrifice	13	16	7	16
Natural Death	5	4	6	11
Survivors				
Terminal Sacrifice	30	30	37	23
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Adenocarcinoma			1 (2%)	
Adenoma		1 (2%)		
Liposarcoma		1 (2%)		
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Carcinoma	1 (2%)			
Liver	(50)	(50)	(50)	(50)
Hemangiosarcoma, Multiple			1 (2%)	
Hepatocellular Adenoma		1 (2%)		2 (4%)
Hepatocellular Adenoma, Multiple			1 (2%)	
Hepatocellular Carcinoma	1 (2%)			
Hepatocellular Carcinoma, Multiple			1 (2%)	
Mesentery	(13)	(9)	(6)	(5)
Carcinoma, Metastatic, Kidney	1 (8%)			
Schwannoma Malignant			1 (17%)	
Oral Mucosa	(0)	(1)	(1)	(1)
Squamous Cell Carcinoma		1 (100%)		
Squamous Cell Papilloma			1 (100%)	1 (100%)
Pancreas	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Kidney	1 (2%)			
Schwannoma Malignant, Metastatic,			1 (2%)	

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

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Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Mesentery				
Salivary Glands	(50)	(50)	(50)	(50)
Sarcoma				1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
Tongue	(0)	(0)	(1)	(0)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung				1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma		2 (4%)		1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	3 (6%)	6 (12%)	6 (12%)	2 (4%)
Pheochromocytoma Benign, Multiple	1 (2%)	2 (4%)		1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma		1 (2%)	2 (4%)	
Parathyroid Gland	(50)	(49)	(49)	(46)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	20 (40%)	15 (30%)	16 (32%)	16 (32%)
Thyroid Gland	(50)	(50)	(50)	(50)
Bilateral, C-cell, Adenoma			1 (2%)	
C-cell, Adenoma	11 (22%)	8 (16%)	5 (10%)	5 (10%)
C-cell, Carcinoma			1 (2%)	
Follicular Cell, Adenoma		2 (4%)		1 (2%)
Follicular Cell, Carcinoma	1 (2%)			
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Epididymis	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Kidney	1 (2%)			
Schwannoma Malignant, Metastatic, Mesentery			1 (2%)	
Preputial Gland	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Prostate	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Seminal Vesicle	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Testes	(50)	(50)	(50)	(50)
Interstitial Cell, Adenoma	13 (26%)	6 (12%)	10 (20%)	10 (20%)
Interstitial Cell, Adenoma, Multiple	32 (64%)	38 (76%)	36 (72%)	36 (72%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(7)	(15)	(4)	(6)
Lymph Node, Mesenteric	(49)	(50)	(50)	(50)
Schwannoma Malignant, Metastatic, Mesentery			1 (2%)	
Spleen	(50)	(50)	(50)	(50)
Thymus	(50)	(47)	(49)	(50)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Fibroadenoma	2 (4%)	2 (4%)	2 (4%)	
Skin	(50)	(50)	(50)	(50)
Epidermis, Basal Cell Adenoma	1 (2%)	1 (2%)	2 (4%)	1 (2%)
Epidermis, Basal Cell Carcinoma				1 (2%)
Epidermis, Squamous Cell Carcinoma	1 (2%)			
Epidermis, Squamous Cell Papilloma		1 (2%)	1 (2%)	
Pinna, Neural Crest Tumor		1 (2%)		1 (2%)
Sebaceous Gland, Adenoma		1 (2%)		
Subcutaneous Tissue, Fibroma	2 (4%)	6 (12%)	2 (4%)	7 (14%)
Subcutaneous Tissue, Fibrosarcoma			1 (2%)	1 (2%)
Subcutaneous Tissue, Fibrous Histiocytoma	1 (2%)			

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Subcutaneous Tissue, Sarcoma			1 (2%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Cranium, Osteosarcoma		1 (2%)		
Femur, Osteosarcoma	1 (2%)			1 (2%)
Mandible, Squamous Cell Carcinoma, Metastatic, Oral Mucosa		1 (2%)		
Rib, Osteosarcoma			1 (2%)	
Skeletal Muscle	(0)	(0)	(0)	(1)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung				1 (100%)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Glioma Benign			1 (2%)	
Granular Cell Tumor Benign				1 (2%)
Peripheral Nerve	(0)	(0)	(2)	(0)
RESPIRATORY SYSTEM				
Larynx	(1)	(0)	(0)	(0)
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma			1 (2%)	
Alveolar/Bronchiolar Carcinoma				1 (2%)
Carcinoma, Metastatic, Harderian Gland	1 (2%)			
Carcinoma, Metastatic, Kidney	1 (2%)			
Carcinoma, Metastatic, Thyroid Gland	1 (2%)			
Carcinoma, Metastatic, Zymbal'S Gland				1 (2%)
Nose	(50)	(50)	(50)	(50)
Adenoma				1 (2%)
Trachea	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)

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Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Harderian Gland Carcinoma	(50) 1 (2%)	(50)	(50)	(50)
Zymbal's Gland Carcinoma	(0)	(0)	(0)	(1) 1 (100%)
URINARY SYSTEM				
Kidney Renal Tubule, Adenoma	(50) 1 (2%)	(50)	(50)	(50)
Renal Tubule, Carcinoma	1 (2%)			
Urinary Bladder	(50)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma			2 (4%)	
Leukemia Mononuclear	18 (36%)	25 (50%)	15 (30%)	12 (24%)
Mesothelioma Malignant	2 (4%)	3 (6%)	4 (8%)	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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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Tumor Summary for Males				
Total Animals with Primary Neoplasms (b)	49	50	49	48
Total Primary Neoplasms	116	126	117	106
Total Animals with Benign Neoplasms	49	49	49	47
Total Benign Neoplasms	88	94	88	85
Total Animals with Malignant Neoplasms	26	28	26	18
Total Malignant Neoplasms	28	31	29	20
Total Animals with Metastatic Neoplasms	3	1	1	2
Total Metastatic Neoplasms	6	1	3	3
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain-Benign or Malignant		1		1
Total Uncertain Neoplasms		1		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

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident			3	1
Moribund Sacrifice	8	12	7	10
Natural Death	6	11	6	15
Survivors				
Terminal Sacrifice	36	27	34	24
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Squamous Cell Papilloma				1 (2%)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Adenoma				1 (2%)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Leiomyoma	1 (2%)			
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Leiomyoma		1 (2%)		
Liver	(50)	(50)	(50)	(50)
Hepatocellular Carcinoma		1 (2%)		
Mesentery	(9)	(8)	(6)	(6)
Schwannoma Malignant		1 (13%)		
Oral Mucosa	(0)	(0)	(1)	(0)
Pharyngeal, Squamous Cell Papilloma			1 (100%)	
Pancreas	(50)	(50)	(50)	(50)
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
Tongue	(1)	(0)	(0)	(0)
Tooth	(1)	(0)	(0)	(0)
CARDIOVASCULAR SYSTEM				

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	1 (2%)			1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Parathyroid Gland	(48)	(45)	(46)	(50)
Pituitary Gland	(50)	(49)	(50)	(50)
Pars Distalis, Adenoma	16 (32%)	15 (31%)	13 (26%)	11 (22%)
Pars Intermedia, Adenoma		1 (2%)		
Thyroid Gland	(50)	(50)	(50)	(50)
Bilateral, C-cell, Adenoma		2 (4%)		
C-cell, Adenoma	6 (12%)	5 (10%)	5 (10%)	3 (6%)
C-cell, Carcinoma				1 (2%)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(50)
Adenoma	1 (2%)		4 (8%)	
Carcinoma	1 (2%)			
Ovary	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)		
Uterus	(50)	(50)	(50)	(50)
Polyp Stromal	7 (14%)	3 (6%)	7 (14%)	5 (10%)
Polyp Stromal, Multiple	1 (2%)			1 (2%)
Vagina	(0)	(0)	(2)	(0)
Polyp			1 (50%)	
HEMATOPOIETIC SYSTEM				

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Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(1)	(5)	(4)	(4)
Mediastinal, Carcinoma, Metastatic,				1 (25%)
Thyroid Gland				
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Thymus	(48)	(49)	(50)	(50)
Thymoma Malignant	1 (2%)			
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Adenoma	2 (4%)			1 (2%)
Carcinoma		3 (6%)		
Fibroadenoma	24 (48%)	18 (36%)	22 (44%)	11 (22%)
Fibroadenoma, Multiple	8 (16%)	12 (24%)	8 (16%)	5 (10%)
Skin	(50)	(50)	(50)	(50)
Epidermis, Basal Cell Adenoma	1 (2%)			
Epidermis, Keratoacanthoma	2 (4%)			
Epidermis, Squamous Cell Papilloma	1 (2%)		1 (2%)	
Subcutaneous Tissue, Fibroma			2 (4%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(1)	(1)	(0)	(0)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Astrocytoma Benign		1 (2%)		
Peripheral Nerve	(1)	(1)	(0)	(0)
Spinal Cord	(1)	(1)	(0)	(0)
Glioma Malignant	1 (100%)			
RESPIRATORY SYSTEM				
Larynx	(1)	(0)	(0)	(2)

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Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)			
Carcinoma, Metastatic, Mammary Gland		1 (2%)		
Nose	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Iris, Melanoma Malignant	1 (2%)			1 (2%)
Harderian Gland	(50)	(50)	(50)	(50)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Lipoma		1 (2%)		1 (2%)
Urethra	(0)	(1)	(0)	(0)
Urinary Bladder	(50)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Leukemia Mononuclear	6 (12%)	9 (18%)	8 (16%)	9 (18%)

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* Number of animals with any tissue examined microscopically

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	45	40	40	34
Total Primary Neoplasms	84	74	73	52
Total Animals with Benign Neoplasms	42	34	39	28
Total Benign Neoplasms	74	59	65	41
Total Animals with Malignant Neoplasms	10	14	8	11
Total Malignant Neoplasms	10	15	8	11
Total Animals with Metastatic Neoplasms		1		1
Total Metastatic Neoplasms		1		1
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