

**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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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
<b>Disposition Summary</b>				
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
<b>ALIMENTARY SYSTEM</b>				
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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Species/Strain: RATS/F 344

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)
<b>CARDIOVASCULAR SYSTEM</b>				
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung				1 (2%)
<b>ENDOCRINE SYSTEM</b>				
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%)			
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				

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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%)
<b>HEMATOPOIETIC SYSTEM</b>				
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)
<b>INTEGUMENTARY SYSTEM</b>				
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%)	
<b>MUSCULOSKELETAL SYSTEM</b>				
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%)
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(50)	(50)
Glioma Benign			1 (2%)	
Granular Cell Tumor Benign				1 (2%)
Peripheral Nerve	(0)	(0)	(2)	(0)
<b>RESPIRATORY SYSTEM</b>				
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)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(50)	(50)	(50)	(50)

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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
Harderian Gland Carcinoma	(50) 1 (2%)	(50)	(50)	(50)
Zymbal's Gland Carcinoma	(0)	(0)	(0)	(1) 1 (100%)
<b>URINARY SYSTEM</b>				
Kidney Renal Tubule, Adenoma	(50) 1 (2%)	(50)	(50)	(50)
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%)	
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

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FISCHER 344 RATS MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
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**Tumor Summary for Males**

<b>Total Animals with Primary Neoplasms (b)</b>	49	50	49	48
<b>Total Primary Neoplasms</b>	116	126	117	106
<b>Total Animals with Benign Neoplasms</b>	49	49	49	47
<b>Total Benign Neoplasms</b>	88	94	88	85
<b>Total Animals with Malignant Neoplasms</b>	26	28	26	18
<b>Total Malignant Neoplasms</b>	28	31	29	20
<b>Total Animals with Metastatic Neoplasms</b>	3	1	1	2
<b>Total Metastatic Neoplasms</b>	6	1	3	3
<b>Total Animals with Malignant Neoplasms Uncertain Primary Site</b>				
<b>Total Animals with Neoplasms Uncertain-Benign or Malignant</b>		1		1
<b>Total Uncertain Neoplasms</b>		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

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 FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
<b>Disposition Summary</b>				
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
<b>ALIMENTARY SYSTEM</b>				
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)
<b>CARDIOVASCULAR SYSTEM</b>				

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



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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)
<b>ENDOCRINE SYSTEM</b>				
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%)
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
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%)	
<b>HEMATOPOIETIC SYSTEM</b>				

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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%)			
<b>INTEGUMENTARY SYSTEM</b>				
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%)	
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(1)	(1)	(0)	(0)
<b>NERVOUS SYSTEM</b>				
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%)			
<b>RESPIRATORY SYSTEM</b>				
Larynx	(1)	(0)	(0)	(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: 01/21/04 / 01/22/04

Species/Strain: RATS/F 344

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%)			
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(50)	(50)	(50)	(50)
Iris, Melanoma Malignant	1 (2%)			1 (2%)
Harderian Gland	(50)	(50)	(50)	(50)
<b>URINARY SYSTEM</b>				
Kidney	(50)	(50)	(50)	(50)
Lipoma		1 (2%)		1 (2%)
Urethra	(0)	(1)	(0)	(0)
Urinary Bladder	(50)	(50)	(50)	(50)
<b>SYSTEMIC LESIONS</b>				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Leukemia Mononuclear	6 (12%)	9 (18%)	8 (16%)	9 (18%)

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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Species/Strain: RATS/F 344

Lab: BAT

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

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