

TDMS No. 99007 - 05

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

Date Report Requested: 08/15/2008

Test Type: CHRONIC

Goldenseal root powder

Time Report Requested: 08:34:31

Route: DOSED FEED

CAS Number: GOLDENSEALRT

First Dose M/F: 04/21/03 / 04/21/03

Species/Strain: RATS/F 344

Lab: SRI

F1_R2

C Number: C99007B
Lock Date: 08/07/2006
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

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CAS Number: GOLDENSEALRT

First Dose M/F: 04/21/03 / 04/21/03

Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	12	19	11	24
Natural Death	5	2	9	1
Survivors				
Natural Death				1
Terminal Sacrifice	33	29	30	24
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Intestine Large, Cecum	(49)	(50)	(48)	(50)
Intestine Large, Colon	(50)	(48)	(50)	(50)
Intestine Small, Duodenum	(49)	(49)	(49)	(49)
Carcinoma				1 (2%)
Intestine Small, Ileum	(47)	(49)	(45)	(48)
Intestine Small, Jejunum	(48)	(48)	(46)	(48)
Adenoma				1 (2%)
Carcinoma			1 (2%)	
Liver	(50)	(50)	(50)	(50)
Hepatocellular Adenoma	1 (2%)	1 (2%)	2 (4%)	8 (16%)
Hepatocellular Adenoma, Multiple				2 (4%)
Hepatocellular Carcinoma				1 (2%)
Rhabdomyosarcoma, Metastatic, Skeletal Muscle	1 (2%)			
Mesentery	(9)	(9)	(11)	(7)
Lipoma	1 (11%)			
Oral Mucosa	(1)	(0)	(0)	(0)
Squamous Cell Carcinoma	1 (100%)			
Pancreas	(50)	(50)	(49)	(50)
Mixed Tumor Malignant	1 (2%)			
Acinus, Adenoma				1 (2%)
Salivary Glands	(50)	(49)	(50)	(50)
Schwannoma Malignant				1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(49)

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 PPM	3000 PPM	9000 PPM	25000 PPM
Tongue Squamous Cell Papilloma	(2) 1 (50%)	(1) 1 (100%)	(0)	(0)
CARDIOVASCULAR SYSTEM				
Heart Alveolar/Bronchiolar Carcinoma, Metastatic, Lung Carcinoma, Metastatic, Uncertain Primary Site Schwannoma Malignant	(50)	(50)	(50)	(50) 1 (2%) 1 (2%) 2 (4%)
ENDOCRINE SYSTEM				
Adrenal Cortex Adenoma	(50)	(50)	(50) 1 (2%)	(50)
Adrenal Medulla Pheochromocytoma Benign Pheochromocytoma Benign, Multiple Pheochromocytoma Malignant Pheochromocytoma Malignant, Multiple	(49) 4 (8%) 1 (2%) 1 (2%)	(49) 7 (14%) 5 (10%) 1 (2%)	(50) 7 (14%) 2 (4%)	(48) 4 (8%) 1 (2%)
Islets, Pancreatic Adenoma Adenoma, Multiple Carcinoma	(50) 6 (12%) 1 (2%)	(50) 3 (6%)	(49) 4 (8%) 1 (2%)	(50) 2 (4%)
Pituitary Gland Pars Distalis, Adenoma Pars Distalis, Carcinoma Pars Intermedia, Adenoma	(50) 8 (16%)	(50) 18 (36%) 1 (2%)	(49) 16 (33%) 1 (2%)	(50) 13 (26%)
Thyroid Gland C-cell, Adenoma C-cell, Adenoma, Multiple C-cell, Carcinoma C-cell, Carcinoma, Multiple Follicular Cell, Adenoma	(50) 7 (14%) 1 (2%)	(50) 4 (8%) 1 (2%) 2 (4%) 1 (2%)	(50) 6 (12%)	(50) 3 (6%) 1 (2%) 1 (2%)
GENERAL BODY SYSTEM				
Tissue NOS	(0)	(1)	(1)	(0)

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Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(50)	(50)	(50)
Adenoma		3 (6%)	2 (4%)	2 (4%)
Carcinoma	2 (4%)	2 (4%)	1 (2%)	4 (8%)
Prostate	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	1 (2%)	3 (6%)	2 (4%)
Seminal Vesicle	(50)	(50)	(50)	(50)
Testes	(50)	(50)	(50)	(50)
Bilateral, Interstitial Cell, Adenoma	31 (62%)	31 (62%)	38 (76%)	33 (66%)
Interstitial Cell, Adenoma	11 (22%)	12 (24%)	6 (12%)	9 (18%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(49)	(50)	(50)	(50)
Lymph Node	(11)	(11)	(14)	(19)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung				1 (5%)
Deep Cervical, Carcinoma, Metastatic, Thyroid Gland		2 (18%)		
Deep Cervical, Rhabdomyosarcoma, Metastatic, Harderian Gland		1 (9%)		
Inguinal, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung				1 (5%)
Mediastinal, Carcinoma, Metastatic, Thyroid Gland		1 (9%)		
Mediastinal, Rhabdomyosarcoma, Metastatic, Harderian Gland		1 (9%)		
Lymph Node, Mesenteric	(49)	(49)	(50)	(50)
Spleen	(49)	(50)	(49)	(50)
Fibrous Histiocytoma	1 (2%)			
Thymus	(48)	(49)	(49)	(47)
Thymoma Benign	1 (2%)			
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)

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Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Fibroadenoma	1 (2%)	1 (2%)	3 (6%)	1 (2%)
Fibroadenoma, Multiple			1 (2%)	
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma			1 (2%)	
Basal Cell Carcinoma		1 (2%)		2 (4%)
Keratoacanthoma	2 (4%)	4 (8%)	5 (10%)	2 (4%)
Sebaceous Gland, Adenoma				2 (4%)
Subcutaneous Tissue, Fibroma	4 (8%)	4 (8%)	2 (4%)	5 (10%)
Subcutaneous Tissue, Fibroma, Multiple	1 (2%)			
Subcutaneous Tissue, Fibrosarcoma			2 (4%)	
Subcutaneous Tissue, Lipoma	1 (2%)		2 (4%)	
Subcutaneous Tissue, Myxosarcoma		1 (2%)		
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Chordoma	1 (2%)			1 (2%)
Osteosarcoma	2 (4%)		1 (2%)	
Skeletal Muscle	(3)	(1)	(1)	(3)
Rhabdomyosarcoma	1 (33%)			
NERVOUS SYSTEM				
Brain	(49)	(50)	(50)	(50)
Astrocytoma Malignant				1 (2%)
Ependymoma Malignant	1 (2%)			
Granular Cell Tumor Malignant		1 (2%)		
Oligodendroglioma Malignant			1 (2%)	
Peripheral Nerve	(4)	(3)	(4)	(3)
Schwannoma Malignant				1 (33%)
Spinal Cord	(4)	(3)	(4)	(2)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma		2 (4%)		2 (4%)
Alveolar/Bronchiolar Carcinoma		1 (2%)		1 (2%)
Carcinoma	1 (2%)			
Carcinoma, Metastatic, Thyroid Gland		1 (2%)		

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Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Chordoma, Metastatic, Bone Pheochromocytoma Malignant, Metastatic, Adrenal Medulla Nose	(50)	1 (2%) (50)	(50)	1 (2%) (50)
SPECIAL SENSES SYSTEM				
Eye Rhabdomyosarcoma, Metastatic, Harderian Gland Harderian Gland Adenoma Rhabdomyosarcoma	(50)	(50) 1 (2%) (50) 1 (2%)	(50)	(50) (50) 1 (2%)
URINARY SYSTEM				
Kidney Renal Tubule, Adenoma Transitional Epithelium, Carcinoma Urethra Urinary Bladder	(50) 1 (2%) (0) (50)	(50) (1)	(50) 1 (2%) (0) (50)	(50) (0) (50)
SYSTEMIC LESIONS				
Multiple Organs Histiocytic Sarcoma Leukemia Mononuclear Mesothelioma Malignant	*(50) 21 (42%)	*(50) 1 (2%) 16 (32%) 3 (6%)	*(50) 2 (4%) 24 (48%) 2 (4%)	*(50) 1 (2%) 28 (56%)

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* Number of animals with any tissue examined microscopically

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Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	50	50	50	49
Total Primary Neoplasms	118	130	140	138
Total Animals with Benign Neoplasms	47	48	48	47
Total Benign Neoplasms	83	93	101	95
Total Animals with Malignant Neoplasms	29	29	31	37
Total Malignant Neoplasms	35	37	39	43
Total Animals with Metastatic Neoplasms	1	3		3
Total Metastatic Neoplasms	1	8		5
Total Animals with Malignant Neoplasms Uncertain Primary Site				1
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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First Dose M/F: 04/21/03 / 04/21/03

Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	14	9	5	12
Natural Death	6	5	3	2
Survivors				
Terminal Sacrifice	30	36	42	36
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Intestine Large, Cecum	(48)	(50)	(50)	(49)
Intestine Small, Jejunum	(46)	(47)	(48)	(50)
Liver	(50)	(50)	(50)	(50)
Hepatocellular Adenoma			1 (2%)	8 (16%)
Mesentery	(9)	(7)	(4)	(2)
Oral Mucosa	(0)	(0)	(1)	(0)
Pancreas	(49)	(50)	(50)	(50)
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma	1 (2%)	1 (2%)		
Stomach, Glandular	(50)	(50)	(50)	(50)
Tongue	(1)	(0)	(0)	(1)
Squamous Cell Papilloma	1 (100%)			1 (100%)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Schwannoma Malignant	1 (2%)			1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	1 (2%)	3 (6%)	2 (4%)
Adrenal Medulla	(48)	(50)	(49)	(50)
Pheochromocytoma Benign		2 (4%)		

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Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Pheochromocytoma Malignant			1 (2%)	
Islets, Pancreatic	(49)	(50)	(50)	(50)
Adenoma		1 (2%)		
Parathyroid Gland	(49)	(49)	(48)	(46)
Pituitary Gland	(50)	(50)	(50)	(50)
Carcinoma		1 (2%)		
Pars Distalis, Adenoma	25 (50%)	20 (40%)	16 (32%)	16 (32%)
Pars Distalis, Carcinoma		3 (6%)	2 (4%)	1 (2%)
Pars Distalis, Sarcoma, Metastatic, Skin	1 (2%)			
Pars Intermedia, Adenoma		1 (2%)		
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Adenoma	4 (8%)	4 (8%)	3 (6%)	3 (6%)
C-cell, Adenoma, Multiple				1 (2%)
C-cell, Carcinoma	1 (2%)	1 (2%)		
GENERAL BODY SYSTEM				
Tissue NOS	(1)	(0)	(0)	(0)
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(49)	(50)
Adenoma	5 (10%)	9 (18%)	4 (8%)	3 (6%)
Carcinoma	3 (6%)	3 (6%)	1 (2%)	
Carcinoma, Multiple	1 (2%)			
Fibrosarcoma				1 (2%)
Ovary	(50)	(50)	(50)	(49)
Granulosa-Theca Tumor Benign		1 (2%)		
Tubulostromal Adenoma			1 (2%)	
Uterus	(50)	(50)	(50)	(50)
Adenocarcinoma				1 (2%)
Adenoma				1 (2%)
Fibroma			1 (2%)	
Leiomyoma			1 (2%)	
Leiomyosarcoma	1 (2%)			
Polyp Stromal	12 (24%)	10 (20%)	14 (28%)	9 (18%)
Polyp Stromal, Multiple	2 (4%)	1 (2%)	2 (4%)	1 (2%)

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Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Mast Cell Tumor Malignant		1 (2%)		
Lymph Node	(9)	(7)	(7)	(8)
Deep Cervical, Carcinoma, Metastatic, Thyroid Gland		1 (14%)		
Mediastinal, Carcinoma, Metastatic, Thyroid Gland		1 (14%)		
Lymph Node, Mandibular	(2)	(3)	(3)	(5)
Lymph Node, Mesenteric	(49)	(50)	(50)	(49)
Spleen	(49)	(50)	(50)	(50)
Hemangiosarcoma			1 (2%)	
Thymus	(49)	(50)	(49)	(49)
Thymoma Benign			1 (2%)	
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	2 (4%)		1 (2%)
Adenoma, Multiple	1 (2%)			
Carcinoma	3 (6%)	1 (2%)	1 (2%)	2 (4%)
Carcinoma, Multiple	1 (2%)			
Fibroadenoma	22 (44%)	17 (34%)	7 (14%)	16 (32%)
Fibroadenoma, Multiple	8 (16%)	3 (6%)	4 (8%)	1 (2%)
Skin	(50)	(49)	(50)	(50)
Neural Crest Tumor	1 (2%)			
Squamous Cell Papilloma		1 (2%)		
Trichoepithelioma	1 (2%)			
Subcutaneous Tissue, Fibroma	1 (2%)	4 (8%)	3 (6%)	1 (2%)
Subcutaneous Tissue, Fibrosarcoma		2 (4%)		
Subcutaneous Tissue, Sarcoma	2 (4%)			
Subcutaneous Tissue, Schwannoma Benign		1 (2%)		
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(0)	(0)	(2)

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First Dose M/F: 04/21/03 / 04/21/03

Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Astrocytoma Malignant		1 (2%)	1 (2%)	
Carcinoma, Metastatic, Pituitary Gland		2 (4%)	1 (2%)	
Ependymoma Malignant		1 (2%)		
Granular Cell Tumor Benign			1 (2%)	1 (2%)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)	1 (2%)		
Hemangiosarcoma, Metastatic, Spleen			1 (2%)	
Nose	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(49)
Zymbal's Gland	(0)	(0)	(1)	(0)
Carcinoma			1 (100%)	
URINARY SYSTEM				
Kidney	(49)	(50)	(50)	(50)
Sarcoma	1 (2%)			
Urinary Bladder	(50)	(49)	(50)	(50)
Transitional Epithelial Carcinoma		1 (2%)		
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)			
Leukemia Granulocytic				1 (2%)
Leukemia Mononuclear	9 (18%)	9 (18%)	7 (14%)	6 (12%)

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* Number of animals with any tissue examined microscopically

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Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	48	47	45	39
Total Primary Neoplasms	111	104	77	78
Total Animals with Benign Neoplasms	46	44	40	36
Total Benign Neoplasms	86	80	62	65
Total Animals with Malignant Neoplasms	19	18	13	12
Total Malignant Neoplasms	24	24	15	13
Total Animals with Metastatic Neoplasms	1	3	2	
Total Metastatic Neoplasms	1	4	2	
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain-Benign or Malignant	1			
Total Uncertain Neoplasms	1			

*** END OF REPORT ***

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b - Primary tumors: all tumors except metastatic tumors