

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

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

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Goldenseal root powder

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Route: DOSED FEED

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
<b>GENITAL SYSTEM</b>				
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%)
<b>HEMATOPOIETIC SYSTEM</b>				
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%)			
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(50)	(50)	(50)	(50)

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

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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
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%)		
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Chordoma	1 (2%)			1 (2%)
Osteosarcoma	2 (4%)		1 (2%)	
Skeletal Muscle	(3)	(1)	(1)	(3)
Rhabdomyosarcoma	1 (33%)			
<b>NERVOUS SYSTEM</b>				
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)
<b>RESPIRATORY SYSTEM</b>				
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%)		

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
Chordoma, Metastatic, Bone Pheochromocytoma Malignant, Metastatic, Adrenal Medulla		1 (2%)		1 (2%)
Nose	(50)	(50)	(50)	(50)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(50)	(50)	(50)	(50)
Rhabdomyosarcoma, Metastatic, Harderian Gland		1 (2%)		
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma				1 (2%)
Rhabdomyosarcoma		1 (2%)		
<b>URINARY SYSTEM</b>				
Kidney	(50)	(50)	(50)	(50)
Renal Tubule, Adenoma			1 (2%)	
Transitional Epithelium, Carcinoma	1 (2%)			
Urethra	(0)	(1)	(0)	(0)
Urinary Bladder	(50)	(50)	(50)	(50)
<b>SYSTEMIC LESIONS</b>				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		1 (2%)	2 (4%)	1 (2%)
Leukemia Mononuclear	21 (42%)	16 (32%)	24 (48%)	28 (56%)
Mesothelioma Malignant		3 (6%)	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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First Dose M/F: 04/21/03 / 04/21/03

Species/Strain: RATS/F 344

Lab: SRI

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

<b>Total Animals with Primary Neoplasms (b)</b>	50	50	50	49
<b>Total Primary Neoplasms</b>	118	130	140	138
<b>Total Animals with Benign Neoplasms</b>	47	48	48	47
<b>Total Benign Neoplasms</b>	83	93	101	95
<b>Total Animals with Malignant Neoplasms</b>	29	29	31	37
<b>Total Malignant Neoplasms</b>	35	37	39	43
<b>Total Animals with Metastatic Neoplasms</b>	1	3		3
<b>Total Metastatic Neoplasms</b>	1	8		5
<b>Total Animals with Malignant Neoplasms Uncertain Primary Site</b>				1
<b>Total Animals with Neoplasms Uncertain-Benign or Malignant</b>				
<b>Total Uncertain Neoplasms</b>				

\*\*\* 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

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

FISCHER 344 RATS FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Disposition Summary</b>				
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
<b>ALIMENTARY SYSTEM</b>				
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%)
<b>CARDIOVASCULAR SYSTEM</b>				
Heart	(50)	(50)	(50)	(50)
Schwannoma Malignant	1 (2%)			1 (2%)
<b>ENDOCRINE SYSTEM</b>				
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%)		

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 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%)		
<b>GENERAL BODY SYSTEM</b>				
Tissue NOS	(1)	(0)	(0)	(0)
<b>GENITAL SYSTEM</b>				
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%)

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

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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 FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>HEMATOPOIETIC SYSTEM</b>				
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%)	
<b>INTEGUMENTARY SYSTEM</b>				
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%)		
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(0)	(0)	(2)

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

Test Type: CHRONIC

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Route: DOSED FEED

CAS Number: GOLDENSEALRT

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
<b>NERVOUS SYSTEM</b>				
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%)
<b>RESPIRATORY SYSTEM</b>				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)	1 (2%)		
Hemangiosarcoma, Metastatic, Spleen			1 (2%)	
Nose	(50)	(50)	(50)	(50)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(49)
Zymbal's Gland	(0)	(0)	(1)	(0)
Carcinoma			1 (100%)	
<b>URINARY SYSTEM</b>				
Kidney	(49)	(50)	(50)	(50)
Sarcoma	1 (2%)			
Urinary Bladder	(50)	(49)	(50)	(50)
Transitional Epithelial Carcinoma		1 (2%)		
<b>SYSTEMIC LESIONS</b>				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)			
Leukemia Granulocytic				1 (2%)
Leukemia Mononuclear	9 (18%)	9 (18%)	7 (14%)	6 (12%)

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: 04/21/03 / 04/21/03

Species/Strain: RATS/F 344

Lab: SRI

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

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