

TDMS No. 99007 - 05
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Goldenseal root powder
CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
Time Report Requested: 08:34:31
First Dose M/F: 04/21/03 / 04/21/03
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

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)
Edema	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Intestine Large, Colon	(50)	(48)	(50)	(50)
Intestine Small, Duodenum	(49)	(49)	(49)	(49)
Intestine Small, Ileum	(47)	(49)	(45)	(48)
Inflammation, Chronic				1 (2%)
Intestine Small, Jejunum	(48)	(48)	(46)	(48)
Liver	(50)	(50)	(50)	(50)
Angiectasis		1 (2%)	2 (4%)	
Atrophy, Focal	1 (2%)			
Basophilic Focus	20 (40%)	33 (66%)	22 (44%)	13 (26%)
Clear Cell Focus	19 (38%)	17 (34%)	3 (6%)	2 (4%)
Degeneration, Cystic	6 (12%)	4 (8%)	4 (8%)	7 (14%)
Eosinophilic Focus	4 (8%)	5 (10%)	25 (50%)	28 (56%)
Hematopoietic Cell Proliferation		1 (2%)		
Hemorrhage	1 (2%)	6 (12%)		
Hepatodiaphragmatic Nodule	3 (6%)	13 (26%)	6 (12%)	2 (4%)
Infarct				1 (2%)
Infiltration Cellular, Mixed Cell	4 (8%)	6 (12%)	6 (12%)	6 (12%)
Mixed Cell Focus	9 (18%)	21 (42%)	13 (26%)	7 (14%)
Necrosis, Focal	1 (2%)	2 (4%)	1 (2%)	2 (4%)
Bile Duct, Hyperplasia	43 (86%)	38 (76%)	45 (90%)	39 (78%)
Centrilobular, Necrosis		2 (4%)		1 (2%)
Hepatocyte, Degeneration		22 (44%)	30 (60%)	19 (38%)
Hepatocyte, Hyperplasia, Focal	1 (2%)			
Hepatocyte, Hypertrophy		19 (38%)	31 (62%)	27 (54%)
Hepatocyte, Vacuolization Cytoplasmic	2 (4%)	4 (8%)	2 (4%)	1 (2%)
Kupffer Cell, Pigmentation	2 (4%)		2 (4%)	3 (6%)
Mesentery	(9)	(9)	(11)	(7)
Accessory Spleen	3 (33%)		1 (9%)	1 (14%)

FISCHER 344 RATS MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Angiectasis			1 (9%)	
Hemorrhage			2 (18%)	
Inflammation, Chronic	1 (11%)			
Fat, Necrosis	4 (44%)	5 (56%)	7 (64%)	3 (43%)
Oral Mucosa	(1)	(0)	(0)	(0)
Pancreas	(50)	(50)	(49)	(50)
Atrophy	19 (38%)	19 (38%)	25 (51%)	18 (36%)
Cyst	10 (20%)	12 (24%)	15 (31%)	14 (28%)
Necrosis			1 (2%)	
Acinus, Cytoplasmic Alteration	1 (2%)	3 (6%)		1 (2%)
Acinus, Hyperplasia, Focal	6 (12%)		5 (10%)	1 (2%)
Salivary Glands	(50)	(49)	(50)	(50)
Atrophy	4 (8%)	2 (4%)	4 (8%)	6 (12%)
Infiltration Cellular, Polymorphonuclear			1 (2%)	
Stomach, Forestomach	(50)	(50)	(50)	(50)
Edema	2 (4%)	5 (10%)	2 (4%)	1 (2%)
Erosion		1 (2%)		
Hyperplasia, Squamous			1 (2%)	
Inflammation, Chronic Active		1 (2%)	1 (2%)	
Perforation			1 (2%)	
Ulcer	3 (6%)	8 (16%)	2 (4%)	1 (2%)
Epithelium, Hyperplasia	5 (10%)	7 (14%)	3 (6%)	3 (6%)
Stomach, Glandular	(50)	(50)	(50)	(49)
Erosion	3 (6%)	2 (4%)	3 (6%)	3 (6%)
Ulcer		3 (6%)	2 (4%)	
Epithelium, Hyperplasia	3 (6%)		1 (2%)	
Tongue	(2)	(1)	(0)	(0)
Epithelium, Hyperplasia	1 (50%)			
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	47 (94%)	38 (76%)	39 (78%)	36 (72%)
Thrombosis	1 (2%)		1 (2%)	1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Accessory Adrenal Cortical Nodule	17 (34%)	7 (14%)	14 (28%)	19 (38%)
Degeneration, Fatty		1 (2%)		
Hyperplasia	10 (20%)	2 (4%)	5 (10%)	7 (14%)
Hyperplasia, Focal	3 (6%)	2 (4%)	4 (8%)	2 (4%)
Hypertrophy, Focal	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Necrosis	1 (2%)		1 (2%)	1 (2%)

FISCHER 344 RATS MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Vacuolization Cytoplasmic, Focal	2 (4%)	6 (12%)	3 (6%)	4 (8%)
Vacuolization Cytoplasmic, Diffuse		1 (2%)	1 (2%)	1 (2%)
Adrenal Medulla	(49)	(49)	(50)	(48)
Hyperplasia	5 (10%)	10 (20%)	14 (28%)	9 (19%)
Islets, Pancreatic	(50)	(50)	(49)	(50)
Hyperplasia	1 (2%)	1 (2%)	1 (2%)	
Pituitary Gland	(50)	(50)	(49)	(50)
Pars Distalis, Angiectasis	2 (4%)	4 (8%)	2 (4%)	5 (10%)
Pars Distalis, Cyst	7 (14%)		6 (12%)	4 (8%)
Pars Distalis, Hemorrhage, Chronic	1 (2%)			
Pars Distalis, Hyperplasia, Focal	14 (28%)	6 (12%)	8 (16%)	10 (20%)
Pars Intermedia, Cyst	3 (6%)	2 (4%)	2 (4%)	5 (10%)
Thyroid Gland	(50)	(50)	(50)	(50)
Ultimobranchial Cyst			1 (2%)	1 (2%)
C-cell, Hyperplasia	8 (16%)	4 (8%)	4 (8%)	6 (12%)
Follicle, Cyst	3 (6%)	1 (2%)	1 (2%)	2 (4%)
Follicular Cell, Hyperplasia				1 (2%)
GENERAL BODY SYSTEM				
Tissue NOS	(0)	(1)	(1)	(0)
Hemorrhage		1 (100%)		
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm	1 (2%)			2 (4%)
Inflammation, Acute		1 (2%)	1 (2%)	
Inflammation, Chronic	1 (2%)	2 (4%)	3 (6%)	2 (4%)
Preputial Gland	(50)	(50)	(50)	(50)
Cyst	2 (4%)	1 (2%)	3 (6%)	
Hyperplasia	2 (4%)		2 (4%)	1 (2%)
Hyperplasia, Focal	1 (2%)	1 (2%)		
Inflammation, Chronic	19 (38%)	10 (20%)	14 (28%)	20 (40%)
Prostate	(50)	(50)	(50)	(50)
Angiectasis				1 (2%)
Inflammation, Acute				1 (2%)
Inflammation, Chronic	12 (24%)	15 (30%)	14 (28%)	10 (20%)
Epithelium, Hyperplasia	4 (8%)	4 (8%)	5 (10%)	
Seminal Vesicle	(50)	(50)	(50)	(50)
Inflammation, Chronic				1 (2%)
Testes	(50)	(50)	(50)	(50)
Germinal Epithelium, Atrophy	5 (10%)	8 (16%)	3 (6%)	8 (16%)
Interstitial Cell, Hyperplasia	2 (4%)	6 (12%)	4 (8%)	3 (6%)

FISCHER 344 RATS MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
HEMATOPOIETIC SYSTEM				
Bone Marrow	(49)	(50)	(50)	(50)
Hemorrhage	1 (2%)			
Hyperplasia	4 (8%)	4 (8%)	4 (8%)	8 (16%)
Infiltration Cellular, Histiocyte			2 (4%)	
Myelofibrosis	2 (4%)	2 (4%)		3 (6%)
Lymph Node	(11)	(11)	(14)	(19)
Deep Cervical, Hyperplasia	1 (9%)			
Mediastinal, Ectasia	1 (9%)		2 (14%)	1 (5%)
Mediastinal, Hemorrhage	1 (9%)	2 (18%)	1 (7%)	1 (5%)
Mediastinal, Hyperplasia, Lymphoid	3 (27%)	1 (9%)	2 (14%)	3 (16%)
Mediastinal, Pigmentation		1 (9%)		1 (5%)
Pancreatic, Ectasia		1 (9%)	1 (7%)	1 (5%)
Pancreatic, Hemorrhage	1 (9%)		1 (7%)	1 (5%)
Pancreatic, Hyperplasia, Lymphoid		1 (9%)		1 (5%)
Lymph Node, Mesenteric	(49)	(49)	(50)	(50)
Atrophy				1 (2%)
Ectasia	2 (4%)	1 (2%)	4 (8%)	2 (4%)
Hemorrhage		2 (4%)	2 (4%)	1 (2%)
Hyperplasia, Lymphoid	4 (8%)	11 (22%)	9 (18%)	8 (16%)
Infiltration Cellular, Mixed Cell		1 (2%)		
Spleen	(49)	(50)	(49)	(50)
Accessory Spleen		1 (2%)		
Fibrosis	1 (2%)	2 (4%)	1 (2%)	2 (4%)
Hematopoietic Cell Proliferation	2 (4%)	8 (16%)	4 (8%)	11 (22%)
Hemorrhage			1 (2%)	2 (4%)
Hyperplasia, Lymphoid			2 (4%)	1 (2%)
Infiltration Cellular, Mixed Cell		3 (6%)	1 (2%)	
Metaplasia, Lipocyte		1 (2%)		
Necrosis			3 (6%)	1 (2%)
Thymus	(48)	(49)	(49)	(47)
Atrophy				2 (4%)
Cyst		2 (4%)		
Fibrosis		1 (2%)		
Hyperplasia, Lymphoid	1 (2%)			
Epithelial Cell, Hyperplasia		1 (2%)		
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Hyperplasia	7 (14%)	13 (26%)	6 (12%)	8 (16%)
Skin	(50)	(50)	(50)	(50)

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Goldenseal root powder
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FISCHER 344 RATS MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Cyst Epithelial Inclusion	1 (2%)	3 (6%)	2 (4%)	2 (4%)
Edema		2 (4%)		
Hyperkeratosis	4 (8%)	2 (4%)	4 (8%)	1 (2%)
Inflammation, Chronic	2 (4%)		2 (4%)	
Ulcer	1 (2%)		1 (2%)	1 (2%)
Epidermis, Hyperplasia	5 (10%)		4 (8%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Fracture				1 (2%)
Skeletal Muscle	(3)	(1)	(1)	(3)
Atrophy	1 (33%)			1 (33%)
NERVOUS SYSTEM				
Brain	(49)	(50)	(50)	(50)
Angiectasis		1 (2%)		
Compression	2 (4%)	10 (20%)	3 (6%)	4 (8%)
Gliososis				1 (2%)
Hemorrhage	2 (4%)	4 (8%)	2 (4%)	1 (2%)
Hydrocephalus			1 (2%)	
Metaplasia, Lipocyte				1 (2%)
Necrosis	1 (2%)	4 (8%)	1 (2%)	
Peripheral Nerve	(4)	(3)	(4)	(3)
Spinal Cord	(4)	(3)	(4)	(2)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Cyst	1 (2%)			
Edema			1 (2%)	
Emphysema	1 (2%)			
Foreign Body		1 (2%)	1 (2%)	
Hemorrhage	1 (2%)	4 (8%)	4 (8%)	4 (8%)
Infiltration Cellular, Histiocyte	34 (68%)	24 (48%)	25 (50%)	24 (48%)
Inflammation, Suppurative		1 (2%)		
Inflammation, Chronic	16 (32%)	10 (20%)	17 (34%)	3 (6%)
Metaplasia, Osseous	5 (10%)	3 (6%)		1 (2%)
Alveolar Epithelium, Hyperplasia	8 (16%)	3 (6%)	3 (6%)	8 (16%)
Nose	(50)	(50)	(50)	(50)
Foreign Body	6 (12%)	5 (10%)	5 (10%)	6 (12%)
Inflammation, Chronic	12 (24%)	4 (8%)	3 (6%)	3 (6%)

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

FISCHER 344 RATS MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Respiratory Epithelium, Hyperplasia	5 (10%)	3 (6%)	3 (6%)	3 (6%)
Respiratory Epithelium, Metaplasia, Squamous	2 (4%)			
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Cataract	2 (4%)			1 (2%)
Inflammation, Chronic		1 (2%)		
Retina, Degeneration	2 (4%)	3 (6%)	1 (2%)	2 (4%)
Harderian Gland	(50)	(50)	(50)	(50)
Hyperplasia, Focal	1 (2%)		1 (2%)	1 (2%)
Inflammation, Chronic		1 (2%)		
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Cyst		2 (4%)		1 (2%)
Hydronephrosis				1 (2%)
Infarct			3 (6%)	2 (4%)
Inflammation, Suppurative	1 (2%)			
Nephropathy	46 (92%)	49 (98%)	46 (92%)	49 (98%)
Renal Tubule, Accumulation, Hyaline Droplet	2 (4%)			1 (2%)
Renal Tubule, Mineralization				1 (2%)
Renal Tubule, Necrosis	1 (2%)	1 (2%)	2 (4%)	2 (4%)
Renal Tubule, Pigmentation	3 (6%)	1 (2%)	4 (8%)	4 (8%)
Transitional Epithelium, Hyperplasia		2 (4%)		
Urethra	(0)	(1)	(0)	(0)
Angiectasis		1 (100%)		
Urinary Bladder	(50)	(50)	(50)	(50)
Hemorrhage		1 (2%)		1 (2%)
Inflammation, Acute				1 (2%)

*** END OF MALE ***

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Goldenseal root powder
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 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)
Edema	1 (2%)			2 (4%)
Intestine Small, Jejunum	(46)	(47)	(48)	(50)
Epithelium, Hyperplasia				1 (2%)
Liver	(50)	(50)	(50)	(50)
Angiectasis		1 (2%)	2 (4%)	
Basophilic Focus	44 (88%)	44 (88%)	46 (92%)	27 (54%)
Clear Cell Focus	4 (8%)	5 (10%)	10 (20%)	2 (4%)
Cyst			1 (2%)	1 (2%)
Eosinophilic Focus	2 (4%)	24 (48%)	29 (58%)	22 (44%)
Hematopoietic Cell Proliferation	1 (2%)			
Hemorrhage		1 (2%)	1 (2%)	1 (2%)
Hepatodiaphragmatic Nodule	7 (14%)	17 (34%)	8 (16%)	9 (18%)
Infiltration Cellular, Mixed Cell	7 (14%)	7 (14%)	9 (18%)	11 (22%)
Mixed Cell Focus	6 (12%)	5 (10%)	13 (26%)	9 (18%)
Necrosis, Focal	1 (2%)			1 (2%)
Bile Duct, Hyperplasia	2 (4%)	4 (8%)	9 (18%)	3 (6%)
Centrilobular, Necrosis	1 (2%)		1 (2%)	
Hepatocyte, Degeneration	1 (2%)	2 (4%)	12 (24%)	24 (48%)
Hepatocyte, Hypertrophy	2 (4%)	10 (20%)	27 (54%)	38 (76%)
Hepatocyte, Vacuolization Cytoplasmic	4 (8%)	4 (8%)	1 (2%)	3 (6%)
Kupffer Cell, Pigmentation	1 (2%)	2 (4%)	1 (2%)	3 (6%)
Mesentery	(9)	(7)	(4)	(2)
Accessory Spleen		2 (29%)	2 (50%)	1 (50%)
Fat, Necrosis	9 (100%)	5 (71%)	3 (75%)	1 (50%)
Oral Mucosa	(0)	(0)	(1)	(0)
Ulcer			1 (100%)	
Pancreas	(49)	(50)	(50)	(50)
Atrophy	10 (20%)	17 (34%)	17 (34%)	14 (28%)
Cyst	4 (8%)	10 (20%)	6 (12%)	13 (26%)
Acinus, Cytoplasmic Alteration	1 (2%)	1 (2%)		1 (2%)

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

FISCHER 344 RATS FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Acinus, Hyperplasia, Focal		1 (2%)	1 (2%)	
Salivary Glands	(50)	(50)	(50)	(50)
Atrophy	7 (14%)		5 (10%)	3 (6%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Edema		1 (2%)	1 (2%)	2 (4%)
Ulcer	2 (4%)	2 (4%)		3 (6%)
Epithelium, Hyperplasia		2 (4%)	1 (2%)	2 (4%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Edema		1 (2%)		
Erosion	4 (8%)	2 (4%)	1 (2%)	2 (4%)
Ulcer				1 (2%)
Tongue	(1)	(0)	(0)	(1)
Inflammation, Granulomatous				1 (100%)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	24 (48%)	24 (48%)	21 (42%)	15 (30%)
Inflammation, Chronic	1 (2%)			
Thrombosis	1 (2%)	1 (2%)		
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Accessory Adrenal Cortical Nodule	3 (6%)	3 (6%)	9 (18%)	6 (12%)
Angiectasis			2 (4%)	1 (2%)
Degeneration, Fatty	9 (18%)	15 (30%)	11 (22%)	11 (22%)
Hematopoietic Cell Proliferation	1 (2%)			
Hyperplasia, Focal	5 (10%)	6 (12%)	4 (8%)	5 (10%)
Hypertrophy, Focal	1 (2%)	2 (4%)	6 (12%)	5 (10%)
Necrosis	1 (2%)	1 (2%)		2 (4%)
Adrenal Medulla	(48)	(50)	(49)	(50)
Hyperplasia	1 (2%)	2 (4%)	5 (10%)	7 (14%)
Infiltration Cellular, Mononuclear Cell		1 (2%)		
Islets, Pancreatic	(49)	(50)	(50)	(50)
Hyperplasia			1 (2%)	
Parathyroid Gland	(49)	(49)	(48)	(46)
Hyperplasia		1 (2%)		
Pituitary Gland	(50)	(50)	(50)	(50)
Infiltration Cellular, Mononuclear Cell		1 (2%)		
Pigmentation	1 (2%)			
Pars Distalis, Angiectasis	8 (16%)	7 (14%)	3 (6%)	8 (16%)
Pars Distalis, Cyst	30 (60%)	23 (46%)	27 (54%)	20 (40%)
Pars Distalis, Hyperplasia, Focal	13 (26%)	4 (8%)	12 (24%)	9 (18%)

FISCHER 344 RATS FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Pars Intermedia, Angiectasis	1 (2%)	1 (2%)		2 (4%)
Pars Intermedia, Cyst	3 (6%)			2 (4%)
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Hyperplasia	17 (34%)	5 (10%)	6 (12%)	5 (10%)
Follicle, Cyst		2 (4%)	2 (4%)	1 (2%)
Follicular Cell, Hyperplasia		2 (4%)		
GENERAL BODY SYSTEM				
Tissue NOS	(1)	(0)	(0)	(0)
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(49)	(50)
Cyst	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Hyperplasia	1 (2%)	2 (4%)		
Hyperplasia, Focal	1 (2%)	5 (10%)	6 (12%)	
Inflammation, Chronic		4 (8%)	2 (4%)	2 (4%)
Ovary	(50)	(50)	(50)	(49)
Cyst	8 (16%)	5 (10%)	14 (28%)	8 (16%)
Corpus Luteum, Vacuolization Cytoplasmic			1 (2%)	
Uterus	(50)	(50)	(50)	(50)
Cyst				1 (2%)
Decidual Reaction		1 (2%)		
Hemorrhage	1 (2%)			
Hyperplasia, Cystic	8 (16%)	9 (18%)	14 (28%)	13 (26%)
Inflammation, Suppurative			1 (2%)	
Cervix, Cyst, Squamous				1 (2%)
Myometrium, Hypertrophy			1 (2%)	
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Hyperplasia	10 (20%)	3 (6%)	5 (10%)	6 (12%)
Infiltration Cellular, Histiocyte		1 (2%)	1 (2%)	3 (6%)
Infiltration Cellular, Mixed Cell			1 (2%)	
Myelofibrosis	1 (2%)	1 (2%)		5 (10%)
Lymph Node	(9)	(7)	(7)	(8)
Hemorrhage	1 (11%)			
Pigmentation	1 (11%)			
Deep Cervical, Ectasia			1 (14%)	
Mediastinal, Hematopoietic Cell Proliferation	1 (11%)			
Mediastinal, Hemorrhage	5 (56%)	2 (29%)	4 (57%)	1 (13%)

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FISCHER 344 RATS FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Mediastinal, Hyperplasia, Lymphoid	4 (44%)	3 (43%)	1 (14%)	2 (25%)
Mediastinal, Pigmentation	2 (22%)	3 (43%)	2 (29%)	1 (13%)
Pancreatic, Hemorrhage	2 (22%)	2 (29%)		1 (13%)
Pancreatic, Pigmentation		1 (14%)		
Lymph Node, Mandibular	(2)	(3)	(3)	(5)
Ectasia		1 (33%)		
Hyperplasia, Lymphoid		1 (33%)		
Lymph Node, Mesenteric	(49)	(50)	(50)	(49)
Ectasia				1 (2%)
Hemorrhage	3 (6%)	1 (2%)	3 (6%)	3 (6%)
Hyperplasia, Lymphoid	15 (31%)	8 (16%)	10 (20%)	9 (18%)
Spleen	(49)	(50)	(50)	(50)
Accessory Spleen	2 (4%)			
Fibrosis		1 (2%)		2 (4%)
Hematopoietic Cell Proliferation	37 (76%)	34 (68%)	42 (84%)	35 (70%)
Hemorrhage				1 (2%)
Infiltration Cellular, Mixed Cell				3 (6%)
Necrosis				1 (2%)
Lymphoid Follicle, Atrophy				1 (2%)
Thymus	(49)	(50)	(49)	(49)
Atrophy		1 (2%)		1 (2%)
Cyst	1 (2%)		1 (2%)	
Hyperplasia, Lymphoid			1 (2%)	
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Hyperplasia	49 (98%)	46 (92%)	45 (90%)	34 (68%)
Skin	(50)	(49)	(50)	(50)
Cyst Epithelial Inclusion			1 (2%)	
Edema				1 (2%)
Hemorrhage	1 (2%)			
Hyperkeratosis	1 (2%)		1 (2%)	1 (2%)
Inflammation, Chronic			1 (2%)	
Ulcer	1 (2%)			
Epidermis, Hyperplasia	1 (2%)		1 (2%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Fracture	1 (2%)			
Osteopetrosis		1 (2%)		
Skeletal Muscle	(0)	(0)	(0)	(2)
Hemorrhage				1 (50%)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

FISCHER 344 RATS FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Inflammation, Suppurative				1 (50%)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Compression	9 (18%)	8 (16%)	3 (6%)	8 (16%)
Gliosis	1 (2%)			
Hemorrhage	2 (4%)		1 (2%)	2 (4%)
Necrosis	1 (2%)			1 (2%)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Edema	1 (2%)	1 (2%)		
Foreign Body		1 (2%)	1 (2%)	
Hemorrhage	6 (12%)		2 (4%)	10 (20%)
Hyperplasia, Lymphoid	1 (2%)			
Infiltration Cellular, Histiocyte	39 (78%)	34 (68%)	37 (74%)	39 (78%)
Inflammation, Chronic	18 (36%)	21 (42%)	19 (38%)	14 (28%)
Metaplasia, Osseous		2 (4%)	2 (4%)	2 (4%)
Alveolar Epithelium, Hyperplasia	7 (14%)	7 (14%)	5 (10%)	6 (12%)
Serosa, Hyperplasia		1 (2%)	1 (2%)	1 (2%)
Nose	(50)	(50)	(50)	(50)
Foreign Body	4 (8%)	3 (6%)	2 (4%)	2 (4%)
Inflammation, Chronic	2 (4%)		1 (2%)	2 (4%)
Respiratory Epithelium, Hyperplasia	1 (2%)			1 (2%)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Cataract	4 (8%)	2 (4%)	1 (2%)	2 (4%)
Retina, Degeneration	4 (8%)	2 (4%)	1 (2%)	2 (4%)
Harderian Gland	(50)	(50)	(50)	(49)
Hyperplasia, Focal	2 (4%)			
Inflammation, Chronic				2 (4%)
Zymbal's Gland	(0)	(0)	(1)	(0)
URINARY SYSTEM				
Kidney	(49)	(50)	(50)	(50)
Cyst	1 (2%)		1 (2%)	
Glomerulosclerosis				1 (2%)

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

TDMS No. 99007 - 05

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/F 344

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Goldenseal root powder

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

Lab: SRI

FISCHER 344 RATS FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Infarct		1 (2%)		
Infiltration Cellular, Mononuclear Cell		1 (2%)		
Inflammation, Suppurative	1 (2%)		1 (2%)	
Metaplasia, Osseous	1 (2%)			
Nephropathy	36 (73%)	24 (48%)	33 (66%)	45 (90%)
Papilla, Necrosis	1 (2%)			
Renal Tubule, Accumulation, Hyaline Droplet	2 (4%)		1 (2%)	1 (2%)
Renal Tubule, Necrosis	1 (2%)			1 (2%)
Renal Tubule, Pigmentation	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Transitional Epithelium, Hyperplasia	2 (4%)		2 (4%)	
Urinary Bladder	(50)	(49)	(50)	(50)
Edema	1 (2%)			
Transitional Epithelium, Hyperplasia	1 (2%)			

*** END OF REPORT ***