

**Experiment Number:** 99007-03

**Test Type:** 90-DAY

**Species/Strain:** Rat/F 344/N

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]**

**Test Compound:** Goldenseal root powder

**CAS Number:** GOLDENSEALRT

**Date Report Requested:** 10/16/2014

**Time Report Requested:** 02:33:13

**First Dose M/F:** NA / NA

**Lab:** SRI

<b>C Number:</b>	C99007B
<b>Lock Date:</b>	09/23/2002
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Both
<b>PWG Approval Date</b>	NONE

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Lab: SRI

F 344/N Rat MALE	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Disposition Summary</b>						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Fatty Change	1 [1.0]					
Hematopoietic Cell Proliferation, Focal	1 [1.0]		3 [1.0]	3 [1.0]		3 [1.0]
Hepatocyte, Hypertrophy			2 [1.0]	9 [1.0]	10 [1.3]	10 [1.8]
Hepatocyte, Vacuolization Cytoplasmic	1 [1.0]	10 [1.0]	10 [1.0]	10 [1.0]	10 [1.0]	10 [1.0]
Hepatodiaphragmatic Nodule		2 [2.0]	2 [2.0]		1 [2.0]	
Inflammation, Chronic, Focal				1 [1.0]	1 [1.0]	
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Acinus, Atrophy, Focal	2 [1.5]					2 [1.5]
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Parotid Gl, Basophilic Focus, Multiple	7 [1.0]					7 [1.0]
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
Tooth	(0)	(0)	(1)	(0)	(0)	(0)

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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First Dose M/F: NA / NA

Lab: SRI

F 344/N Rat MALE	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
Malformation			1 [2.0]			
<b>CARDIOVASCULAR SYSTEM</b>						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy, Focal	2 [1.0]					3 [1.0]
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Ultimobranchial Cyst	1 [1.0]					3 [1.0]
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
Duct, Ectasia	1 [2.0]					
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(1)	(0)	(0)	(0)	(10)
Atrophy		1 [3.0]				
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node	(0)	(0)	(1)	(0)	(0)	(0)
Mediastinal, Hyperplasia, Lymphoid			1 [2.0]			
Lymph Node, Mandibular	(1)	(0)	(0)	(0)	(0)	(0)
Hemorrhage	1 [2.0]					

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Lab: SRI

F 344/N Rat MALE	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(1)	(0)	(0)	(10)
Accessory Spleen			1 [1.0]			
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(8)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Alveolus, Infiltration Cellular, Histiocyte, Focal						1 [1.0]
Hemorrhage	1 [2.0]					
Inflammation, Chronic, Focal						1 [1.0]
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(0)	(0)	(1)	(0)	(10)
Atrophy				1 [2.0]		
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Lymphocyte						1 [2.0]
<b>URINARY SYSTEM</b>						
Kidney	(10)	(0)	(1)	(0)	(0)	(10)
Nephropathy	3 [1.0]					1 [1.0]

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<b>F 344/N Rat MALE</b>	<b>0 PPM</b>	<b>3125 PPM</b>	<b>6250 PPM</b>	<b>12500 PPM</b>	<b>25000 PPM</b>	<b>50000 PPM</b>
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

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\*\*\*END OF MALE DATA\*\*\*

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

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<b>Disposition Summary</b>						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Hepatocyte, Hypertrophy			3 [1.0]	10 [1.0]	10 [1.9]	10 [2.0]
Hepatodiaphragmatic Nodule	1 [2.0]			2 [2.0]		
Infiltration Cellular, Lymphocyte, Focal	1 [1.0]					
Inflammation, Chronic, Focal	1 [1.0]		2 [1.0]	1 [1.0]		1 [1.0]
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Parotid G1, Basophilic Focus, Multiple	1 [1.0]					6 [1.0]
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Lymphocyte, Focal						1 [2.0]
<b>CARDIOVASCULAR SYSTEM</b>						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy, Focal						1 [1.0]

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<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Accessory Adrenal Cortical Nodule	1 [2.0]					
Hyperplasia, Focal						1 [2.0]
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Rathkes Cleft, Cyst						1 [1.0]
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Ultimobranchial Cyst	2 [1.0]					2 [1.0]
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Ovary	(10)	(0)	(0)	(1)	(1)	(10)
Cyst				1 [2.0]	1 [2.0]	1 [1.0]
Uterus	(10)	(0)	(0)	(0)	(0)	(10)
Cervix, Cyst						1 [2.0]
Hydrometra	3 [2.0]					
Vagina	(0)	(0)	(1)	(0)	(0)	(0)
Cyst			1 [3.0]			
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node	(2)	(0)	(0)	(0)	(0)	(0)
Pancreatic, Hemorrhage	2 [2.0]					
Pancreatic, Infiltration Cellular, Histiocyte	1 [2.0]					
Lymph Node, Mandibular	(2)	(0)	(0)	(0)	(0)	(0)

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Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(1)	(0)	(0)	(10)
Alveolus, Infiltration Cellular, Histiocyte, Focal						1 [1.0]
Hemorrhage			1 [2.0]			
Perivascular, Edema			1 [2.0]			
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Nephropathy	1 [1.0]					
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

**\*\* END OF REPORT \*\***

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)