

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

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DAY ON TEST	0 0																								
	5 6 6 5 5 7 7 7 7 7 7 7 6 7 7 7 7 4 4 4 7 5 7 7 7																								
7 1 5 0 7 2 3 3 3 3 3 3 0 0 3 3 3 0 5 2 2 9 3 3 3																									
1 1 6 1 5 9 1 1 1 0 0 0 0 6 0 0 0 7 6 2 9 3 0 0 0																									
<b>FISCHER 344 RATS MALE</b> <b>0 PPM</b>	ANIMAL ID																								
	0 0																								
	0 0																								
	0 0																								
	1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 2 2 2																								

males  
(cont...)

**ALIMENTARY SYSTEM**

Esophagus	+ +																								
Intestine Large, Cecum Edema	+ A + + + + + + +																								
Intestine Large, Colon	+ +																								
Intestine Large, Rectum	+ +																								
Intestine Small, Duodenum	+ A + + + + + + +																								
Intestine Small, Ileum	+ M + + + + + A + + + + + + +																								
Intestine Small, Jejunum	+ A + + + + + A + + + + + + +																								
Liver	+ +																								
Atrophy, Focal																									
Basophilic Focus	X X																								
Clear Cell Focus	X X																								
Degeneration, Cystic	1 2 2																								
Eosinophilic Focus	X																								
Hemorrhage																									
Hepatodiaphragmatic Nodule	X X																								
Infiltration Cellular, Mixed Cell	2 1																								
Mixed Cell Focus	X X																								

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
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 I .. Insufficient tissue  
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 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
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DAY ON TEST	ANIMAL ID																									males (cont...)
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
5	6	6	5	5	7	7	7	7	7	7	7	6	7	7	7	7	4	4	4	7	5	7	7	7	0	
7	1	5	0	7	2	3	3	3	3	3	3	0	0	3	3	3	0	5	2	2	9	3	3	3	0	
1	1	6	1	5	9	1	1	1	0	0	0	0	6	0	0	0	7	6	2	9	3	0	0	0	0	
<hr/>																										
<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	1	2	3	4	5	6	7	8	9	0	1	1	1	1	1	1	1	1	1	2	2	2	2	2	0	
<hr/>																										
Necrosis, Focal	3	1	3	1	1	1	1	2	1	2	1	3	2		1	3	2				2	1	2	3	2	
Bile Duct, Hyperplasia																										
Hepatocyte, Hyperplasia, Focal																										
Hepatocyte, Vacuolization Cytoplasmic																										
Kupffer Cell, Pigmentation	3																				3					
<hr/>																										
Mesentery																										
Accessory Spleen																										
Inflammation, Chronic																										
Fat, Necrosis																										
<hr/>																										
Oral Mucosa																										
<hr/>																										
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Atrophy		4	2		2				2		1			3	1		1	3	1					1		
Cyst		X	X		X									X												
Acinus, Cytoplasmic Alteration																										
Acinus, Hyperplasia, Focal				2			2							1							3					
<hr/>																										
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Atrophy																										
<hr/>																										
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Edema	3		3																							
Ulcer	3		4	4																						
Epithelium, Hyperplasia	2		2	4																						
<hr/>																										
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Erosion	1		2																							

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DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	5	6	6	5	5	7	7	7	7	7	7	7	6	7	7	7	7	4	4	4	4	7	5	7	7	7	
	7	1	5	0	7	2	3	3	3	3	3	3	0	0	3	3	3	0	5	2	2	9	3	3	3		
	1	1	6	1	5	9	1	1	1	0	0	0	0	6	0	0	0	7	6	2	9	3	0	0	0		
.....																											
<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5		
	<b>males (cont...)</b>																										

Epithelium, Hyperplasia 1

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Tongue  
Epithelium, Hyperplasia +

**CARDIOVASCULAR SYSTEM**

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Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cardiomyopathy		1	1	2	3	2	1	3	1	3	2	1	1	3	1	1	3	1	1	3	1	3		3	3
Thrombosis																									

**ENDOCRINE SYSTEM**

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Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Accessory Adrenal Cortical Nodule				3					3				3						3	3			3	3			
Hyperplasia	3	3						2					2			2				1				2			
Hyperplasia, Focal																					2						
Hypertrophy, Focal		2									1																
Necrosis																											
Vacuolization Cytoplasmic, Focal														1													
.....																											
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Hyperplasia													2									1		+	+	+	
.....																											
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Hyperplasia																											

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DAY ON TEST	0 0																									
	5 6 6 5 5 7 7 7 7 7 7 7 6 7 7 7 7 4 4 4 7 5 7 7 7																									
FISCHER 344 RATS MALE ANIMAL ID	7 1 5 0 7 2 3 3 3 3 3 3 0 0 3 3 3 0 5 2 2 9 3 3 3																									
	1 1 6 1 5 9 1 1 1 0 0 0 0 6 0 0 0 7 6 2 9 3 0 0 0																									
0 PPM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	males (cont...)
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	1	2	3	4	5	6	7	8	9	0	1	1	1	1	1	1	1	1	1	2	2	2	2	2		

Parathyroid Gland	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Pars Distalis, Angiectasis																							2	
Pars Distalis, Cyst																								
Pars Distalis, Hemorrhage, Chronic																								
Pars Distalis, Hyperplasia, Focal			3											1		1						1		2
Pars Intermedia, Cyst															X							X		
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
C-cell, Hyperplasia	1			1							2					1						3		
Follicle, Cyst				X																				

**GENERAL BODY SYSTEM**  
 NONE

**GENITAL SYSTEM**

Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Granuloma Sperm																								
Inflammation, Chronic																								3
Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyst																								
Hyperplasia				X																				
Hyperplasia, Focal																								
Inflammation, Chronic										2		2		2		2					2		2	2

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	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
5	6	6	5	5	7	7	7	7	7	7	7	7	6	7	7	7	7	4	4	4	7	5	7	7	7	
7	1	5	0	7	2	3	3	3	3	3	3	0	0	3	3	3	0	5	2	2	9	3	3	3		
1	1	6	1	5	9	1	1	1	1	0	0	0	0	6	0	0	0	7	6	2	9	3	0	0		

FISCHER 344 RATS MALE

0 PPM

ANIMAL ID

males  
(cont...)

Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Inflammation, Chronic	3													2				3						2	2
Epithelium, Hyperplasia								1								1							1		
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Germinal Epithelium, Atrophy																									4
Interstitial Cell, Hyperplasia	1																							1	

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+
Hemorrhage																									
Hyperplasia										2						4				4					
Myelofibrosis													4												
Lymph Node	+			+			+	+					+											+	
Deep Cervical, Hyperplasia																									
Mediastinal, Ectasia																									
Mediastinal, Hemorrhage																									3
Mediastinal, Hyperplasia, Lymphoid				2																					3
Pancreatic, Hemorrhage								1																	
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M	M	M	M	+	M	M	M	M	M	M	M	M	M	M	M
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+
Ectasia																									

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DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	6	6	5	5	7	7	7	7	7	7	7	6	7	7	7	7	4	4	4	7	5	7	7	7
	7	1	5	0	7	2	3	3	3	3	3	3	0	0	3	3	3	0	5	2	2	9	3	3	3
	1	1	6	1	5	9	1	1	1	0	0	0	0	6	0	0	0	7	6	2	9	3	0	0	0

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FISCHER 344 RATS MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0 PPM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5

**males (cont...)**

Hyperplasia, Lymphoid	3						3																		
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+
Fibrosis			3																						
Hematopoietic Cell Proliferation												3							3						
Thymus	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia, Lymphoid																									

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia	3										2	2				2									2
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyst Epithelial Inclusion																									X
Hyperkeratosis								4					3												
Inflammation, Chronic																									
Ulcer																		4							
Epidermis, Hyperplasia								3				2													

**MUSCULOSKELETAL SYSTEM**

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Skeletal Muscle																	+			+					+
Atrophy																2									

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DAY ON TEST	Animals																									males (cont...)
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
5	6	6	5	5	7	7	7	7	7	7	7	6	7	7	7	7	4	4	4	7	5	7	7	7	0	
7	1	5	0	7	2	3	3	3	3	3	3	0	0	3	3	3	0	5	2	2	9	3	3	3	0	
1	1	6	1	5	9	1	1	1	0	0	0	0	6	0	0	0	7	6	2	9	3	0	0	0	0	

  

FISCHER 344 RATS MALE	Animals																									males (cont...)
0 PPM	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1	2	3	4	5	6	7	8	9	0	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	

**NERVOUS SYSTEM**

Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Compression														3										
Hemorrhage																						3	3	
Necrosis					2																			
Peripheral Nerve														+								+	+	
Spinal Cord														+								+	+	

**RESPIRATORY SYSTEM**

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyst																								
Emphysema																								
Hemorrhage																							2	
Infiltration Cellular, Histiocyte				1			1	1	1	1	3	1			1	1	1	3			1	1	1	1
Inflammation, Chronic					2				2		3							3				1		2
Metaplasia, Osseous							1			1		1				2								
Alveolar Epithelium, Hyperplasia							3									2							1	1
Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Foreign Body		X								X			X											X
Inflammation, Chronic		2			1	1				1										1	1			1
Respiratory Epithelium, Hyperplasia		2				1																		

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 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

DAY ON TEST	ANIMAL ID																									males (cont...)
	0 5 7 1	0 6 1 1	0 6 5 6	0 5 7 1	0 5 2 5	0 7 3 9	0 7 3 1	0 7 3 1	0 7 3 1	0 7 3 0	0 7 3 0	0 6 0 0	0 7 3 0	0 7 3 0	0 7 3 0	0 4 0 7	0 4 5 6	0 4 2 2	0 7 2 9	0 5 3 3	0 7 3 0	0 7 3 0	0 7 3 0			
<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	2	2	2	2	2	2			
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	

Respiratory Epithelium, Metaplasia,  
Squamous

Trachea +

**SPECIAL SENSES SYSTEM**

Eye +  
 Cataract 3  
 Retina, Degeneration 3

Harderian Gland +  
 Hyperplasia, Focal

**URINARY SYSTEM**

Kidney +  
 Inflammation, Suppurative  
 Nephropathy 2 1 1 2 1 1 1 1 1 2 1 1 3 1 1 1 1 1 1 1 1 1 1  
 Renal Tubule, Accumulation, Hyaline Droplet 3  
 Renal Tubule, Necrosis  
 Renal Tubule, Pigmentation 2 2

Urinary Bladder +

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 Page 9



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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

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

DAY ON TEST	0																								* TOTALS
	7	7	7	7	5	7	7	7	5	5	7	7	7	7	7	7	7	7	6	7	7	7	7	7	
	3	3	3	3	8	3	3	3	6	6	3	1	3	3	3	3	3	3	6	2	2	2	3	1	
	0	0	0	0	3	0	0	0	1	3	1	1	0	0	0	0	0	0	3	9	9	9	0	6	
<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	5	
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
Necrosis, Focal									3																
Bile Duct, Hyperplasia	2	1	1	2	3	1		2		1	1	2	1	3		3	1	2	2	3	1	1	3	2	3
Hepatocyte, Hyperplasia, Focal																2									
Hepatocyte, Vacuolization Cytoplasmic																			3		2				
Kupffer Cell, Pigmentation																									
Mesentery										+					+										9
Accessory Spleen																						X			3
Inflammation, Chronic													3												1
Fat, Necrosis								2								3									4
Oral Mucosa												+													1
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Atrophy	3		2				2	1					1										1	2	19
Cyst	X	X													X		X	X	X						10
Acinus, Cytoplasmic Alteration																									1
Acinus, Hyperplasia, Focal					2							2									1				6
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Atrophy					1			1		3										3					4
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Edema																									2
Ulcer																									3
Epithelium, Hyperplasia																			1		2				5
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Erosion													1												3

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

DAY ON TEST		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
FISCHER 344 RATS MALE		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
0 PPM		2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5	
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
		* TOTALS																								

Epithelium, Hyperplasia	1	3	3	1.7
Tongue	+	2	1	1.0
Epithelium, Hyperplasia	1	1	1	1.0

CARDIOVASCULAR SYSTEM

Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	47	2.0
Cardiomyopathy	3	1	1	2	1	3	1	2	3	3	3	1	3	1	3	3	2	2	2	3	1	1	2			1	3.0
Thrombosis	3																										

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	17	3.0	
Accessory Adrenal Cortical Nodule			3						3	3	3	3				3	3	3	3									
Hyperplasia										2							2						2					
Hyperplasia, Focal												2									1							
Hypertrophy, Focal																												
Necrosis								4																				
Vacuolization Cytoplasmic, Focal															1													
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49	5	1.4	
Hyperplasia	1	1									1													2				
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	1	1.0	
Hyperplasia							1																					

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

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

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	* TOTALS
	7	7	7	7	5	7	7	7	5	5	7	7	7	7	7	7	7	7	6	7	7	7	7	7		
	3	3	3	3	8	3	3	3	6	6	3	1	3	3	3	3	3	3	6	2	2	2	3	1		
	0	0	0	0	3	0	0	0	1	3	1	1	0	0	0	0	0	0	3	9	9	9	0	6		
<b>FISCHER 344 RATS MALE</b>																										
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2	2	2	2	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	4	5	
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49	
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Pars Distalis, Angiectasis																							2		2 2.0	
Pars Distalis, Cyst		X		X		X		X		X		X							X		X				7 1.0	
Pars Distalis, Hemorrhage, Chronic											1														1 1.0	
Pars Distalis, Hyperplasia, Focal		1									1	2	3	3		1				2		1		3	14 1.8	
Pars Intermedia, Cyst		X																							3	
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
C-cell, Hyperplasia														1					1					1	8 1.4	
Follicle, Cyst																X			X						3	

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Granuloma Sperm																											1 3.0	
Inflammation, Chronic							3																				1 3.0	
Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Cyst													X														2	
Hyperplasia																2				1							2 1.5	
Hyperplasia, Focal																								2			1 2.0	
Inflammation, Chronic	2	3	2				2								3	2				2	2		2	2			19 2.1	

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DAY ON TEST		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		7	7	7	7	5	7	7	7	5	5	7	7	7	7	7	7	7	6	7	7	7	7	7	7
		3	3	3	3	8	3	3	3	6	6	3	1	3	3	3	3	3	3	6	2	2	2	3	1
		0	0	0	0	3	0	0	0	1	3	1	1	0	0	0	0	0	0	3	9	9	9	0	6
<b>FISCHER 344 RATS MALE</b>	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	<b>0 PPM</b>	2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	5	
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
		<b>* TOTALS</b>																							

Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Inflammation, Chronic			2			2																			12 2.0
Epithelium, Hyperplasia																	2				1	3	1		4 1.3
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Germinal Epithelium, Atrophy																									5 3.2
Interstitial Cell, Hyperplasia	1														3	4									2 1.0

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Hemorrhage	2																								1 2.0
Hyperplasia													3												4 3.3
Myelofibrosis						3																			2 3.5
Lymph Node						+					+	+					+								11
Deep Cervical, Hyperplasia																									1 3.0
Mediastinal, Ectasia																									1 4.0
Mediastinal, Hemorrhage																									1 3.0
Mediastinal, Hyperplasia, Lymphoid																									3 2.7
Pancreatic, Hemorrhage																									1 1.0
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	1
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Ectasia																									2 2.5

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

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DAY ON TEST		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		7	7	7	7	5	7	7	7	5	5	7	7	7	7	7	7	7	7	6	7	7	7	7
		3	3	3	3	8	3	3	3	6	6	3	1	3	3	3	3	3	3	6	2	2	2	3
		0	0	0	0	3	0	0	0	1	3	1	1	0	0	0	0	0	0	3	9	9	9	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	2	2	2	3	3	3	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

**FISCHER 344 RATS MALE**

**0 PPM**

ANIMAL ID

**\* TOTALS**

Hyperplasia, Lymphoid																								3	3	4	3.0
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49			
Fibrosis																										1	3.0
Hematopoietic Cell Proliferation																										2	3.0
Thymus	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	48			
Hyperplasia, Lymphoid																								3		1	3.0

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50					
Hyperplasia																										2	2	7	2.1
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50					
Cyst Epithelial Inclusion																												1	
Hyperkeratosis																								3	2	4	3.0		
Inflammation, Chronic																								2		2	2.5		
Ulcer																										3	4.0		
Epidermis, Hyperplasia																								3	2	5	2.6		

**MUSCULOSKELETAL SYSTEM**

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50					
Skeletal Muscle																										3			
Atrophy																										1	2.0		

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**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

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 Lab: SRI

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7	7	7	7	5	7	7	7	5	5	7	7	7	7	7	7	7	7	7	6	7	7	7	7	7
	3	3	3	3	8	3	3	3	6	6	3	1	3	3	3	3	3	3	3	6	2	2	2	3	1
	0	0	0	0	3	0	0	0	1	3	1	1	0	0	0	0	0	0	0	3	9	9	9	0	6
<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
	<b>* TOTALS</b>																								

**NERVOUS SYSTEM**

Brain	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	49
Compression																									2 3.0
Hemorrhage																									2 3.0
Necrosis																									1 2.0
Peripheral Nerve																							+		4
Spinal Cord																							+		4

**RESPIRATORY SYSTEM**

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Cyst												X													1
Emphysema	2																								1 2.0
Hemorrhage																									1 2.0
Infiltration Cellular, Histiocyte	2	1		1		1	1	1	2	1	1	1	1	1				1	1		1	1	1	2	34 1.2
Inflammation, Chronic		1	1			2	1					1	2					1	1		3	1			16 1.7
Metaplasia, Osseous												1													5 1.2
Alveolar Epithelium, Hyperplasia	1						3								1					2					8 1.8
Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Foreign Body																		X	X						6
Inflammation, Chronic							1																	1	12 1.3
Respiratory Epithelium, Hyperplasia																			2	1				1	5 1.4

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 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

DAY ON TEST	0 0																								
	7 7 7 7 5 7 7 7 5 5 7 7 7 7 7 7 7 7 6 7 7 7 7 7																								
FISCHER 344 RATS MALE ANIMAL ID	3 3 3 3 8 3 3 3 6 6 3 1 3 3 3 3 3 3 6 2 2 2 3 1																								
	0 0 0 0 3 0 0 0 1 3 1 1 0 0 0 0 0 0 3 9 9 9 0 6																								
0 PPM	0 0																								
	0 0																								
	2 2 2 2 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 4 5																								
	6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0																								
		<b>* TOTALS</b>																							

Respiratory Epithelium, Metaplasia, Squamous	1	1	2 1.0																						
Trachea	+ +																								50

**SPECIAL SENSES SYSTEM**

Eye	+ +																								50	
Cataract																									3	2 3.0
Retina, Degeneration																									4	2 3.5
Harderian Gland	+ +																								50	
Hyperplasia, Focal	1																								1 1.0	

**URINARY SYSTEM**

Kidney	+ +																								50	
Inflammation, Suppurative	1																								1 1.0	
Nephropathy	1 1 1 1 1 1 1 1 1 1 3 2 1 1 2 1 1 1 1 1 1 1 1 1																								46 1.2	
Renal Tubule, Accumulation, Hyaline Droplet	4																								2 3.5	
Renal Tubule, Necrosis																									1	1 1.0
Renal Tubule, Pigmentation																									4	3 2.7
Urinary Bladder	+ +																								50	

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DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	5	7	6	6	6	7	7	7	5	7	5	6	7	3	7	7	7	7	6	7	6	7	6
	0	6	3	9	4	5	2	2	2	3	3	7	3	2	5	3	3	3	3	7	3	4	3	3
	6	5	0	6	5	6	9	9	9	0	1	6	2	9	5	0	0	0	0	8	0	2	1	1

  

FISCHER 344 RATS MALE 3000 PPM	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7
	6	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	7	7	7	7	
	7	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	
	8	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	
	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	
	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	
	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7	
	6	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7	

males (cont...)

ALIMENTARY SYSTEM

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Cecum Edema	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
						2																		
Intestine Large, Colon	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Ileum	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Jejunum	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Angiectasis																								
Basophilic Focus				X	X		X	X	X		X	X		X	X	X	X	X		X	X		X	
Clear Cell Focus							X	X		X				X	X	X	X		X	X				
Degeneration, Cystic																		1						3
Eosinophilic Focus				X		X											X					X		
Hematopoietic Cell Proliferation												1												
Hemorrhage	4							2																
Hepatodiaphragmatic Nodule				X		X				X	X											X		
Infiltration Cellular, Mixed Cell								1										1		1				

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

DAY ON TEST	0 0																									males (cont...)	
	5 5 7 6 6 6 7 7 7 5 7 5 6 7 3 7 7 7 7 6 7 6 7 7 6																										
FISCHER 344 RATS MALE 3000 PPM ANIMAL ID	0 0																									males (cont...)	
	0 0																										
																									1		
Mixed Cell Focus			X	X			X	X	X		X								X		X						
Necrosis, Focal																											
Bile Duct, Hyperplasia		2	1	1	1	1		1	1		1		1	1	3	1	2	2		2		2	1	2	3		
Centrilobular, Necrosis	4																										
Hepatocyte, Degeneration			1	1			1	1	1									1	1			1	1				
Hepatocyte, Hypertrophy									1		1						1	1	2				1				
Hepatocyte, Vacuolization Cytoplasmic															3										3		
Mesentery	+			+										+					+					+			
Fat, Necrosis	4			3										2					3								
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Atrophy					2													2	2		3	2	1		2	4	
Cyst				X						X	X									X	X	X					
Acinus, Cytoplasmic Alteration										3																	
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Atrophy																2											
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Edema						2																					
Erosion						1																					
Inflammation, Chronic Active																											
Ulcer											3		3		3										3		
Epithelium, Hyperplasia			1								2		3												3		
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Erosion						1											3										
Ulcer											3														3		

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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**

DAY ON TEST	0 0																								
	5	5	7	6	6	6	7	7	7	5	7	5	6	7	3	7	7	7	7	6	7	6	7	7	6
	0	6	3	9	4	5	2	2	2	3	3	7	3	2	5	3	3	3	3	7	3	4	3	3	8
	6	5	0	6	5	6	9	9	9	0	1	6	2	9	5	0	0	0	0	8	0	2	1	1	4
<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>3000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>ANIMAL ID</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
																								<b>males (cont...)</b>	

Tongue +

**CARDIOVASCULAR SYSTEM**

Blood Vessel

Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Cardiomyopathy	3	1	2	1	2		3	3	1	1		1		1	1		2	3	3	1	3		3	3	2

**ENDOCRINE SYSTEM**

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Accessory Adrenal Cortical Nodule							3										3		3					
Degeneration, Fatty																								
Hyperplasia																								2
Hyperplasia, Focal											1													
Hypertrophy, Focal																								
Vacuolization Cytoplasmic, Focal									2		1													
Vacuolization Cytoplasmic, Diffuse															3									
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia							2											1						1
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia																								

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

DAY ON TEST	ANIMAL ID																									males (cont...)
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
5	5	7	6	6	6	7	7	7	5	7	5	6	7	3	7	7	7	7	6	7	6	7	7	6	0	
0	6	3	9	4	5	2	2	2	3	3	7	3	2	5	3	3	3	3	7	3	4	3	3	8	0	
6	5	0	6	5	6	9	9	9	0	1	6	2	9	5	0	0	0	0	8	0	2	1	1	4	0	

**FISCHER 344 RATS MALE**  
**3000 PPM**

Parathyroid Gland	+	M	+	+	+	+	+	+	+	+	+	+	+	M	+	M	+	+	+	+	+	+	+	+	+
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Pars Distalis, Angiectasis											1			4											
Pars Distalis, Hyperplasia, Focal											2								3		2				
Pars Intermedia, Cyst																							X		
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
C-cell, Hyperplasia																									
Follicle, Cyst		1								2															

**GENERAL BODY SYSTEM**

Tissue NOS																									
Hemorrhage																									

**GENITAL SYSTEM**

Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Inflammation, Acute																									
Inflammation, Chronic																								2	
Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyst																									
Hyperplasia, Focal																									
Inflammation, Chronic																									

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 Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

DAY ON TEST	ANIMAL ID																									males (cont...)	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
5	5	7	6	6	6	7	7	7	5	7	5	6	7	3	7	7	7	7	6	7	6	7	7	6	0		
0	6	3	9	4	5	2	2	2	3	3	7	3	2	5	3	3	3	3	7	3	4	3	3	8	0		
6	5	0	6	5	6	9	9	9	0	1	6	2	9	5	0	0	0	0	8	0	2	1	1	4	0		
<hr/>																											
<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
<b>3000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7			
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5		

Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Inflammation, Chronic												3						2	3		3						
Epithelium, Hyperplasia														1											4		
<hr/>																											
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
<hr/>																											
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Germinal Epithelium, Atrophy											2							4									
Interstitial Cell, Hyperplasia					2															1				1			

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Hyperplasia												4												2			
Myelofibrosis																								2			
<hr/>																											
Lymph Node																											
Mediastinal, Hemorrhage					+						+													+			
Mediastinal, Hyperplasia, Lymphoid																											
Mediastinal, Pigmentation																											
Pancreatic, Ectasia																											
Pancreatic, Hyperplasia, Lymphoid																											
<hr/>																											
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M		
<hr/>																											
Lymph Node, Mesenteric	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Ectasia																											
Hemorrhage																									1		

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 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

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

DAY ON TEST		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		5	5	7	6	6	6	7	7	7	5	7	5	6	7	3	7	7	7	7	6	7	6	7	7	6
		0	6	3	9	4	5	2	2	2	3	3	7	3	2	5	3	3	3	3	7	3	4	3	3	8
		6	5	0	6	5	6	9	9	9	0	1	6	2	9	5	0	0	0	0	8	0	2	1	1	4
<b>FISCHER 344 RATS MALE</b>		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>3000 PPM</b>		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5

males (cont...)

Hyperplasia, Lymphoid Infiltration Cellular, Mixed Cell

2 2 2

Spleen  
 Accessory Spleen  
 Fibrosis  
 Hematopoietic Cell Proliferation  
 Infiltration Cellular, Mixed Cell  
 Metaplasia, Lipocyte

+  
 X  
 2 2 1 2 1 2  
 2

Thymus  
 Cyst  
 Fibrosis  
 Epithelial Cell, Hyperplasia

+ + + + + + + + + + + + + + + + M + + + + + + +

**INTEGUMENTARY SYSTEM**

Mammary Gland  
 Hyperplasia

+  
 3 2 3

Skin  
 Cyst Epithelial Inclusion  
 Edema  
 Hyperkeratosis

+  
 X  
 2 3  
 4

**MUSCULOSKELETAL SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                                    | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  | 5 5 7 6 6 6 7 7 7 5 7 5 6 7 3 7 7 7 7 6 7 6 7 7 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS MALE<br>3000 PPM<br>ANIMAL ID | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

males  
(cont...)

|                 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-----------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Bone            | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Skeletal Muscle | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**NERVOUS SYSTEM**

|                  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Brain            | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Angiectasis      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Compression      | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hemorrhage       | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Necrosis         | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Peripheral Nerve | + + +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Spinal Cord      | + + +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**RESPIRATORY SYSTEM**

|                                   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Lung                              | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Foreign Body                      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hemorrhage                        | 2 2 3 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Infiltration Cellular, Histiocyte | 3 1 1 3 1 1 3 1 1 1 1                             |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Inflammation, Suppurative         | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Inflammation, Chronic             | 1 1 1 1 1 1 1 1 1 1 1                             |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Metaplasia, Osseous               | 1 1 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Alveolar Epithelium, Hyperplasia  | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
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 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
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 Lab: SRI

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|             | 5 | 5 | 7 | 6 | 6 | 6 | 7 | 7 | 7 | 5 | 7 | 5 | 6 | 7 | 3 | 7 | 7 | 7 | 7 | 6 | 7 | 6 | 7 | 7 | 6 | 7 | 6 |
|             | 0 | 6 | 3 | 9 | 4 | 5 | 2 | 2 | 2 | 3 | 3 | 7 | 3 | 2 | 5 | 3 | 3 | 3 | 3 | 7 | 3 | 4 | 3 | 3 | 3 | 8 |   |
|             | 6 | 5 | 0 | 6 | 5 | 6 | 9 | 9 | 9 | 0 | 1 | 6 | 2 | 9 | 5 | 0 | 0 | 0 | 0 | 8 | 0 | 2 | 1 | 1 | 1 | 4 |   |

  

| FISCHER 344 RATS MALE<br>3000 PPM<br>ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  | 0 |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|---|
|  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  | 0 |
|  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  | 0 |
|  | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7                  | 7 |
|  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   | males<br>(cont...) |   |

|                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nose                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Foreign Body                        |   |   |   |   | X |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |
| Inflammation, Chronic               | 1 |   |   |   | 1 |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |
| Respiratory Epithelium, Hyperplasia |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Trachea                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

### SPECIAL SENSES SYSTEM

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Retina, Degeneration  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Harderian Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

### URINARY SYSTEM

|                                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney                               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst                                 |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Nephropathy                          | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
| Renal Tubule, Necrosis               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Renal Tubule, Pigmentation           |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Transitional Epithelium, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |
| Urethra                              |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Angiectasis                          |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

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1-4 .. Lesion qualified as:

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|                              | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
|------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|
|                              | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |
|                              | 5           | 5 | 7 | 6 | 6 | 6 | 7 | 7 | 7 | 5 | 7 | 5 | 6 | 7 | 3 | 7 | 7 | 7 | 7 | 6 | 7 | 6 | 7 | 7 | 6                  |
|                              | 0           | 6 | 3 | 9 | 4 | 5 | 2 | 2 | 2 | 3 | 3 | 7 | 3 | 2 | 5 | 3 | 3 | 3 | 3 | 7 | 3 | 4 | 3 | 3 | 8                  |
|                              | 6           | 5 | 0 | 6 | 5 | 6 | 9 | 9 | 9 | 0 | 1 | 6 | 2 | 9 | 5 | 0 | 0 | 0 | 0 | 8 | 0 | 2 | 1 | 1 | 4                  |
| <b>FISCHER 344 RATS MALE</b> | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |
| ANIMAL ID                    | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |
| 3000 PPM                     | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |
|                              | 5           | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7                  |
|                              | 1           | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5                  |
|                              |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | males<br>(cont...) |

Urinary Bladder  
Hemorrhage

+  
1

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

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 Lab: SRI

| DAY ON TEST                  | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                              | 7               | 7 | 7 | 5 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 6 | 7 | 7 | 5 | 6 |   |   |
|                              | 3               | 3 | 1 | 1 | 2 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 6 | 3 | 3 | 0 | 4 |
|                              | 1               | 1 | 1 | 7 | 9 | 3 | 9 | 9 | 9 | 9 | 9 | 1 | 3 | 1 | 1 | 1 | 1 | 3 | 0 | 7 | 6 | 1 | 1 | 9 | 9 |
| <b>FISCHER 344 RATS MALE</b> | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| <b>3000 PPM</b>              | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID                    | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                              | 7               | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |
|                              | 6               | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
|                              | <b>* TOTALS</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**ALIMENTARY SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Esophagus                         | + | I | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49    |
| Intestine Large, Cecum            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Edema                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 2.0 |
| Intestine Large, Colon            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48    |
| Intestine Large, Rectum           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Intestine Small, Duodenum         | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49    |
| Intestine Small, Ileum            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49    |
| Intestine Small, Jejunum          | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48    |
| Liver                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Angiectasis                       |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 1.0 |
| Basophilic Focus                  | X |   |   | X | X | X | X | X | X | X | X | X | X | X | X | X |   |   |   |   |   |   | X | X | 33    |
| Clear Cell Focus                  | X |   |   |   |   |   | X | X | X |   | X |   |   | X | X |   |   |   |   |   |   |   | X | X | 17    |
| Degeneration, Cystic              |   |   | 1 |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 1.5 |
| Eosinophilic Focus                |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 5     |
| Hematopoietic Cell Proliferation  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 1.0 |
| Hemorrhage                        |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   | 2 |   |   |   |   |   |   |   | 2 | 2 | 6 2.2 |
| Hepatodiaphragmatic Nodule        | X |   |   |   |   |   | X |   |   |   | X | X |   | X |   | X |   |   |   |   |   | X |   |   | 13    |
| Infiltration Cellular, Mixed Cell |   |   |   |   |   |   | 1 |   |   |   |   |   | 3 |   |   | 3 |   |   |   |   |   |   |   |   | 6 1.7 |

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| DAY ON TEST                                    | 0   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |       |
|--|---|---|---|---|---|---|---|---|---|---|---|---|--|---|---|---|---|---|---|---|---|---|---|---|----------|-------|
|  | 7 7 7 5 7 5 7 7 7 7 7 7 7 7 7 6 7 4 6 7 7 5 6<br>3 3 1 1 2 6 2 2 2 2 2 3 2 3 3 3 3 6 3 3 6 3 3 0 4<br>1 1 1 7 9 3 9 9 9 9 9 1 3 1 1 1 1 3 0 7 6 1 1 9 9 |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          |       |
| FISCHER 344 RATS MALE<br>3000 PPM<br>ANIMAL ID | 0   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          |       |
|  | 0   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          |       |
|  | 0   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          |       |
|  | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          |       |
| Mixed Cell Focus                               | X   |   |   |   | X |   | X | X |   | X | X | X |  | X | X | X |   | X |   | X | X |   |   |   | 21       |       |
| Necrosis, Focal                                |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 1        | 2 2.0 |
| Bile Duct, Hyperplasia                         | 1   | 3 | 3 | 1 | 1 |   | 1 | 2 | 1 | 2 | 1 | 1 |  | 1 | 2 | 1 |   | 1 | 2 |   | 3 | 1 |   | 1 | 38 1.5   |       |
| Centrilobular, Necrosis                        |   |   |   | 2 |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 2 3.0    |       |
| Hepatocyte, Degeneration                       | 1   |   |   |   | 1 |   |   | 1 | 1 | 1 | 1 | 1 |  | 1 |   | 1 | 1 |   | 1 |   |   | 2 | 2 |   | 22 1.1   |       |
| Hepatocyte, Hypertrophy                        | 2   |   |   |   | 2 |   | 1 | 2 | 1 | 1 | 2 | 1 |  | 1 | 2 | 1 |   |   |   |   |   | 1 | 2 |   | 19 1.4   |       |
| Hepatocyte, Vacuolization Cytoplasmic          |   |   |   |   |   | 4 |   |   |   |   |   |   |  |   |   |   |   | 3 |   |   |   |   |   |   | 4 3.3    |       |
| Mesentery                                      |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 9        |       |
| Fat, Necrosis                                  |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 2        | 5 2.8 |
| Pancreas                                       |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 50       |       |
| Atrophy  |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 19 2.2   |       |
| Cyst   | X   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 12       |       |
| Acinus, Cytoplasmic Alteration                 |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 3 3.0    |       |
| Salivary Glands                                |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 49       |       |
| Atrophy  |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 2 1.5    |       |
| Stomach, Forestomach                           |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 50       |       |
| Edema  |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 5 3.0    |       |
| Erosion  |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 1 1.0    |       |
| Inflammation, Chronic Active                   |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 1 3.0    |       |
| Ulcer  |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 8 3.5    |       |
| Epithelium, Hyperplasia                        |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 7 2.4    |       |
| Stomach, Glandular                             |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 50       |       |
| Erosion  |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 2 2.0    |       |
| Ulcer  |   |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 3 2.7    |       |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL  
 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

| DAY ON TEST                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
|                              | 7 | 7 | 7 | 5 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 6 | 7 | 7 | 5 | 6 |   |   |   |                 |
|                              | 3 | 3 | 1 | 1 | 2 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 6 | 3 | 3 | 0 | 4 |   |   |                 |
|                              | 1 | 1 | 1 | 7 | 9 | 3 | 9 | 9 | 9 | 9 | 9 | 9 | 1 | 3 | 1 | 1 | 1 | 3 | 0 | 7 | 6 | 1 | 1 | 9 | 9 |   |   |                 |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
| <b>3000 PPM</b>              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
| ANIMAL ID                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
|                              | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |                 |
|                              | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 0 |   | <b>* TOTALS</b> |

Tongue

1

**CARDIOVASCULAR SYSTEM**

Blood Vessel

+

1

Heart

Cardiomyopathy

+ 50  
 2 1 1 2 1 2 3 2 3 1 2 1 2 1 2 1 1 3 3 1 38 1.9

**ENDOCRINE SYSTEM**

Adrenal Cortex

Accessory Adrenal Cortical Nodule  
 Degeneration, Fatty  
 Hyperplasia  
 Hyperplasia, Focal  
 Hypertrophy, Focal  
 Vacuolization Cytoplasmic, Focal  
 Vacuolization Cytoplasmic, Diffuse

+ 50  
 3 3 3 2 2 1 1 1 2 2 6 1 3  
 7 3.0  
 1 2.0  
 2 2.0  
 2 1.5  
 1 2.0  
 6 1.3  
 1 3.0

Adrenal Medulla

Hyperplasia

+ M + + + 49  
 1 2 2 1 2 2 1 1 2 1 10 1.5

Islets, Pancreatic

Hyperplasia

+ 50  
 2 1 2.0

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 29

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | * TOTALS |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|                              | 7 | 7 | 7 | 5 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 6 | 7 | 7 | 5 | 6 | 6 |   |          |
|                              | 3 | 3 | 1 | 1 | 2 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 6 | 3 | 3 | 6 | 3 | 3 | 0 | 4 |   |          |
|                              | 1 | 1 | 1 | 7 | 9 | 3 | 9 | 9 | 9 | 9 | 9 | 1 | 3 | 1 | 1 | 1 | 1 | 3 | 0 | 7 | 6 | 1 | 1 | 9 | 9 |          |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
| ANIMAL ID                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
| 0                            | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |          |
| <b>3000 PPM</b>              | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |          |
|                              | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |          |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |       |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Parathyroid Gland                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | M | + | + | +  | 45    |
| Pituitary Gland                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 50    |
| Pars Distalis, Angiectasis        | 2 |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 4 2.0 |
| Pars Distalis, Hyperplasia, Focal | 2 |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 6 2.0 |
| Pars Intermedia, Cyst             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |    | 2     |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |
| C-cell, Hyperplasia               |   | 1 |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 4 1.3 |
| Follicle, Cyst                    |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1     |

**GENERAL BODY SYSTEM**

|            |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |       |
|------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|-------|
| Tissue NOS |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1     |
| Hemorrhage |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 3.0 |

**GENITAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |        |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--------|
| Epididymis            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |        |
| Inflammation, Acute   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |    | 1 3.0  |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |    | 2 2.0  |
| Preputial Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |        |
| Cyst                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |    | 1      |
| Hyperplasia, Focal    |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 1.0  |
| Inflammation, Chronic | 2 |   |   |   |   |   | 3 |   |   |   | 2 |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |    | 10 2.4 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



TDMS No. 99007 - 05

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

|                              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                 |  |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|--|
| DAY ON TEST                  | 7 | 7 | 7 | 5 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 6 | 7 | 7 | 5 | 6 |   |   |                 |  |
|                              | 3 | 3 | 1 | 1 | 2 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 6 | 3 | 3 | 0 | 4               |  |
|                              | 1 | 1 | 1 | 7 | 9 | 3 | 9 | 9 | 9 | 9 | 9 | 1 | 3 | 1 | 1 | 1 | 1 | 1 | 3 | 0 | 7 | 6 | 1 | 1 | 9 | 9               |  |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |  |
| <b>3000 PPM</b>              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |  |
| ANIMAL ID                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |  |
|                              | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0               |  |
|                              | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | <b>* TOTALS</b> |  |

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               |              |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|--------------|
| Hyperplasia, Lymphoid Infiltration Cellular, Mixed Cell |   |   |   |   | 3 |   |   |   | 2 |   | 2 |   |   |   |   | 2 | 2 | 2 |   | 2 |   | 2 |   |   |   | <b>11 2.1</b> |              |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               | <b>1 4.0</b> |
| Spleen  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>     |              |
| Accessory Spleen  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               | <b>1</b>     |
| Fibrosis  |   |   |   |   | 2 |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               | <b>2 1.5</b> |
| Hematopoietic Cell Proliferation                        |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |               | <b>8 1.8</b> |
| Infiltration Cellular, Mixed Cell                       |   |   |   |   |   |   |   |   |   |   |   | 3 |   | 4 |   |   |   |   |   |   |   |   |   |   |   |               | <b>3 3.0</b> |
| Metaplasia, Lipocyte                                    |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |               | <b>1 3.0</b> |
| Thymus  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>49</b>     |              |
| Cyst  |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |               | <b>2</b>     |
| Fibrosis  |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               | <b>1 3.0</b> |
| Epithelial Cell, Hyperplasia                            |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |               | <b>1 3.0</b> |

INTEGUMENTARY SYSTEM

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|
| Mammary Gland             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>     |
| Hyperplasia               |   |   | 1 |   |   | 3 | 4 |   |   | 2 |   |   | 2 | 4 |   |   |   | 1 | 4 |   | 3 |   |   |   | 1 | <b>13 2.5</b> |
| Skin                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>     |
| Cyst Epithelial Inclusion |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   | X |   | <b>3</b>      |
| Edema                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2 2.5</b>  |
| Hyperkeratosis            |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2 3.5</b>  |

MUSCULOSKELETAL SYSTEM

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

Page 32

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked



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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                       | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | * TOTALS |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
|                                   | 7 7 7 5 7 5 7 7 7 7 7 7 7 7 7 7 6 7 4 6 7 7 5 6   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|                                   | 3 3 1 1 2 6 2 2 2 2 2 3 2 3 3 3 6 3 3 6 3 3 0 4   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|                                   | 1 1 1 7 9 3 9 9 9 9 9 1 3 1 1 1 3 0 7 6 1 1 9 9   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
| FISCHER 344 RATS MALE<br>3000 PPM | ANIMAL ID   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|                                   | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|                                   | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|                                   | 0 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|                                   | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|                                   | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |

|                 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    |
|-----------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|
| Bone            | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50 |
| Skeletal Muscle |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1  |

**NERVOUS SYSTEM**

|                  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |        |
|------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Brain            | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50     |
| Angiectasis      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 2.0  |
| Compression      | 2 2 4 2 4 4 2                                   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 10 3.0 |
| Hemorrhage       | 3 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 4 2.5  |
| Necrosis         | 3 2 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 4 2.5  |
| Peripheral Nerve |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3      |
| Spinal Cord      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3      |

**RESPIRATORY SYSTEM**

|                                   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |        |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Lung                              | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50     |
| Foreign Body                      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1      |
| Hemorrhage                        |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 4 2.3  |
| Infiltration Cellular, Histiocyte | 2 1 1 1 1 1 1 1 1 1 1 1                         |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 24 1.3 |
| Inflammation, Suppurative         |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 2.0  |
| Inflammation, Chronic             | 1 1 1 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 10 1.2 |
| Metaplasia, Osseous               | 1 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3 1.0  |
| Alveolar Epithelium, Hyperplasia  | 1 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3 1.3  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

| DAY ON TEST                       |  | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|-----------------------------------|--|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ANIMAL ID                         |  | 7               | 7 | 7 | 5 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 6 | 7 | 7 | 5 | 6 |   |   |
| FISCHER 344 RATS MALE<br>3000 PPM |  | 3               | 3 | 1 | 1 | 2 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 6 | 3 | 3 | 0 | 4 |
|                                   |  | 1               | 1 | 1 | 7 | 9 | 3 | 9 | 9 | 9 | 9 | 9 | 1 | 3 | 1 | 1 | 1 | 1 | 3 | 0 | 7 | 6 | 1 | 1 | 9 | 9 |
|                                   |  | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|                                   |  | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|                                   |  | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|                                   |  | 7               | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |   |
|                                   |  | 6               | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
|                                   |  | <b>* TOTALS</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

|                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Nose                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Foreign Body                        |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 5  |
| Inflammation, Chronic               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4  |
| Respiratory Epithelium, Hyperplasia | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   | 3  |
| <b>1.0</b>                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
| <b>3.0</b>                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
| Trachea                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

**SPECIAL SENSES SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |     |     |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|-----|
| Eye                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50  |     |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |     | 1   |
| Retina, Degeneration  |   | 2 | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |     | 4.0 |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3   |     |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3   |     |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2.3 |     |
| Harderian Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50  |     |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |     | 1   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |     | 2.0 |

**URINARY SYSTEM**

|                                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |
|--------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Kidney                               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |
| Cyst                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 2   |
| Nephropathy                          | 2 | 3 | 1 | 1 | 1 | 4 | 1 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 3 | 2 | 1 | 1 | 1 | 2 | 1 | 1 |   |   | 49 |     |
| Renal Tubule, Necrosis               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1.4 |
| Renal Tubule, Pigmentation           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1   |
| Transitional Epithelium, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 3.0 |
|                                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1   |
|                                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 3.0 |
| Urethra                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1   |
| Angiectasis                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1   |
|                                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 3.0 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
|                              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                 |
| DAY ON TEST                  | 7 | 7 | 7 | 5 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 6 | 7 | 7 | 5 | 6 |   |   |                 |
|                              | 3 | 3 | 1 | 1 | 2 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 6 | 3 | 3 | 6 | 3 | 3 | 0 | 4 |   |   |                 |
|                              | 1 | 1 | 1 | 7 | 9 | 3 | 9 | 9 | 9 | 9 | 9 | 1 | 3 | 1 | 1 | 1 | 1 | 3 | 0 | 7 | 6 | 1 | 1 | 9 | 9 |   |                 |
| .....                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                 |
| ANIMAL ID                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                 |
| <b>3000 PPM</b>              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |   |                 |
|                              | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |   |                 |
|                              | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |   |                 |
|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |
| .....                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |
| Urinary Bladder              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>50</b>       |
| Hemorrhage                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 1 |                 |
|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1.0</b>      |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 35



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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                                    | 0   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | males<br>(cont...) |  |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|--|
|  | 7 7 7 3 7 7 7 7 6 5 5 4 6 7 6 7 7 7 7 7 5 7 7 7 7 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
| FISCHER 344 RATS MALE<br>9000 PPM<br>ANIMAL ID | 3 3 3 1 2 3 3 3 9 9 5 3 4 3 9 3 3 0 2 2 2 3 2 2 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
|  | 0 0 0 6 4 0 0 0 6 4 6 1 4 0 6 0 0 9 9 9 9 4 9 9 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
|  | 0   | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5                  |  |
| Bile Duct, Hyperplasia                         | 1   | 1 | 1 |   | 1 | 1 | 1 | 1 | 3 |   | 1 | 3 | 2 | 4 | 3 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 2 | 1 |                    |  |
| Hepatocyte, Degeneration                       |   |   |   | 2 |   | 1 | 1 | 1 |   |   | 1 |   |   |   |   |   | 1 | 2 |   | 1 | 2 | 2 |   | 3 | 2 | 3                  |  |
| Hepatocyte, Hypertrophy                        | 2   |   | 3 |   |   | 2 | 1 | 1 |   |   | 2 |   |   |   |   |   | 2 | 2 |   | 3 | 2 | 1 |   | 4 | 2 | 3                  |  |
| Hepatocyte, Vacuolization Cytoplasmic          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
| Kupffer Cell, Pigmentation                     |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
| Mesentery                                      |   |   |   |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   | + | + | + |   |   | +                  |  |
| Accessory Spleen                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
| Angiectasis                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3                  |  |
| Hemorrhage                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 | 2 |   |   |   |                    |  |
| Fat, Necrosis                                  |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   | 4 | 2 |   |   |   | 3                  |  |
| Pancreas                                       | +   | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + |                    |  |
| Atrophy  |   | 2 | 1 |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   | 2 | 3 | 3                  |  |
| Cyst   |   | X | X |   | X | X |   |   |   |   |   |   |   | X | X |   |   |   | X |   | X |   |   | X | X |                    |  |
| Necrosis                                       |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
| Acinus, Hyperplasia, Focal                     |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |                    |  |
| Salivary Glands                                | +   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |                    |  |
| Atrophy  |   | 1 |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |                    |  |
| Infiltration Cellular, Polymorphonuclear       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
| Stomach, Forestomach                           | +   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |                    |  |
| Edema  |   |   |   |   | 3 |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |                    |  |
| Hyperplasia, Squamous                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
| Inflammation, Chronic Active                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
| Perforation                                    |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
| Ulcer  |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
| Epithelium, Hyperplasia                        |   |   |   |   | 3 |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   | 3 |   |   |   |   |   |                    |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 37

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                              | 7 | 7 | 7 | 3 | 7 | 7 | 7 | 7 | 6 | 5 | 5 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 |   |
|                              | 3 | 3 | 3 | 1 | 2 | 3 | 3 | 3 | 9 | 9 | 5 | 3 | 4 | 3 | 9 | 3 | 3 | 0 | 2 | 2 | 2 | 3 | 2 | 2 | 3 |   |
|                              | 0 | 0 | 0 | 6 | 4 | 0 | 0 | 0 | 6 | 4 | 6 | 1 | 4 | 0 | 6 | 0 | 0 | 9 | 9 | 9 | 9 | 4 | 9 | 9 | 1 |   |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>9000 PPM</b>              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| ANIMAL ID                    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |
|                              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|                              | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   |

males (cont...)

|                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Stomach, Glandular Erosion | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ulcer                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Epithelium, Hyperplasia    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**CARDIOVASCULAR SYSTEM**

|                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Heart          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Cardiomyopathy | 1 | 1 | 1 | 2 | 2 | 2 | 3 | 2 |   |   |   | 2 | 1 | 3 |   |   | 1 |   | 2 | 1 | 3 |   |   | 1 | 3 | 1 |
| Thrombosis     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**ENDOCRINE SYSTEM**

|                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Accessory Adrenal Cortical Nodule  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia, Focal                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hypertrophy, Focal                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Necrosis                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Vacuolization Cytoplasmic, Focal   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Vacuolization Cytoplasmic, Diffuse |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Adrenal Medulla                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Islets, Pancreatic                 | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 Page 38  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
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

| DAY ON TEST                        | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|
|                                    | 7 | 7 | 7 | 3 | 7 | 7 | 7 | 7 | 6 | 5 | 5 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7                  |
| FISCHER 344 RATS MALE<br>ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |
|                                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |
| 9000 PPM                           | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1                  |
|                                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |
|                                    | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | males<br>(cont...) |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Parathyroid Gland                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pituitary Gland                   | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pars Distalis, Angiectasis        |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pars Distalis, Cyst               |   |   |   |   |   |   | X |   | X |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   | X |
| Pars Distalis, Hyperplasia, Focal |   | 1 |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   | 2 |   | X |
| Pars Intermedia, Cyst             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ultimobranchial Cyst              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |
| C-cell, Hyperplasia               |   |   |   |   |   | 1 |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |
| Follicle, Cyst                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |

**GENERAL BODY SYSTEM**

|            |  |  |  |  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------------|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Tissue NOS |  |  |  |  | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------------|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|

**GENITAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Epididymis            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Acute   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic |   | 2 |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |
| Preputial Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |
| Hyperplasia           |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic |   | 2 | 2 |   |   |   |   |   | 3 |   |   |   | 2 |   | 3 | 2 | 2 | 2 |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ .. Tissue examined microscopically  
x .. Lesion present  
I .. Insufficient tissue  
M .. Missing tissue  
A .. Autolysis precludes evaluation  
BLANK .. Not examined microscopically  
1-4 .. Lesion qualified as:  
1) Minimal 3) Moderate  
2) Mild 4) Marked  
Page 39

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                              | 7 | 7 | 7 | 3 | 7 | 7 | 7 | 7 | 6 | 5 | 5 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 |   |
|                              | 3 | 3 | 3 | 1 | 2 | 3 | 3 | 3 | 9 | 9 | 5 | 3 | 4 | 3 | 9 | 3 | 3 | 0 | 2 | 2 | 2 | 3 | 2 | 2 | 3 |
|                              | 0 | 0 | 0 | 6 | 4 | 0 | 0 | 0 | 6 | 4 | 6 | 1 | 4 | 0 | 6 | 0 | 0 | 9 | 9 | 9 | 9 | 4 | 9 | 9 | 1 |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| ANIMAL ID                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>9000 PPM</b>              | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |
|                              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|                              | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males  
(cont...)

|                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Prostate                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Chronic          |   |   | 2 |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   | 2 | 2 | 2 | 1 |   |   |
| Epithelium, Hyperplasia        |   |   |   |   |   | 1 |   |   |   |   |   | 1 |   | 2 |   |   |   |   |   |   | 2 |   |   |   |
| Seminal Vesicle                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Testes                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Germinal Epithelium, Atrophy   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Interstitial Cell, Hyperplasia |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |

**HEMATOPOIETIC SYSTEM**

|                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow                        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia                        |   | 3 |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Infiltration Cellular, Histiocyte  |   | 3 |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |
| Lymph Node                         |   | + |   | + | + |   |   |   | + | + |   |   | + | + |   |   |   | + |   |   |   | + |   |   |
| Mediastinal, Ectasia               |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mediastinal, Hemorrhage            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mediastinal, Hyperplasia, Lymphoid |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pancreatic, Ectasia                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pancreatic, Hemorrhage             |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Lymph Node, Mandibular             | M | M | + | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M |
| Lymph Node, Mesenteric             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ectasia                            |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 40



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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL  
 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

|             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|             | 7 | 7 | 7 | 3 | 7 | 7 | 7 | 7 | 6 | 5 | 5 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 |
|             | 3 | 3 | 3 | 1 | 2 | 3 | 3 | 3 | 9 | 9 | 5 | 3 | 4 | 3 | 9 | 3 | 3 | 0 | 2 | 2 | 2 | 3 | 2 | 2 | 3 |
|             | 0 | 0 | 0 | 6 | 4 | 0 | 0 | 0 | 6 | 4 | 6 | 1 | 4 | 0 | 6 | 0 | 0 | 9 | 9 | 9 | 9 | 4 | 9 | 9 | 1 |

FISCHER 344 RATS MALE

9000 PPM

ANIMAL ID

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |
| 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1                  |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2                  |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | males<br>(cont...) |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hemorrhage                        |   |   |   |   |   |   |   |   | 2 | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia, Lymphoid             |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   | 2 |   |   | 2 |   |   |   |   |   |   |
| Spleen                            | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Fibrosis                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hematopoietic Cell Proliferation  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   | 1 |
| Hemorrhage                        |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia, Lymphoid             |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Infiltration Cellular, Mixed Cell |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Necrosis                          |   |   |   |   | 4 |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Thymus                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

INTEGUMENTARY SYSTEM

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia               |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |
| Skin                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst Epithelial Inclusion |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperkeratosis            |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic     |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Ulcer                     |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |
| Epidermis, Hyperplasia    |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

MUSCULOSKELETAL SYSTEM

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

|                       |  | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
|-----------------------|--|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|--|
|                       |  | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                    |  |
|                       |  | 7           | 7 | 7 | 3 | 7 | 7 | 7 | 7 | 6 | 5 | 5 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 |   |                    |  |
|                       |  | 3           | 3 | 3 | 1 | 2 | 3 | 3 | 3 | 9 | 9 | 5 | 3 | 4 | 3 | 9 | 3 | 3 | 0 | 2 | 2 | 2 | 3 | 2 | 2 | 3 |                    |  |
|                       |  | 0           | 0 | 0 | 6 | 4 | 0 | 0 | 0 | 6 | 4 | 6 | 1 | 4 | 0 | 6 | 0 | 0 | 9 | 9 | 9 | 9 | 4 | 9 | 9 | 1 |                    |  |
| FISCHER 344 RATS MALE |  | ANIMAL ID   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | males<br>(cont...) |  |
| 9000 PPM              |  | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                    |  |
|                       |  | 1           | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |                    |  |
|                       |  | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                    |  |
|                       |  | 1           | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5                  |  |

|                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Skeletal Muscle |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |

**NERVOUS SYSTEM**

|                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Brain            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Compression      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Hemorrhage       |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |  |
| Hydrocephalus    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Necrosis         |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Peripheral Nerve |   |   |   |   |   |   |   |   |   |   | + |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Spinal Cord      |   |   |   |   |   |   |   |   |   |   |   | + |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |  |

**RESPIRATORY SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Edema                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Foreign Body                      |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hemorrhage                        |   |   |   |   |   |   |   |   |   |   | 3 |   |   | 3 |   | 1 |   |   |   |   | 1 |   | 1 | 1 | 1 | 1 | 1 |   |
| Infiltration Cellular, Histiocyte | 1 | 1 | 1 |   | 1 | 1 |   |   | 3 |   |   |   | 3 |   | 1 |   |   |   |   |   | 1 |   | 1 | 1 | 1 | 1 | 1 |   |
| Inflammation, Chronic             | 1 | 1 |   |   |   | 1 | 2 |   |   |   |   |   | 1 |   |   |   |   |   |   |   | 1 | 1 |   |   |   | 2 | 1 |   |
| Alveolar Epithelium, Hyperplasia  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |
| Nose                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 42

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                              | 7 | 7 | 7 | 3 | 7 | 7 | 7 | 7 | 6 | 5 | 5 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 |   |
|                              | 3 | 3 | 3 | 1 | 2 | 3 | 3 | 3 | 9 | 9 | 5 | 3 | 4 | 3 | 9 | 3 | 3 | 0 | 2 | 2 | 2 | 3 | 2 | 2 | 3 |
|                              | 0 | 0 | 0 | 6 | 4 | 0 | 0 | 0 | 6 | 4 | 6 | 1 | 4 | 0 | 6 | 0 | 0 | 9 | 9 | 9 | 9 | 4 | 9 | 9 | 1 |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>9000 PPM</b>              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| ANIMAL ID                    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |
|                              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|                              | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males  
(cont...)

|                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Foreign Body                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Inflammation, Chronic               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Respiratory Epithelium, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Trachea                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |

**SPECIAL SENSES SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Retina, Degeneration |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Harderian Gland      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia, Focal   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**URINARY SYSTEM**

|                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Infarct                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Nephropathy                | 1 | 1 | 1 |   | 1 | 2 | 1 | 1 | 1 |   | 1 |   | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 1 | 1 | 1 | 1 |
| Renal Tubule, Necrosis     |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Renal Tubule, Pigmentation |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Urinary Bladder            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 43

| DAY ON TEST                  |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 | 0 | 0 | 0 |
|------------------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|---|---|---|
| 7                            |  | 7 | 7 | 7 | 5 | 7 | 7 | 6 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 6 | 7               | 7 | 6 | 0 |   |
| 3                            |  | 3 | 3 | 0 | 6 | 0 | 3 | 3 | 3 | 4 | 6 | 2 | 2 | 2 | 2 | 3 | 3 | 9 | 2 | 2 | 1 | 2 | 8               | 2 | 3 | 5 |   |
| 1                            |  | 1 | 3 | 3 | 1 | 0 | 5 | 0 | 9 | 3 | 9 | 9 | 9 | 9 | 0 | 0 | 0 | 9 | 9 | 8 | 9 | 8 | 9               | 1 | 9 | 0 |   |
| <b>FISCHER 344 RATS MALE</b> |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 | 0 | 0 |   |
| ANIMAL ID                    |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 | 0 | 0 |   |
| <b>9000 PPM</b>              |  | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1               | 1 | 1 | 1 |   |
| 2                            |  | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4               | 4 | 5 |   |   |
| 6                            |  | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8               | 9 | 0 |   |   |
|                              |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |   |   |   |   |

**ALIMENTARY SYSTEM**

|                                   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |       |  |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|-------|--|
| Esophagus                         | +           |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50    |  |
| Intestine Large, Cecum            | + A M + +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 48    |  |
| Edema                             | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 2.0 |  |
| Intestine Large, Colon            | +           |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50    |  |
| Intestine Large, Rectum           | + + + + + + + + + + I + + + + + + + + + + + + M +       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 48    |  |
| Intestine Small, Duodenum         | +           |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 49    |  |
| Intestine Small, Ileum            | + + + + A + + + + + + + + + + + + + + + A + A + + +     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 45    |  |
| Intestine Small, Jejunum          | + + + + + + + + + + + + + + + + + + + A + + A + A + + + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 46    |  |
| Liver                             | +           |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50    |  |
| Angiectasis                       | 4   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2 4.0 |  |
| Basophilic Focus                  | X X X X X X X X X X X X                                 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 22    |  |
| Clear Cell Focus                  | X X X X X X X X X X X X                                 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3     |  |
| Degeneration, Cystic              | 3 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 4 2.0 |  |
| Eosinophilic Focus                | X X X X X X X X X X X X X                               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 25    |  |
| Hepatodiaphragmatic Nodule        | X X X X X X X X X X X X X X                             |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 6     |  |
| Infiltration Cellular, Mixed Cell | 2 1 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 6 1.8 |  |
| Mixed Cell Focus                  | X X X X X X X X X X X X X                               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 13    |  |
| Necrosis, Focal                   | X X X X X X X X X X X X X                               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 3.0 |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 Page 44  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0         | 0               |            |            |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|-----------------|------------|------------|
| FISCHER 344 RATS MALE                    | 7 | 7 | 7 | 5 | 7 | 7 | 6 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 6 | 7 | 7 | 6 | 7 | 6         |                 |            |            |
| 9000 PPM                                 | 3 | 3 | 0 | 6 | 0 | 3 | 3 | 3 | 4 | 6 | 2 | 2 | 2 | 2 | 3 | 3 | 9 | 2 | 2 | 1 | 2 | 8 | 2 | 3 | 5 |           |                 |            |            |
| ANIMAL ID                                | 1 | 1 | 3 | 3 | 1 | 0 | 5 | 0 | 9 | 3 | 9 | 9 | 9 | 9 | 0 | 0 | 9 | 9 | 8 | 9 | 8 | 9 | 1 | 9 |   |           |                 |            |            |
|  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0         | 0               |            |            |
|  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0         | 0               |            |            |
|  | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1         | 1               |            |            |
|  | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |           |                 |            |            |
|  | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |           | <b>* TOTALS</b> |            |            |
| Bile Duct, Hyperplasia                   | 1 | 2 | 3 |   | 3 | 2 | 2 | 2 | 2 | 4 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 |   | 1 | 2 | 1 | 1 |   | <b>45</b> | <b>1.6</b>      |            |            |
| Hepatocyte, Degeneration                 |   | 2 |   |   | 1 | 2 |   |   |   |   | 2 | 2 | 2 | 2 | 2 | 3 | 1 | 2 | 2 |   | 1 | 2 |   | 2 | 2 |           | <b>30</b>       | <b>1.8</b> |            |
| Hepatocyte, Hypertrophy                  | 1 | 2 |   | 2 |   |   |   | 2 |   |   | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 2 | 3 |   | 2 | 2 |   | 2 | 3 |           | <b>31</b>       | <b>1.9</b> |            |
| Hepatocyte, Vacuolization Cytoplasmic    |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |           | <b>2</b>        | <b>3.0</b> |            |
| Kupffer Cell, Pigmentation               |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>2</b>        | <b>2.0</b> |            |
| Mesentery                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>11</b>  |            |
| Accessory Spleen                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>1</b>   |            |
| Angiectasis                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>1</b>   | <b>3.0</b> |
| Hemorrhage                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>2</b>   | <b>2.5</b> |
| Fat, Necrosis                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>7</b>   | <b>2.7</b> |
| Pancreas                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>49</b>  |            |
| Atrophy                                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>25</b>  | <b>1.9</b> |
| Cyst                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>15</b>  |            |
| Necrosis                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>1</b>   | <b>3.0</b> |
| Acinus, Hyperplasia, Focal               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>5</b>        | <b>2.2</b> |            |
| Salivary Glands                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>50</b>  |            |
| Atrophy                                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>4</b>   | <b>1.8</b> |
| Infiltration Cellular, Polymorphonuclear |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>1</b>   | <b>2.0</b> |
| Stomach, Forestomach                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>50</b>  |            |
| Edema                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>2</b>   | <b>3.0</b> |
| Hyperplasia, Squamous                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>1</b>   | <b>2.0</b> |
| Inflammation, Chronic Active             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>1</b>   | <b>4.0</b> |
| Perforation                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>1</b>   |            |
| Ulcer                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>2</b>   | <b>3.5</b> |
| Epithelium, Hyperplasia                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 | <b>3</b>   | <b>2.7</b> |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

l .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                  | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                              | 7               | 7 | 7 | 5 | 7 | 7 | 6 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 6 | 7 | 7 | 6 |   |
|                              | 3               | 3 | 0 | 6 | 0 | 3 | 3 | 3 | 4 | 6 | 2 | 2 | 2 | 2 | 3 | 3 | 9 | 2 | 2 | 1 | 2 | 8 | 2 | 3 | 5 |
|                              | 1               | 1 | 3 | 3 | 1 | 0 | 5 | 0 | 9 | 3 | 9 | 9 | 9 | 9 | 0 | 0 | 0 | 9 | 9 | 8 | 9 | 8 | 9 | 1 | 9 |
| <b>FISCHER 344 RATS MALE</b> | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| <b>9000 PPM</b>              | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID                    | 1               | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
|                              | 2               | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |
|                              | 6               | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
|                              | <b>* TOTALS</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

|                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Stomach, Glandular      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |
| Erosion                 |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3  | 1.7 |
| Ulcer                   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  | 2.0 |
| Epithelium, Hyperplasia | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 2.0 |

**CARDIOVASCULAR SYSTEM**

|                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |     |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|-----|
| Heart          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |     |
| Cardiomyopathy | 3 | 3 | 2 |   | 3 |   |   | 3 | 3 | 1 | 2 | 3 | 3 | 2 | 3 | 1 | 3 | 3 |   | 3 | 2 | 2 | 2 | 3 | 1 | 39 | 2.1 |     |
| Thrombosis     |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1   | 4.0 |

**ENDOCRINE SYSTEM**

|                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Adrenal Cortex                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |
| Accessory Adrenal Cortical Nodule  | 3 |   | 3 |   |   |   |   |   | 3 |   |   |   |   |   | 3 |   | 3 |   | 3 | 3 |   |   |   |   |   | 14 | 3.0 |
| Hyperplasia                        |   | 1 |   |   |   |   | 2 |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   | 2 |   | 5  | 1.6 |
| Hyperplasia, Focal                 | 1 |   |   |   |   |   |   | 1 |   |   | 1 |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   | 4  | 1.0 |
| Hypertrophy, Focal                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 1.0 |
| Necrosis                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 3.0 |
| Vacuolization Cytoplasmic, Focal   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   | 3  | 1.3 |
| Vacuolization Cytoplasmic, Diffuse | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 2.0 |
| Adrenal Medulla                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |
| Hyperplasia                        |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   | 3 |   | 1 |   |   |   | 1 |   |   | 1 |   | 14 | 1.3 |
| Islets, Pancreatic                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |     |
| Hyperplasia                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   | 1  | 2.0 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 46

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST | FISCHER 344 RATS MALE |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |  |
|-------------|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|--|
|             | ANIMAL ID             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |  |
| 0           | 0                     | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |  |
| 7           | 7                     | 7 | 5 | 7 | 7 | 6 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 6 | 7 | 6 | 7 | 7 | 6        |  |
| 3           | 3                     | 0 | 6 | 0 | 3 | 3 | 3 | 4 | 6 | 2 | 2 | 2 | 2 | 3 | 3 | 9 | 2 | 2 | 1 | 2 | 8 | 2 | 3 | 5 |          |  |
| 1           | 1                     | 3 | 3 | 1 | 0 | 5 | 0 | 9 | 3 | 9 | 9 | 9 | 9 | 0 | 0 | 0 | 9 | 9 | 8 | 9 | 8 | 9 | 1 | 9 |          |  |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| 9000 PPM                          | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |       |
|                                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |       |
|                                   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |       |
|                                   | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |       |
|                                   | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |       |
| Parathyroid Gland                 | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | M | + | + | + | + | + | + | + | 48    |
| Pituitary Gland                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49    |
| Pars Distalis, Angiectasis        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   | 2 2.5 |
| Pars Distalis, Cyst               |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   | 6 |       |
| Pars Distalis, Hyperplasia, Focal |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   | 2 |   | 1 |   |   |   |   |   | 1 | 8 1.6 |
| Pars Intermedia, Cyst             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   | 2     |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Ultimobranchial Cyst              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1     |
| C-cell, Hyperplasia               |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   | 4 1.5 |
| Follicle, Cyst                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1     |

**GENERAL BODY SYSTEM**

|            |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |
|------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|
| Tissue NOS |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 |
|------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|

**GENITAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Epididymis            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Inflammation, Acute   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   | 1 3.0  |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 2.0  |
| Preputial Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Cyst                  |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   | X |   |   |   |   | 3      |
| Hyperplasia           |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   | 2 1.5  |
| Inflammation, Chronic | 2 |   |   |   | 2 | 2 |   |   |   |   |   | 2 | 3 |   |   |   |   |   | 2 |   |   |   |   |   | 14 2.2 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                  | 0 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |   |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|
|                              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          | 0 |
|                              | 7 | 7 | 7 | 5 | 7 | 7 | 6 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 6 | 7 | 7 | 6 |          |   |
|                              | 3 | 3 | 0 | 6 | 0 | 3 | 3 | 3 | 4 | 6 | 2 | 2 | 2 | 2 | 3 | 3 | 9 | 2 | 2 | 1 | 2 | 8 | 2 | 3 | 5        |   |
|                              | 1 | 1 | 3 | 3 | 1 | 0 | 5 | 0 | 9 | 3 | 9 | 9 | 9 | 9 | 0 | 0 | 0 | 9 | 9 | 8 | 9 | 8 | 9 | 1 | 9        |   |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |   |
| <b>9000 PPM</b>              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |   |
| ANIMAL ID                    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |          |   |
|                              | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |          |   |
|                              | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |          |   |

|                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Prostate                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Inflammation, Chronic          | 2 |   |   |   | 3 |   |   |   | 2 | 2 |   |   |   | 1 |   |   | 3 | 2 |   |   | 2 |   |   |   | 14 2.0 |
| Epithelium, Hyperplasia        |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   | 5 1.4  |
| Seminal Vesicle                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Testes                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Germinal Epithelium, Atrophy   | 2 |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 2.0  |
| Interstitial Cell, Hyperplasia |   |   |   | 1 |   |   |   |   |   | 1 |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   | 4 1.0  |

**HEMATOPOIETIC SYSTEM**

|                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Bone Marrow                        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Hyperplasia                        |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   | 4 3.0 |
| Infiltration Cellular, Histiocyte  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 2.5 |
| Lymph Node                         | + |   |   |   | + |   |   |   | + | + |   |   |   |   |   |   |   |   |   | + |   |   |   |   | 14    |
| Mediastinal, Ectasia               |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 3.0 |
| Mediastinal, Hemorrhage            | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 2.0 |
| Mediastinal, Hyperplasia, Lymphoid | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 3.5 |
| Pancreatic, Ectasia                |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 3.0 |
| Pancreatic, Hemorrhage             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 1.0 |
| Lymph Node, Mandibular             | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 1     |
| Lymph Node, Mesenteric             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Ectasia                            |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   | 4 1.8 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                  |                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 | 0 |
|------------------------------|------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|---|
|                              |                  | 7 | 7 | 7 | 5 | 7 | 7 | 6 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 6 | 7 | 7               | 6 | 0 |
|                              |                  | 3 | 3 | 0 | 6 | 0 | 3 | 3 | 3 | 4 | 6 | 2 | 2 | 2 | 2 | 3 | 3 | 9 | 2 | 2 | 1 | 2 | 8 | 2               | 3 | 5 |
|                              |                  | 1 | 1 | 3 | 3 | 1 | 0 | 5 | 0 | 9 | 3 | 9 | 9 | 9 | 9 | 0 | 0 | 0 | 9 | 9 | 8 | 9 | 8 | 9               | 1 | 9 |
| <b>FISCHER 344 RATS MALE</b> | <b>ANIMAL ID</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 | 0 |
| <b>9000 PPM</b>              |                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 | 0 |
|                              |                  | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1               | 1 | 1 |
|                              |                  | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4               | 4 | 5 |
|                              |                  | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8               | 9 | 0 |
|                              |                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |   |   |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |            |          |            |   |   |   |          |            |           |            |            |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|------------|----------|------------|---|---|---|----------|------------|-----------|------------|------------|
| Hemorrhage                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |            |          |            |   |   |   | <b>2</b> | <b>1.5</b> |           |            |            |
| Hyperplasia, Lymphoid             | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |            |          | 2          | 2 | 2 | 2 | <b>9</b> | <b>2.0</b> |           |            |            |
| Spleen                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | +          | +        | +          | + | + | + | +        | +          | <b>49</b> |            |            |
| Fibrosis                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |          |            | <b>1</b> | <b>3.0</b> |   |   |   |          |            |           |            |            |
| Hematopoietic Cell Proliferation  |   |   |   |   |   |   |   |   |   |   |   |   | 3 | 2 |   |   | <b>4</b> | <b>2.3</b> |          |            |   |   |   |          |            |           |            |            |
| Hemorrhage                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |            |          |            |   |   |   | <b>1</b> | <b>3.0</b> |           |            |            |
| Hyperplasia, Lymphoid             | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |            |          |            |   |   |   |          |            |           | <b>2</b>   | <b>2.5</b> |
| Infiltration Cellular, Mixed Cell |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |            |          |            |   |   |   | <b>1</b> | <b>4.0</b> |           |            |            |
| Necrosis                          | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |            |          |            |   |   |   |          |            | <b>3</b>  | <b>4.0</b> |            |
| Thymus                            | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | +          | +        | +          | + | + | + | +        | +          | <b>49</b> |            |            |

**INTEGUMENTARY SYSTEM**

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |            |            |            |           |            |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|------------|------------|------------|-----------|------------|
| Mammary Gland             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | +          | +          | +          | <b>50</b> |            |
| Hyperplasia               | 1 | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |          |            | 1          |            | <b>6</b>  | <b>2.2</b> |
| Skin                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | +          | +          | +          | <b>50</b> |            |
| Cyst Epithelial Inclusion |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |          |            | <b>2</b>   |            |           |            |
| Hyperkeratosis            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   | 3 | 4 |   | <b>4</b> | <b>3.5</b> |            |            |           |            |
| Inflammation, Chronic     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |          | <b>2</b>   | <b>2.0</b> |            |           |            |
| Ulcer                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |            | <b>1</b>   | <b>4.0</b> |           |            |
| Epidermis, Hyperplasia    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   | 2 | 3 |   | <b>4</b> | <b>2.8</b> |            |            |           |            |

**MUSCULOSKELETAL SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

Page 49

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

|                                   | DAY ON TEST |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         | * TOTALS |
|-----------------------------------|-------------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|----------|
|                                   | 0 7 3 1     | 0 7 3 1 | 0 7 3 1 | 0 5 6 0 | 0 7 3 0 | 0 6 3 5 | 0 7 3 0 | 0 6 3 9 | 0 7 4 3 | 0 6 6 3 | 0 7 2 9 | 0 7 2 9 | 0 7 2 9 | 0 7 2 9 | 0 3 3 0 | 0 3 3 0 | 0 9 2 0 | 0 7 2 9 | 0 7 6 8 | 0 7 6 8 | 0 7 2 9 | 0 7 2 9 | 0 0 3 5 | 0 0 1 9 |          |
| <b>FISCHER 344 RATS MALE</b>      | 0           | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       |          |
| <b>9000 PPM</b>                   | 0           | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       |          |
| ANIMAL ID                         | 1           | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       | 1       |          |
|                                   | 2           | 2       | 2       | 2       | 3       | 3       | 3       | 3       | 3       | 3       | 3       | 3       | 3       | 3       | 4       | 4       | 4       | 4       | 4       | 4       | 4       | 4       | 4       | 5       |          |
|                                   | 6           | 7       | 8       | 9       | 0       | 1       | 2       | 3       | 4       | 5       | 6       | 7       | 8       | 9       | 0       | 1       | 2       | 3       | 4       | 5       | 6       | 7       | 8       | 9       |          |
| Bone                              | +           | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | 50      |          |
| Skeletal Muscle                   |             |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         | 1       |          |
| <b>NERVOUS SYSTEM</b>             |             |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |          |
| Brain                             | +           | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | 50      |          |
| Compression                       |             |         |         |         | 3       |         |         |         |         |         |         |         |         |         |         |         | 3       |         |         |         |         |         | 3       | 3 3.0   |          |
| Hemorrhage                        |             |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         | 2 2.5   |          |
| Hydrocephalus                     |             |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         | 2       |         |         |         |         |         |         | 1 2.0   |          |
| Necrosis                          |             |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         | 1 3.0   |          |
| Peripheral Nerve                  |             |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         | + 4     |          |
| Spinal Cord                       |             |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         | + 4     |          |
| <b>RESPIRATORY SYSTEM</b>         |             |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |          |
| Lung                              | +           | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | 50      |          |
| Edema                             |             |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         | 2       |         |         |         |         |         | 1 2.0   |          |
| Foreign Body                      |             |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         | 1       |          |
| Hemorrhage                        |             |         |         |         |         |         |         |         |         |         |         |         |         |         | 2       | 2       | 2       |         |         |         |         |         |         | 4 2.3   |          |
| Infiltration Cellular, Histiocyte | 1           | 1       |         |         | 1       | 1       |         |         | 1       |         | 1       | 1       |         |         | 1       | 1       |         |         |         | 1       |         |         | 1       | 25 1.2  |          |
| Inflammation, Chronic             |             |         |         |         |         |         |         |         |         |         |         |         |         |         | 2       |         |         | 2       | 1       |         |         |         | 1       | 17 1.2  |          |
| Alveolar Epithelium, Hyperplasia  |             |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         | 1       | 3 1.0   |          |
| Nose                              | +           | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | +       | 50      |          |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically                                    M .. Missing tissue                                    1-4 .. Lesion qualified as:  
 x .. Lesion present    A .. Autolysis precludes evaluation    1) Minimal 3) Moderate  
 l .. Insufficient tissue    BLANK .. Not examined microscopically    2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                                    | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0     | 0 | 0     | 0 | 0      | 0     | 0 |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|---|-------|---|--------|-------|---|
|  | 7   | 7 | 7 | 5 | 7 | 7 | 6 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 6     | 7 | 7     | 6 | 7      | 7     | 6 |
| FISCHER 344 RATS MALE<br>9000 PPM<br>ANIMAL ID | 3   | 3 | 0 | 6 | 0 | 3 | 3 | 3 | 4 | 6 | 2 | 2 | 2 | 2 | 3 | 3 | 9 | 2 | 2 | 1 | 2     | 8 | 2     | 3 | 5      |       |   |
|  | 1   | 1 | 3 | 3 | 1 | 0 | 5 | 0 | 9 | 3 | 9 | 9 | 9 | 9 | 0 | 0 | 0 | 9 | 9 | 8 | 9     | 8 | 9     | 1 | 9      |       |   |
|  | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0     | 0 | 0     | 0 | 0      | 0     |   |
|  | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0     | 0 | 0     | 0 | 0      | 0     |   |
|  | 1   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1     | 1 | 1     | 1 | 1      | 1     |   |
|  | 2   | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4     | 4 | 4     | 4 | 5      |       |   |
|  | 6   | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6     | 7 | 8     | 9 | 0      |       |   |
|  | <b>* TOTALS</b>                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |   |       |   |        |       |   |
| Foreign Body                                   |   |   |   |   |   |   |   |   |   |   | X | X |   |   |   |   |   |   |   |   |       |   | 5     |   |        |       |   |
| Inflammation, Chronic                          |   |   |   |   |   |   |   |   |   |   | 3 | 1 |   |   |   |   |   |   |   |   |       |   | 3 1.7 |   |        |       |   |
| Respiratory Epithelium, Hyperplasia            | 2   |   |   |   |   |   |   |   |   |   |   |   |   | 2 | 1 |   |   |   |   |   |       |   |       |   |        | 3 1.7 |   |
| Trachea  | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |   |       |   | 50     |       |   |
| <b>SPECIAL SENSES SYSTEM</b>                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |   |       |   |        |       |   |
| Eye  | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |   |       |   | 50     |       |   |
| Retina, Degeneration                           |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |   |       |   | 1 2.0  |       |   |
| Harderian Gland                                | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |   |       |   | 50     |       |   |
| Hyperplasia, Focal                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |   |       |   | 1 1.0  |       |   |
| <b>URINARY SYSTEM</b>                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |   |       |   |        |       |   |
| Kidney   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |   |       |   | 50     |       |   |
| Infarct  |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   | 1 |   |   |   |   |   |       |   |       |   | 3 2.3  |       |   |
| Nephropathy                                    | 2   | 2 | 1 | 1 | 2 | 1 | 1 | 2 | 1 | 1 | 2 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2     | 1 | 1     | 1 | 46 1.2 |       |   |
| Renal Tubule, Necrosis                         |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   | 2 4.0 |   |       |   |        |       |   |
| Renal Tubule, Pigmentation                     |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   | 4 2.5 |   |       |   |        |       |   |
| Urinary Bladder                                | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |   |       |   | 50     |       |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

l .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 05

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                  | Animals |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | males<br>(cont...) |
|------------------------------|---------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|--------------------|
|                              | 0635    | 0730 | 0731 | 0732 | 0801 | 0802 | 0803 | 0804 | 0805 | 0806 | 0807 | 0808 | 0809 | 0810 | 0811 | 0812 | 0813 | 0814 | 0815 | 0816 | 0817 | 0818 | 0819 | 0820 | 0821 |                    |
|                              | 0       | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    |                    |
|                              | 6       | 7    | 7    | 7    | 6    | 2    | 6    | 7    | 4    | 6    | 5    | 5    | 7    | 7    | 7    | 6    | 5    | 7    | 6    | 7    | 7    | 5    | 7    | 7    | 5    |                    |
|                              | 3       | 3    | 3    | 3    | 8    | 0    | 1    | 1    | 5    | 1    | 9    | 7    | 3    | 2    | 3    | 9    | 2    | 2    | 3    | 2    | 2    | 9    | 3    | 3    | 0    |                    |
|                              | 5       | 0    | 0    | 1    | 4    | 8    | 2    | 6    | 0    | 2    | 0    | 2    | 0    | 9    | 0    | 6    | 3    | 9    | 0    | 9    | 9    | 0    | 1    | 1    | 9    |                    |
| <b>FISCHER 344 RATS MALE</b> | 0       | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    |                    |
|                              | 0       | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    |                    |
|                              | 1       | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1    |                    |
|                              | 5       | 5    | 5    | 5    | 5    | 5    | 5    | 5    | 5    | 6    | 6    | 6    | 6    | 6    | 6    | 6    | 6    | 6    | 6    | 6    | 7    | 7    | 7    | 7    | 7    |                    |
|                              | 1       | 2    | 3    | 4    | 5    | 6    | 7    | 8    | 9    | 0    | 1    | 2    | 3    | 4    | 5    | 6    | 7    | 8    | 9    | 0    | 1    | 2    | 3    | 4    | 5    |                    |

**ALIMENTARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus                                       | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum<br>Edema                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon                          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum<br>Inflammation, Chronic | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum                        | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Basophilic Focus                                |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   | X |   | X | X |
| Clear Cell Focus                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Degeneration, Cystic                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |
| Eosinophilic Focus                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hepatodiaphragmatic Nodule                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Infarct   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Infiltration Cellular, Mixed Cell               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mixed Cell Focus                                | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ .. Tissue examined microscopically  
x .. Lesion present  
l .. Insufficient tissue  
M .. Missing tissue  
A .. Autolysis precludes evaluation  
BLANK .. Not examined microscopically  
1-4 .. Lesion qualified as:  
1) Minimal 3) Moderate  
2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                            |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|--|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
|  |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |
|  |  | 6 | 7 | 7 | 7 | 6 | 2 | 6 | 7 | 4 | 6 | 5 | 5 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 5 |  |
|  |  | 3 | 3 | 3 | 3 | 8 | 0 | 1 | 1 | 5 | 1 | 9 | 7 | 3 | 2 | 3 | 9 | 2 | 2 | 3 | 2 | 2 | 9 | 3 | 3 | 0 |  |
|  |  | 5 | 0 | 0 | 1 | 4 | 8 | 2 | 6 | 0 | 2 | 0 | 2 | 0 | 9 | 0 | 6 | 3 | 9 | 0 | 9 | 9 | 0 | 1 | 1 | 9 |  |
| FISCHER 344 RATS MALE                  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| ANIMAL ID                              |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |
| 25000 PPM                              |  | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |  |
|  |  | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 |  |
|  |  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |  |
| Necrosis, Focal                        |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Bile Duct, Hyperplasia                 |  | 1 | 2 | 1 | 2 | 3 |   | 3 | 3 |   |   | 3 |   | 2 | 4 | 3 | 3 |   |   | 3 | 1 | 1 | 3 | 1 | 3 | 4 |  |
| Centrilobular, Necrosis                |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Hepatocyte, Degeneration               |  | 2 | 2 | 3 |   |   |   |   |   |   |   |   |   | 3 |   | 1 |   | 1 | 2 |   | 3 | 2 |   | 3 |   |   |  |
| Hepatocyte, Hypertrophy                |  | 3 | 2 | 4 | 1 |   |   |   |   | 4 |   |   | 1 | 4 |   | 3 |   | 3 |   |   | 2 |   | 4 | 2 |   |   |  |
| Hepatocyte, Vacuolization              |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Cytoplasmic Kupffer Cell, Pigmentation |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Mesentery                              |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Accessory Spleen                       |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Fat, Necrosis                          |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Pancreas                               |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Atrophy                                |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Cyst                                   |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Acinus, Cytoplasmic Alteration         |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Acinus, Hyperplasia, Focal             |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Salivary Glands                        |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Atrophy                                |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Stomach, Forestomach                   |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Edema                                  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Ulcer                                  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Epithelium, Hyperplasia                |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Stomach, Glandular                     |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Erosion                                |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

**males (cont...)**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
     1) Minimal   3) Moderate  
     2) Mild      4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
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 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

| DAY ON TEST                        | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|                                    | 6 7 7 7 6 2 6 7 4 6 5 5 7 7 7 6 5 7 6 7 7 5 7 7 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS MALE<br>ANIMAL ID | 3 3 3 3 8 0 1 1 5 1 9 7 3 2 3 9 2 2 3 2 2 9 3 3 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 5 0 0 1 4 8 2 6 0 2 0 2 0 9 0 6 3 9 0 9 9 0 1 1 9 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 25000 PPM                          | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 25000 PPM                          | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 25000 PPM                          | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | males (cont...)                                   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**CARDIOVASCULAR SYSTEM**

|                |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|----------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Heart          | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cardiomyopathy | 3 2 2 2 1 1 1 1 1 1 2 2 1 3 2 3 1 1 1 1 1 1 1 1 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Thrombosis     |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**ENDOCRINE SYSTEM**

|                                    |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Adrenal Cortex                     | +     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accessory Adrenal Cortical Nodule  | 3     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia                        | 2 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia, Focal                 | 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hypertrophy, Focal                 | 2 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Necrosis                           | 3 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Vacuolization Cytoplasmic, Focal   | 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Vacuolization Cytoplasmic, Diffuse | 3 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Adrenal Medulla                    | +     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia                        | 1 2 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Islets, Pancreatic                 | +     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Parathyroid Gland                  | + + + + + + M + + + + + + I + + + + + + + + + + + + + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pituitary Gland                    | +     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pars Distalis, Angiectasis         | 3 2 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pars Distalis, Cyst                | X X X 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
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 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

| DAY ON TEST                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                      |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|------------------------|
|                              | 6 | 7 | 7 | 7 | 6 | 2 | 6 | 7 | 4 | 6 | 5 | 5 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 5 | 7 | 5                      |
|                              | 3 | 3 | 3 | 3 | 8 | 0 | 1 | 1 | 5 | 1 | 9 | 7 | 3 | 2 | 3 | 9 | 2 | 2 | 3 | 2 | 2 | 9 | 3 | 3 | 0 | 0 | 0                      |
|                              | 5 | 0 | 0 | 1 | 4 | 8 | 2 | 6 | 0 | 2 | 0 | 2 | 0 | 9 | 0 | 6 | 3 | 9 | 0 | 9 | 9 | 0 | 1 | 1 | 9 | 0 | 0                      |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                      |
| ANIMAL ID                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                      |
| <b>25000 PPM</b>             | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1                      |
|                              | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7                      |
|                              | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   | <b>males (cont...)</b> |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Pars Distalis, Hyperplasia, Focal |   |   |   |   | 1 | 2 |   |   |   | 3 |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Pars Intermedia, Cyst             |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Ultimobranchial Cyst              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| C-cell, Hyperplasia               |   |   |   |   | 1 |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Follicle, Cyst                    |   |   |   |   |   |   | X |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Follicular Cell, Hyperplasia      |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Epididymis            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Granuloma Sperm       |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Preputial Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Hyperplasia           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic |   | 2 |   | 2 | 2 |   | 2 |   |   | 2 |   |   | 2 |   | 2 |   |   | 2 |   | 2 |   |   | 2 |   |   | 2 | 3 |   |
| Prostate              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis           |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Acute   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic |   |   | 1 |   |   |   |   |   | 2 |   | 4 | 2 |   |   |   | 2 |   | 2 |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

| DAY ON TEST                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                              | 6 | 7 | 7 | 7 | 6 | 2 | 6 | 7 | 4 | 6 | 5 | 5 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 5 |   |
|                              | 3 | 3 | 3 | 3 | 8 | 0 | 1 | 1 | 5 | 1 | 9 | 7 | 3 | 2 | 3 | 9 | 2 | 2 | 3 | 2 | 2 | 9 | 3 | 3 | 0 |   |
|                              | 5 | 0 | 0 | 1 | 4 | 8 | 2 | 6 | 0 | 2 | 0 | 2 | 0 | 9 | 0 | 6 | 3 | 9 | 0 | 9 | 9 | 0 | 1 | 1 | 9 |   |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>25000 PPM</b>             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>ANIMAL ID</b>             | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |
|                              | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 |   |
|                              | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   |

males  
(cont...)

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Seminal Vesicle<br>Inflammation, Chronic                                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Testes<br>Germinal Epithelium, Atrophy<br>Interstitial Cell, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|  |   |   |   |   |   |   |   | 1 |   |   |   |   |   | 2 |   |   | 4 |   |   |   |   |   |   |   | 2 |
|  |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

HEMATOPOIETIC SYSTEM

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow<br>Hyperplasia<br>Myelofibrosis  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|  | 2 | 3 |   |   |   |   |   |   |   | 3 |   |   | 4 |   |   |   |   | 3 |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Lymph Node<br>Mediastinal, Ectasia<br>Mediastinal, Hemorrhage<br>Mediastinal, Hyperplasia, Lymphoid<br>Mediastinal, Pigmentation<br>Pancreatic, Ectasia<br>Pancreatic, Hemorrhage<br>Pancreatic, Hyperplasia, Lymphoid |   | + |   | + |   |   |   |   | + |   | + |   |   | + |   | + | + |   |   | + |   | + |   |   | + |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Lymph Node, Mandibular   | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Lymph Node, Mesenteric<br>Atrophy<br>Ectasia<br>Hemorrhage   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                                      | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | males<br>(cont...) |   |
|--|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|---|
|  | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                    | 0 |
| 6  | 7         | 7 | 7 | 6 | 2 | 6 | 7 | 4 | 6 | 5 | 5 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 5 | 0 |                    |   |
| 3  | 3         | 3 | 3 | 8 | 0 | 1 | 1 | 5 | 1 | 9 | 7 | 3 | 2 | 3 | 9 | 2 | 2 | 3 | 2 | 2 | 9 | 3 | 3 | 0 |   |                    |   |
| 5  | 0         | 0 | 1 | 4 | 8 | 2 | 6 | 0 | 2 | 0 | 2 | 0 | 9 | 0 | 6 | 3 | 9 | 0 | 9 | 9 | 0 | 1 | 1 | 9 |   |                    |   |
| .....  |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |   |
| <b>FISCHER 344 RATS MALE</b><br><b>25000 PPM</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |   |
|  | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |   |
|  | 1         | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1                  |   |
|  | 5         | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7                  |   |
|  | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                    |   |

|                                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Hyperplasia, Lymphoid            | 2 | 2 |   | 2 |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |  |
| Spleen                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |   |  |
| Fibrosis                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Hematopoietic Cell Proliferation |   |   |   |   |   |   | 1 |   | 1 |   | 1 | 1 |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |  |
| Hemorrhage                       |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Hyperplasia, Lymphoid            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Necrosis                         |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Thymus                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |   |  |
| Atrophy                          |   |   |   | 3 |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | M | + | + | + | + | + | + |  |

### INTEGUMENTARY SYSTEM

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Mammary Gland             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Hyperplasia               |   |   |   | 1 |   | 2 |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |  |
| Skin                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Cyst Epithelial Inclusion |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Hyperkeratosis            |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Ulcer                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

### MUSCULOSKELETAL SYSTEM

|          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Bone     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Fracture |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 57

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

|                              |           | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
|------------------------------|-----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|
|                              |           | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                    |
| <b>FISCHER 344 RATS MALE</b> | ANIMAL ID | 6           | 7 | 7 | 7 | 6 | 2 | 6 | 7 | 4 | 6 | 5 | 5 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 5 | males<br>(cont...) |
|                              |           | 3           | 3 | 3 | 3 | 8 | 0 | 1 | 1 | 5 | 1 | 9 | 7 | 3 | 2 | 3 | 9 | 2 | 2 | 3 | 2 | 2 | 9 | 3 | 3 | 0 |                    |
| <b>25000 PPM</b>             |           | 5           | 0 | 0 | 1 | 4 | 8 | 2 | 6 | 0 | 2 | 0 | 2 | 0 | 9 | 0 | 6 | 3 | 9 | 0 | 9 | 9 | 0 | 1 | 1 | 9 |                    |

Skeletal Muscle Atrophy + 1 +

**NERVOUS SYSTEM**

Brain +  
 Compression 2  
 Gliosis  
 Hemorrhage  
 Metaplasia, Lipocyte  
 Peripheral Nerve +  
 Spinal Cord

**RESPIRATORY SYSTEM**

Lung +  
 Hemorrhage 2 2  
 Infiltration Cellular, Histiocyte 3 1 1 1 3 1 1 1 4  
 Inflammation, Chronic 1  
 Metaplasia, Osseous  
 Alveolar Epithelium, Hyperplasia 1 1 2 2 2  
 Nose +  
 Foreign Body X X X X  
 Inflammation, Chronic 1 1 1

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST           |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|-----------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                       |  | 6 | 7 | 7 | 7 | 6 | 2 | 6 | 7 | 4 | 6 | 5 | 5 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 5 |
|                       |  | 3 | 3 | 3 | 3 | 8 | 0 | 1 | 1 | 5 | 1 | 9 | 7 | 3 | 2 | 3 | 9 | 2 | 2 | 3 | 2 | 2 | 9 | 3 | 3 | 0 |
|                       |  | 5 | 0 | 0 | 1 | 4 | 8 | 2 | 6 | 0 | 2 | 0 | 2 | 0 | 9 | 0 | 6 | 3 | 9 | 0 | 9 | 9 | 0 | 1 | 1 | 9 |
| FISCHER 344 RATS MALE |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID             |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 25000 PPM             |  | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
|                       |  | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
|                       |  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males (cont...)

Respiratory Epithelium, Hyperplasia

1 1

Trachea

+ +

**SPECIAL SENSES SYSTEM**

Eye  
 Cataract  
 Retina, Degeneration

+  
 1

Harderian Gland  
 Hyperplasia, Focal

+  
 1

**URINARY SYSTEM**

Kidney  
 Cyst  
 Hydronephrosis  
 Infarct  
 Nephropathy  
 Renal Tubule, Accumulation, Hyaline  
 Droplet  
 Renal Tubule, Mineralization  
 Renal Tubule, Necrosis  
 Renal Tubule, Pigmentation

+  
 X  
 2  
 1 3 2 1 2 2 2 1 2 2 1 2 1 2 2 1 2 1 2 3 1 3 2 1  
 2  
 1  
 3 2

Urinary Bladder

+ +

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 l .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|
| DAY ON TEST                                     | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |   |                    |
|   | 6 | 7 | 7 | 7 | 6 | 2 | 6 | 7 | 4 | 6 | 5 | 5 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 5 |   |   |                    |
|   | 3 | 3 | 3 | 3 | 8 | 0 | 1 | 1 | 5 | 1 | 9 | 7 | 3 | 2 | 3 | 9 | 2 | 2 | 3 | 2 | 2 | 9 | 3 | 3 | 0 |   |   |                    |
|   | 5 | 0 | 0 | 1 | 4 | 8 | 2 | 6 | 0 | 2 | 0 | 2 | 0 | 9 | 0 | 6 | 3 | 9 | 0 | 9 | 9 | 0 | 1 | 1 | 9 |   |   |                    |
| .....   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| FISCHER 344 RATS MALE<br>25000 PPM<br>ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                    |
|   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                    |
|   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |                    |
|   | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | males<br>(cont...) |
|   | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   |   |                    |

Hemorrhage 4  
Inflammation, Acute 3

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 Page 60

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                           | FISCHER 344 RATS MALE |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |   |                 |     |     |
|---------------------------------------|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|-----------------|-----|-----|
|                                       | ANIMAL ID             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   |                 |     |     |
| 0                                     | 0                     | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | 0 | 0               |     |     |
| 7                                     | 7                     | 7 | 6 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 6 | 4 | 6 | 7 | 4 | 7 | 6 | 7 | 7 | 7        | 7 | 7               |     |     |
| 3                                     | 3                     | 2 | 5 | 4 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 7 | 5 | 5 | 2 | 7 | 1 | 8 | 2 | 3 | 3        | 3 | 3               |     |     |
| 1                                     | 1                     | 3 | 3 | 7 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 7 | 4 | 1 | 6 | 9 | 8 | 1 | 8 | 9 | 1        | 1 | 1               |     |     |
| 0                                     | 0                     | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | 0 | 0               |     |     |
| 0                                     | 0                     | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | 0 | 0               |     |     |
| 1                                     | 1                     | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1        | 1 | 1               |     |     |
| 7                                     | 7                     | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9        | 9 | 9               |     |     |
| 6                                     | 7                     | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7        | 8 | 9               |     |     |
|                                       |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   | <b>* TOTALS</b> |     |     |
| Necrosis, Focal                       |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1 | 1               |     |     |
| Bile Duct, Hyperplasia                | 3                     | 2 | 4 | 4 | 1 | 3 | 2 | 3 | 1 | 3 | 3 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 3 |          |   | 39              | 2.2 |     |
| Centrilobular, Necrosis               |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1 | 1.0             |     |     |
| Hepatocyte, Degeneration              | 2                     | 3 |   |   | 2 |   | 3 |   |   |   |   |   |   | 2 |   |   | 3 |   | 2 | 2 |          |   | 19              | 2.3 |     |
| Hepatocyte, Hypertrophy               | 2                     | 4 |   |   | 3 | 2 | 3 |   | 3 |   |   | 2 |   | 2 |   | 1 | 3 | 2 | 2 | 3 | 3        | 3 | 27              | 2.6 |     |
| Hepatocyte, Vacuolization Cytoplasmic |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1 | 4.0             |     |     |
| Kupffer Cell, Pigmentation            |                       |   |   | 3 |   |   |   |   |   |   |   |   |   |   | 2 | 2 |   |   |   |   |          | 3 | 2.3             |     |     |
| -----                                 |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   |                 |     |     |
| Mesentery                             |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | + | 7               |     |     |
| Accessory Spleen                      |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   | X               | 1   |     |
| Fat, Necrosis                         |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   | 3               | 3   | 3.0 |
| -----                                 |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   |                 |     |     |
| Pancreas                              | +                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | + | 50              |     |     |
| Atrophy                               | 1                     |   |   |   | 1 |   | 1 |   | 1 |   |   |   |   | 1 |   | 1 |   | 2 |   | 3 |          | 2 | 3               | 18  | 1.8 |
| Cyst                                  |                       | X |   |   |   |   |   | X |   |   |   |   |   | X |   | X |   |   |   | X | X        |   | 14              |     |     |
| Acinus, Cytoplasmic Alteration        |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   |                 | 1   | 3.0 |
| Acinus, Hyperplasia, Focal            |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   |                 | 1   | 3.0 |
| -----                                 |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   |                 |     |     |
| Salivary Glands                       | +                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | + | 50              |     |     |
| Atrophy                               |                       | 1 |   |   | 1 | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2        |   | 6               | 1.2 |     |
| -----                                 |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   |                 |     |     |
| Stomach, Forestomach                  | +                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | + | 50              |     |     |
| Edema                                 |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   | 2               | 1   | 2.0 |
| Ulcer                                 |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   |                 | 1   | 3.0 |
| Epithelium, Hyperplasia               | 1                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1 | 3               | 1.7 |     |
| -----                                 |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   |                 |     |     |
| Stomach, Glandular                    | +                     | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | + | 49              |     |     |
| Erosion                               |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   | 2               | 3   | 2.0 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
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 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                                     | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | * TOTALS |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
|   | 7 7 7 6 5 7 7 7 7 7 7 6 6 4 6 7 4 7 6 7 7 7 7 7 7 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
| FISCHER 344 RATS MALE<br>25000 PPM<br>ANIMAL ID | 3 3 2 5 4 3 3 3 3 3 0 2 7 5 5 2 7 1 8 2 3 3 3 3 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|   | 1 1 3 3 7 0 0 0 0 0 3 7 4 1 6 9 8 1 8 9 1 1 1 1 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|   | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|   | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|   | 1 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|   | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|   | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |

**CARDIOVASCULAR SYSTEM**

|                |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |        |
|----------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Heart          | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50     |
| Cardiomyopathy | 2 2 1 2 3 3 1 1 1 1 2 3 2 2 2 2 1 1 2 3         |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 36 1.8 |
| Thrombosis     | 4   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 4.0  |

**ENDOCRINE SYSTEM**

|                                    |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |        |
|------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Adrenal Cortex                     | +     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50     |
| Accessory Adrenal Cortical Nodule  | 3     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 19 3.0 |
| Hyperplasia                        | 2 1 1 2 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 7 1.4  |
| Hyperplasia, Focal                 | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2 2.0  |
| Hypertrophy, Focal                 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 2.0  |
| Necrosis                           |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 3.0  |
| Vacuolization Cytoplasmic, Focal   | 1 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 4 1.3  |
| Vacuolization Cytoplasmic, Diffuse |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 3.0  |
| Adrenal Medulla                    | + + + + M + + + + + + + I + + + + + + + + + + + +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 48     |
| Hyperplasia                        | 1 1 2 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 9 1.2  |
| Islets, Pancreatic                 | +     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50     |
| Parathyroid Gland                  | + + + + + + + + + + + + + M + + + + + + + + + + + + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 47     |
| Pituitary Gland                    | +     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50     |
| Pars Distalis, Angiectasis         | 1 2 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 5 2.0  |
| Pars Distalis, Cyst                | X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 4      |

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 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|
|                              | 7 | 7 | 7 | 6 | 5 | 7 | 7 | 7 | 7 | 7 | 6 | 6 | 4 | 6 | 7 | 4 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7               | 7 |
|                              | 3 | 3 | 2 | 5 | 4 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 7 | 5 | 5 | 2 | 7 | 1 | 8 | 2 | 3 | 3 | 3 | 3               | 3 |
|                              | 1 | 1 | 3 | 3 | 7 | 0 | 0 | 0 | 0 | 0 | 3 | 7 | 4 | 1 | 6 | 9 | 8 | 1 | 8 | 9 | 1 | 1 | 1 | 1               | 1 |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
| <b>25000 PPM</b>             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
| ANIMAL ID                    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1               | 2 |
|                              | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9               | 0 |
|                              | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9               | 0 |
|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |   |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |            |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|------------|
| Pars Distalis, Hyperplasia, Focal |   |   |   | 2 |   | 3 |   |   |   | 2 |   | 3 |   |   |   | 1 |   |   |   |   |   |   |   |   |   | <b>10</b> | <b>2.0</b> |
| Pars Intermedia, Cyst             |   |   |   |   |   |   |   |   |   |   |   | X | X |   |   |   |   | X |   |   |   |   |   |   |   | <b>5</b>  |            |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |            |
| Ultimobranchial Cyst              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>  |            |
| C-cell, Hyperplasia               |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>6</b>  | <b>1.7</b> |
| Follicle, Cyst                    |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2</b>  |            |
| Follicular Cell, Hyperplasia      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>  | <b>2.0</b> |

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |            |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|------------|
| Epididymis            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |            |
| Granuloma Sperm       |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2</b>  | <b>2.5</b> |
| Inflammation, Chronic |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2</b>  | <b>2.0</b> |
| Preputial Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |            |
| Hyperplasia           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   | <b>1</b>  | <b>2.0</b> |
| Inflammation, Chronic |   |   |   | 2 |   | 2 |   |   | 2 | 3 |   |   | 2 |   |   | 2 | 2 |   |   |   |   |   |   |   | 2 | <b>20</b> | <b>2.1</b> |
| Prostate              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |            |
| Angiectasis           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>  | <b>3.0</b> |
| Inflammation, Acute   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>  | <b>3.0</b> |
| Inflammation, Chronic |   |   | 2 | 4 |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>10</b> | <b>2.4</b> |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

Page 64

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked



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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                                     | 0     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | * TOTALS |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
|   | 7 7 7 6 5 7 7 7 7 7 7 6 6 4 6 7 4 7 6 7 7 7 7 7 7   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
| FISCHER 344 RATS MALE<br>25000 PPM<br>ANIMAL ID | 3 3 2 5 4 3 3 3 3 3 0 2 7 5 5 2 7 1 8 2 3 3 3 3 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|   | 1 1 3 3 7 0 0 0 0 0 0 3 7 4 1 6 9 8 1 8 9 1 1 1 1 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |     |   |     |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|-----|---|-----|
| Seminal Vesicle<br>Inflammation, Chronic                                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 3.0 |   |     |
| Testes<br>Germinal Epithelium, Atrophy<br>Interstitial Cell, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 8 | 2.6 |   |     |
|  |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |    | 1 | 3   | 3 | 1.0 |

**HEMATOPOIETIC SYSTEM**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |     |     |     |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|-----|-----|-----|
| Bone Marrow<br>Hyperplasia<br>Myelofibrosis  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 8  | 3.0 |     |     |     |
|  |   |   | 3 |   |   | 4 |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |    | 3  | 3   | 3   | 3.0 |     |
| Lymph Node<br>Mediastinal, Ectasia<br>Mediastinal, Hemorrhage<br>Mediastinal, Hyperplasia, Lymphoid<br>Mediastinal, Pigmentation<br>Pancreatic, Ectasia<br>Pancreatic, Hemorrhage<br>Pancreatic, Hyperplasia, Lymphoid |   |   |   | + |   |   |   |   | + | + | + |   |   |   | + |   |   |   |   |   |   |   |   |   |   | +  | 19 | 1   | 3.0 |     |     |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    | 3   |     | 3   | 2.0 |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |     |     | 2.7 |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |     |     | 2.0 |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |     |     | 3.0 |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |     |     | 1.0 |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |     |     | 2.0 |
| Lymph Node, Mandibular   | M | M | M | M | M | M | M | M | M | M | + | M | M | M | M | M | + | M | M | M | M | M | M | M | M | M  | 2  |     |     |     |     |
| Lymph Node, Mesenteric<br>Atrophy<br>Ectasia<br>Hemorrhage   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 50 | 1   | 2.0 |     |     |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |     |     | 2.0 |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |     |     | 3.0 |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |     |     | 1.0 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                                       | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |  |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|--|
|   | 7 7 7 6 5 7 7 7 7 7 7 6 6 4 6 7 4 7 6 7 7 7 7 7   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |  |
| FISCHER 344 RATS MALE<br>25000 PPM<br>ANIMAL ID   | 3 3 2 5 4 3 3 3 3 3 0 2 7 5 5 2 7 1 8 2 3 3 3 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |  |
|   | 1 1 3 3 7 0 0 0 0 0 0 3 7 4 1 6 9 8 1 8 9 1 1 1 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |  |
| 0   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |  |
| 0   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |  |
| 1 2   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |  |
| 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 0   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |  |
| 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |  |
|   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | * TOTALS |  |

|                                  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |    |     |    |     |
|----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|----|-----|----|-----|
| Hyperplasia, Lymphoid            |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2 | 8  | 2.1 |    |     |
| Spleen                           | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | 50 |     |    |     |
| Fibrosis                         |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | 2  | 2.5 |    |     |
| Hematopoietic Cell Proliferation |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3 | 2  | 1   | 11 | 1.6 |
| Hemorrhage                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3 |    |     | 2  | 3.0 |
| Hyperplasia, Lymphoid            |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |    | 2   | 1  | 2.0 |
| Necrosis                         |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |    |     | 1  | 4.0 |
| Thymus                           | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | M |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | 47 |     |    |     |
| Atrophy                          |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | 2  | 2.5 |    |     |

**INTEGUMENTARY SYSTEM**

|                           |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |    |   |   |     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |     |
|---------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|----|---|---|-----|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|---|-----|
| Mammary Gland             | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | 50 |   |   |     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |     |
| Hyperplasia               |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3 |    |   |   |     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2 | 8 | 1.9 |
| Skin                      | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | 50 |   |   |     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |     |
| Cyst Epithelial Inclusion |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |    | X | 2 |     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |     |
| Hyperkeratosis            |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |    |   | 1 | 3.0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |     |
| Ulcer                     |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |    |   | 1 | 3.0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |     |

**MUSCULOSKELETAL SYSTEM**

|          |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    |   |   |  |
|----------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|---|---|--|
| Bone     | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50 |   |   |  |
| Fracture |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    | X | 1 |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
| DAY ON TEST                               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
|   | 7 | 7 | 7 | 6 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 6 | 4 | 6 | 7 | 4 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7               |
|   | 3 | 3 | 2 | 5 | 4 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 7 | 5 | 5 | 2 | 7 | 1 | 8 | 2 | 3 | 3 | 3 | 3 | 3 | 3               |
|   | 1 | 1 | 3 | 3 | 7 | 0 | 0 | 0 | 0 | 0 | 3 | 7 | 4 | 1 | 6 | 9 | 8 | 1 | 8 | 9 | 1 | 1 | 1 | 1 | 1 | 1               |
| <b>FISCHER 344 RATS MALE</b><br>ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
| <b>25000 PPM</b>                          | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
|   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2               |
|   | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0               |
|   | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | <b>* TOTALS</b> |

|                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              |           |
|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|-----------|
| Respiratory Epithelium, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>3 1.0</b> |           |
| Trachea                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +            | <b>50</b> |

**SPECIAL SENSES SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              |           |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|-----------|
| Eye                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +            | <b>50</b> |
| Cataract             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 3.0</b> |           |
| Retina, Degeneration |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2 2.0</b> |           |
| Harderian Gland      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +            | <b>50</b> |
| Hyperplasia, Focal   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 1.0</b> |           |

**URINARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              |               |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|---------------|
| Kidney                                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +            | <b>50</b>     |
| Cyst  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>     |               |
| Hydronephrosis                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 2.0</b> |               |
| Infarct                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2 2.0</b> |               |
| Nephropathy                                 | 2 | 3 | 1 | 1 | 1 | 2 | 1 | 3 | 3 | 2 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 2 | 2 | 1 | 3 | 2 | 2 | 2            | <b>49 1.7</b> |
| Renal Tubule, Accumulation, Hyaline Droplet |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 3.0</b> |               |
| Renal Tubule, Mineralization                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 2.0</b> |               |
| Renal Tubule, Necrosis                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2 2.0</b> |               |
| Renal Tubule, Pigmentation                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>4 2.3</b> |               |
| Urinary Bladder                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +            | <b>50</b>     |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal    3) Moderate  
 2) Mild       4) Marked

Page 68

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

|                              |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |   |   |
|------------------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|---|
| DAY ON TEST                  |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 | 0 |
|                              |  | 7 | 7 | 7 | 6 | 5 | 7 | 7 | 7 | 7 | 7 | 6 | 6 | 4 | 6 | 7 | 4 | 7 | 6 | 7 | 7 | 7               | 7 | 7 |
|                              |  | 3 | 3 | 2 | 5 | 4 | 3 | 3 | 3 | 3 | 0 | 2 | 7 | 5 | 5 | 2 | 7 | 1 | 8 | 2 | 3 | 3               | 3 | 3 |
|                              |  | 1 | 1 | 3 | 3 | 7 | 0 | 0 | 0 | 0 | 3 | 7 | 4 | 1 | 6 | 9 | 8 | 1 | 8 | 9 | 1 | 1               | 1 | 1 |
| <b>FISCHER 344 RATS MALE</b> |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 | 0 |
| ANIMAL ID                    |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 | 0 |
| <b>25000 PPM</b>             |  | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1               | 1 | 2 |
|                              |  | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9               | 9 | 0 |
|                              |  | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6               | 7 | 8 |
|                              |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |   |   |
| Hemorrhage                   |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 4.0</b>    |   |   |
| Inflammation, Acute          |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 3.0</b>    |   |   |

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

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

l .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                                    |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| <b>FISCHER 344 RATS FEMALE</b><br><b>0 PPM</b> | ANIMAL ID | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
|  |           | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 3 | 9 | 3 | 3 | 1 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|  |           | 6 | 6 | 6 | 6 | 9 | 1 | 1 | 1 | 0 | 7 | 2 | 1 | 2 | 2 | 2 | 6 | 3 | 3 | 3 | 3 | 3 | 1 | 1 | 1 | 1 |
|  |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
|  | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   |

females  
(cont...)

**ALIMENTARY SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus                         | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum<br>Edema   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum            | + | + | + | + | + | + | + | + | A | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum          | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Basophilic Focus                  | X | X | X | X | X | X | X | X |   | X | X |   | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Clear Cell Focus                  |   | X |   |   |   |   |   |   |   |   | X |   | X |   |   |   |   |   |   |   |   | X |   |   |   |
| Eosinophilic Focus                |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hematopoietic Cell Proliferation  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hepatodiaphragmatic Nodule        |   |   |   | X |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Infiltration Cellular, Mixed Cell |   |   |   |   |   |   |   |   | 2 | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |
| Mixed Cell Focus                  |   |   |   |   |   |   |   |   | X |   |   |   |   | X |   |   |   |   |   |   | X |   |   |   |   |
| Necrosis, Focal                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Bile Duct, Hyperplasia            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 l .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |   |
|                                | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 3 | 9 | 3 | 3 | 1 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |   |
|                                | 6 | 6 | 6 | 6 | 9 | 1 | 1 | 1 | 0 | 7 | 2 | 1 | 2 | 2 | 2 | 6 | 3 | 3 | 3 | 3 | 1 | 1 | 1 | 1 |   |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>0 PPM</b>                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>ANIMAL ID</b>               | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   |
|                                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |
|                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

females  
(cont...)

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Centrilobular, Necrosis<br>Hepatocyte, Degeneration<br>Hepatocyte, Hypertrophy<br>Hepatocyte, Vacuolization<br>Kupffer Cell, Pigmentation | 2 | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |  |
| Mesentery<br>Fat, Necrosis  | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Pancreas<br>Atrophy<br>Cyst<br>Acinus, Cytoplasmic Alteration   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
|   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Salivary Glands<br>Atrophy  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
|   |   |   |   | 1 | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Stomach, Forestomach<br>Ulcer   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Stomach, Glandular<br>Erosion   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
|   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Tongue  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

CARDIOVASCULAR SYSTEM

|       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL  
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

|  |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                 |
|--|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------------------|
| DAY ON TEST                                    |           | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7                 |
|  |           | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 3 | 9 | 3 | 3 | 1 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3                 |
|  |           | 6 | 6 | 6 | 6 | 9 | 1 | 1 | 1 | 0 | 7 | 2 | 1 | 2 | 2 | 2 | 6 | 3 | 3 | 3 | 3 | 1 | 1 | 1 | 1 | 1 | 1                 |
| <b>FISCHER 344 RATS FEMALE</b><br><b>0 PPM</b> | ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                   |
|  |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                 |
|  |           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2                 |
|  |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2                 |
|  |           | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | females (cont...) |

|   |   |   |   |   |  |   |  |  |   |   |  |  |  |  |   |   |   |   |  |   |  |  |  |  |  |
|---|---|---|---|---|--|---|--|--|---|---|--|--|--|--|---|---|---|---|--|---|--|--|--|--|--|
| Cardiomyopathy<br>Inflammation, Chronic<br>Thrombosis | 1 | 1 | 1 | 2 |  | 1 |  |  | 1 | 2 |  |  |  |  | 2 | 2 | 1 | 1 |  | 1 |  |  |  |  |  |
|---|---|---|---|---|--|---|--|--|---|---|--|--|--|--|---|---|---|---|--|---|--|--|--|--|--|

**ENDOCRINE SYSTEM**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Accessory Adrenal Cortical Nodule<br>Degeneration, Fatty | 1 | 3 |   | 2 |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   | 3 |   |   | 2 |   |   | 3 |   |
| Hematopoietic Cell Proliferation<br>Hyperplasia, Focal   |   |   |   |   |   |   | 1 |   |   |   |   | 1 |   |   |   |   |   | 2 |   | 3 |   |   |   |   |   |   |
| Hypertrophy, Focal<br>Necrosis                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Adrenal Medulla  | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Islets, Pancreatic                                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Parathyroid Gland  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pituitary Gland  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pigmentation   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pars Distalis, Angiectasis                               |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pars Distalis, Cyst                                      |   | X |   | X |   | X |   | X |   |   | X | X | X | X | X | X | X |   |   | X | X |   |   | X | X |   |
| Pars Distalis, Hyperplasia, Focal                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   | 2 | 2 |   |   |   |   |   |   |
| Pars Intermedia, Angiectasis                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pars Intermedia, Cyst                                    |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ .. Tissue examined microscopically  
x .. Lesion present  
I .. Insufficient tissue  
M .. Missing tissue  
A .. Autolysis precludes evaluation  
BLANK .. Not examined microscopically  
1-4 .. Lesion qualified as:  
1) Minimal 3) Moderate  
2) Mild 4) Marked  
Page 72



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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females (cont...) |
|-------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------------------|
|             | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                   |
| 7           | 7         | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0                 |
| 3           | 3         | 3 | 3 | 1 | 3 | 3 | 3 | 9 | 3 | 3 | 1 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 0                 |
| 6           | 6         | 6 | 6 | 9 | 1 | 1 | 1 | 0 | 7 | 2 | 1 | 2 | 2 | 2 | 6 | 3 | 3 | 3 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 0                 |

**FISCHER 344 RATS FEMALE**  
 ANIMAL ID  
 0 PPM

|                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|---------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Thyroid Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| C-cell, Hyperplasia |   | 1 |   |   |   |   |   | 1 |   |   |   |   |   | 1 |   |   |   |   | 1 | 2 | 2 | 1 | 1 |   | 1 |  |

**GENERAL BODY SYSTEM**

Tissue NOS

**GENITAL SYSTEM**

|                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Cyst                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Hyperplasia         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |
| Hyperplasia, Focal  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Ovary               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Cyst                |   |   | X |   |   |   |   | X | X |   |   |   |   |   |   |   |   |   |   |   | X |   | X |   |   |   |
| Uterus              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Hemorrhage          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia, Cystic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |
| Vagina              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |

**HEMATOPOIETIC SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                                   | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|   | 7 7 7 7 7 7 7 7 6 5 7 6 7 7 7 6 7 7 7 7 7 7 7 7 7 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS FEMALE<br>0 PPM              | 3 3 3 3 1 3 3 3 9 3 3 1 3 3 3 6 3 3 3 3 3 3 3 3 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 6 6 6 6 9 1 1 1 0 7 2 1 2 2 2 6 3 3 3 3 1 1 1 1 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ANIMAL ID                                     | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | females (cont...)                                 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Bone Marrow                                   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia                                   | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Myelofibrosis                                 | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Lymph Node                                    | + + + +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hemorrhage                                    | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pigmentation                                  | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mediastinal, Hematopoietic Cell Proliferation |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mediastinal, Hemorrhage                       | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mediastinal, Hyperplasia, Lymphoid            | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mediastinal, Pigmentation                     | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pancreatic, Hemorrhage                        | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Lymph Node, Mandibular                        | M + M M + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Lymph Node, Mesenteric                        | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hemorrhage                                    | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia, Lymphoid                         | 2 2 2 2 2 3 2 2 2 3 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Spleen  | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accessory Spleen                              | X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hematopoietic Cell Proliferation              | 2 2 3 1 2 2 2 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Thymus  | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cyst  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**INTEGUMENTARY SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 74

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL  
 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

|  |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST                                    |           | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
|  |           | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 3 | 9 | 3 | 3 | 1 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|  |           | 6 | 6 | 6 | 6 | 9 | 1 | 1 | 1 | 0 | 7 | 2 | 1 | 2 | 2 | 2 | 6 | 3 | 3 | 3 | 3 | 1 | 1 | 1 | 1 |
| <b>FISCHER 344 RATS FEMALE</b><br><b>0 PPM</b> | ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|  |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|  |           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   |
|  |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |
|  |           | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 |   |

females  
(cont...)

Mammary Gland  
Hyperplasia

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 2 | 2 | 3 | 1 |   | 3 | 3 | 1 | 4 | 4 | 3 | 4 | 3 |

Skin  
Hemorrhage  
Hyperkeratosis  
Ulcer  
Epidermis, Hyperplasia

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**MUSCULOSKELETAL SYSTEM**

Bone  
Fracture

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |

**NERVOUS SYSTEM**

Brain  
Compression  
Gliosis  
Hemorrhage  
Necrosis

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 2 |   |   |   | 4 |   |   |   | 4 | 4 |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |
|   |   |   |   | 2 |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

Peripheral Nerve

Spinal Cord

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 l .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                                | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  | 7 7 7 7 7 7 7 7 6 5 7 6 7 7 7 6 7 7 7 7 7 7 7 7 7 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS FEMALE<br>0 PPM ANIMAL ID | 3 3 3 3 1 3 3 3 9 3 3 1 3 3 3 6 3 3 3 3 3 3 3 3 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 6 6 6 6 9 1 1 1 0 7 2 1 2 2 2 6 3 3 3 3 1 1 1 1 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | <b>females (cont...)</b>                          |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**RESPIRATORY SYSTEM**

|                                     |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Lung                                | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Edema                               |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hemorrhage                          | 2 2 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia, Lymphoid               |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Infiltration Cellular, Histiocyte   | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Inflammation, Chronic               | 1 1 1 1 1 2 1 1 1 1                                 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Alveolar Epithelium, Hyperplasia    | 1 1 1 2 3 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Nose                                | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Foreign Body                        | X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Inflammation, Chronic               |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Respiratory Epithelium, Hyperplasia |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Trachea                             | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**SPECIAL SENSES SYSTEM**

|                      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|----------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Eye                  | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cataract             | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Retina, Degeneration | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Harderian Gland      | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia, Focal   | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
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 M .. Missing tissue  
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 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

|                                | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                | 7           | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |   |
|                                | 3           | 3 | 3 | 3 | 1 | 3 | 3 | 3 | 9 | 3 | 3 | 1 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |   |
|                                | 6           | 6 | 6 | 6 | 9 | 1 | 1 | 1 | 0 | 7 | 2 | 1 | 2 | 2 | 2 | 6 | 3 | 3 | 3 | 3 | 1 | 1 | 1 | 1 |   |
| <b>FISCHER 344 RATS FEMALE</b> | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>0 PPM</b>                   | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>ANIMAL ID</b>               | 2           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   |
|                                | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |
|                                | 1           | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |
|                                |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

females (cont...)

**URINARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney                                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |
| Inflammation, Suppurative                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Metaplasia, Osseous                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |
| Nephropathy                                 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |   | 1 |   |   | 1 |   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Papilla, Necrosis                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Renal Tubule, Accumulation, Hyaline Droplet |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Renal Tubule, Necrosis                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Renal Tubule, Pigmentation                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Transitional Epithelium, Hyperplasia        |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Urinary Bladder                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Edema                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Transitional Epithelium, Hyperplasia        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | 0 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |  |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|--|
|                                | 7 | 4 | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 7 | 5 | 6 | 6 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |          |  |
|                                | 3 | 0 | 1 | 2 | 2 | 3 | 3 | 6 | 3 | 2 | 7 | 8 | 8 | 7 | 0 | 1 | 9 | 3 | 3 | 0 | 3 | 1 | 3 | 3 | 3        |  |
|                                | 3 | 4 | 1 | 7 | 7 | 1 | 1 | 3 | 1 | 3 | 5 | 9 | 2 | 5 | 9 | 6 | 6 | 6 | 6 | 3 | 3 | 1 | 3 | 3 | 3        |  |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |  |
| <b>0 PPM</b>                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |  |
| ANIMAL ID                      | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2        |  |
|                                | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5        |  |
|                                | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |  |

|                                       |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |    |     |  |  |    |     |  |  |   |     |
|---------------------------------------|---|--|--|--|---|--|--|--|---|--|--|--|---|--|--|--|---|--|--|--|---|--|--|--|----|-----|--|--|----|-----|--|--|---|-----|
| Centrilobular, Necrosis               | 1 |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  | 1  | 1.0 |  |  |    |     |  |  |   |     |
| Hepatocyte, Degeneration              |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  | 1  | 1.0 |  |  |    |     |  |  |   |     |
| Hepatocyte, Hypertrophy               |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  | 2  | 2.0 |  |  |    |     |  |  |   |     |
| Hepatocyte, Vacuolization Cytoplasmic | 2 |  |  |  |   |  |  |  | 3 |  |  |  |   |  |  |  | 2 |  |  |  | 2 |  |  |  | 4  | 2.8 |  |  |    |     |  |  |   |     |
| Kupffer Cell, Pigmentation            |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  | 1  | 2.0 |  |  |    |     |  |  |   |     |
| Mesentery                             |   |  |  |  | + |  |  |  |   |  |  |  | + |  |  |  |   |  |  |  | + |  |  |  | 9  |     |  |  |    |     |  |  |   |     |
| Fat, Necrosis                         |   |  |  |  | 4 |  |  |  |   |  |  |  | 3 |  |  |  | 3 |  |  |  |   |  |  |  | 3  |     |  |  | 9  | 3.2 |  |  |   |     |
| Pancreas                              | + |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  | 49 |     |  |  |    |     |  |  |   |     |
| Atrophy                               |   |  |  |  |   |  |  |  | 2 |  |  |  | A |  |  |  | + |  |  |  | + |  |  |  | +  |     |  |  | 10 | 1.5 |  |  |   |     |
| Cyst                                  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  | 4  |     |  |  |    |     |  |  |   |     |
| Acinus, Cytoplasmic Alteration        |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  | 1  | 3.0 |  |  |    |     |  |  |   |     |
| Salivary Glands                       | + |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  | 50 |     |  |  |    |     |  |  |   |     |
| Atrophy                               |   |  |  |  | 1 |  |  |  | 1 |  |  |  |   |  |  |  | 2 |  |  |  |   |  |  |  | 1  |     |  |  | 1  |     |  |  | 7 | 1.1 |
| Stomach, Forestomach                  | + |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  | 50 |     |  |  |    |     |  |  |   |     |
| Ulcer                                 |   |  |  |  |   |  |  |  | 2 |  |  |  | + |  |  |  | + |  |  |  | + |  |  |  | +  |     |  |  | +  |     |  |  | 2 | 2.5 |
| Stomach, Glandular                    | + |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  | 50 |     |  |  |    |     |  |  |   |     |
| Erosion                               |   |  |  |  | 1 |  |  |  |   |  |  |  | 3 |  |  |  | 1 |  |  |  |   |  |  |  |    |     |  |  |    |     |  |  | 4 | 1.8 |
| Tongue                                |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |  |  |  |    | 1   |  |  |    |     |  |  |   |     |

**CARDIOVASCULAR SYSTEM**

|       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    |  |
|-------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|--|
| Heart | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50 |  |
|-------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|--|

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 79

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |                              |           |            |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|------------------------------|-----------|------------|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          | 0                            | 0         |            |
| 7                              | 4         | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 7 | 5 | 6 | 6 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7        | 7                            | 0         |            |
| 3                              | 0         | 1 | 2 | 2 | 3 | 3 | 6 | 3 | 2 | 7 | 8 | 8 | 7 | 0 | 1 | 9 | 3 | 3 | 0 | 3 | 1        | 3                            | 3         | 0          |
| 3                              | 4         | 1 | 7 | 7 | 1 | 1 | 3 | 1 | 3 | 5 | 9 | 2 | 5 | 9 | 6 | 6 | 6 | 6 | 3 | 3 | 1        | 3                            | 3         | 0          |
| <b>FISCHER 344 RATS FEMALE</b> |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |                              |           |            |
| <b>0 PPM</b>                   |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |                              |           |            |
| 0                              | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | 0                            | 0         | 0          |
| 0                              | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | 0                            | 0         | 0          |
| 2                              | 2         | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2        | 2                            | 2         | 2          |
| 2                              | 2         | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4        | 4                            | 5         | 2          |
| 6                              | 7         | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7        | 8                            | 9         | 0          |
|                                |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | <b>Cardiomyopathy</b>        | <b>24</b> | <b>1.5</b> |
|                                |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | <b>Inflammation, Chronic</b> | <b>1</b>  | <b>3.0</b> |
|                                |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | <b>Thrombosis</b>            | <b>1</b>  | <b>4.0</b> |

**ENDOCRINE SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |            |            |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|------------|------------|
| Adrenal Cortex                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |            |            |
| Accessory Adrenal Cortical Nodule |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>3</b>   | <b>3.0</b> |
| Degeneration, Fatty               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>9</b>   | <b>1.9</b> |
| Hematopoietic Cell Proliferation  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>   | <b>3.0</b> |
| Hyperplasia, Focal                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>5</b>   | <b>1.6</b> |
| Hypertrophy, Focal                | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>   | <b>1.0</b> |
| Necrosis                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>   | <b>3.0</b> |
| <hr/>                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |            |            |
| Adrenal Medulla                   | + | I | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>48</b> |            |            |
| Hyperplasia                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>   | <b>1.0</b> |
| <hr/>                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |            |            |
| Islets, Pancreatic                | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>49</b> |            |            |
| <hr/>                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |            |            |
| Parathyroid Gland                 | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>49</b> |            |            |
| <hr/>                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |            |            |
| Pituitary Gland                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |            |            |
| Pigmentation                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>   | <b>3.0</b> |
| Pars Distalis, Angiectasis        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>8</b>   | <b>3.0</b> |
| Pars Distalis, Cyst               | X |   | X |   |   |   |   | X | X |   |   | X | X | X | X | X | X |   |   |   |   |   |   |   | <b>30</b> |            |            |
| Pars Distalis, Hyperplasia, Focal |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>13</b> | <b>2.4</b> |            |
| Pars Intermedia, Angiectasis      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>  | <b>3.0</b> |            |
| Pars Intermedia, Cyst             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>3</b>  |            |            |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | 0 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|                                | 7 | 4 | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 7 | 5 | 6 | 6 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |          |
|                                | 3 | 0 | 1 | 2 | 2 | 3 | 3 | 6 | 3 | 2 | 7 | 8 | 8 | 7 | 0 | 1 | 9 | 3 | 3 | 0 | 3 | 1 | 3 | 3 |          |
|                                | 3 | 4 | 1 | 7 | 7 | 1 | 1 | 3 | 1 | 3 | 5 | 9 | 2 | 5 | 9 | 6 | 6 | 6 | 6 | 3 | 3 | 1 | 3 | 3 |          |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
| <b>0 PPM</b>                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
| ANIMAL ID                      | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |          |
|                                | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |          |
|                                | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |

|                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |    |
|---------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|----|
| Thyroid Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +      | 50 |
| C-cell, Hyperplasia | 2 |   |   |   |   |   | 2 | 1 |   |   | 1 |   |   |   | 1 |   |   | 1 |   | 1 |   | 3 |   | 17 1.4 |    |

**GENERAL BODY SYSTEM**

|            |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |
|------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|
| Tissue NOS |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 |
|------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|

**GENITAL SYSTEM**

|                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |
|---------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Clitoral Gland      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Cyst                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1     |
| Hyperplasia         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 2.0 |
| Hyperplasia, Focal  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   | 1 2.0 |
| Ovary               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Cyst                |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   | X |   | 8     |
| Uterus              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Hemorrhage          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   | 1 3.0 |
| Hyperplasia, Cystic |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 | 4 |   |   |   |   | 3 |   |   |   | 8 2.0 |
| Vagina              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2     |

**HEMATOPOIETIC SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 81

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

|                                | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |
|--------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
|                                | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
|                                | 7           | 4 | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 7 | 5 | 6 | 6 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 |                 |
|                                | 3           | 0 | 1 | 2 | 2 | 3 | 3 | 6 | 3 | 2 | 7 | 8 | 8 | 7 | 0 | 1 | 9 | 3 | 3 | 0 | 3 | 1 | 3 |                 |
|                                | 3           | 4 | 1 | 7 | 7 | 1 | 1 | 3 | 1 | 3 | 5 | 9 | 2 | 5 | 9 | 6 | 6 | 6 | 6 | 3 | 3 | 1 | 3 |                 |
| <hr/>                          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |
| <b>FISCHER 344 RATS FEMALE</b> | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
| <b>0 PPM</b>                   | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
| <b>ANIMAL ID</b>               | 2           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |                 |
|                                | 2           | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |                 |
|                                | 6           | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |                 |
|                                |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|
| Bone Marrow                                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   | <b>50</b>     |
| Hyperplasia                                   |   | 4 |   |   | 2 |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   | 3 |   |   |   |   | <b>10 2.8</b> |
| Myelofibrosis                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   | <b>1 3.0</b>  |
| <hr/>   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               |
| Lymph Node                                    | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   |   |   |   |   |   |   | + | <b>9</b>      |
| Hemorrhage                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 3.0</b>  |
| Pigmentation                                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 3.0</b>  |
| Mediastinal, Hematopoietic Cell Proliferation |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 | <b>1 2.0</b>  |
| Mediastinal, Hemorrhage                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>5 2.4</b>  |
| Mediastinal, Hyperplasia, Lymphoid            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>4 1.8</b>  |
| Mediastinal, Pigmentation                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2 2.0</b>  |
| Pancreatic, Hemorrhage                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2 3.0</b>  |
| <hr/>   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               |
| Lymph Node, Mandibular                        | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | <b>2</b>      |
| <hr/>   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               |
| Lymph Node, Mesenteric                        | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>49</b>     |
| Hemorrhage                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>3 1.7</b>  |
| Hyperplasia, Lymphoid                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>15 2.2</b> |
| <hr/>   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               |
| Spleen  | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>49</b>     |
| Accessory Spleen                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2</b>      |
| Hematopoietic Cell Proliferation              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>37 2.4</b> |
| <hr/>   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               |
| Thymus  | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>49</b>     |
| Cyst  |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>      |

**INTEGUMENTARY SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST             |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|-------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| FISCHER 344 RATS FEMALE | ANIMAL ID | 7 | 4 | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 7 | 5 | 6 | 6 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| 0 PPM                   |           | 3 | 0 | 1 | 2 | 2 | 3 | 3 | 6 | 3 | 2 | 7 | 8 | 8 | 7 | 0 | 1 | 9 | 3 | 3 | 0 | 3 | 1 | 3 | 3 |
|                         |           | 3 | 4 | 1 | 7 | 7 | 1 | 1 | 3 | 1 | 3 | 5 | 9 | 2 | 5 | 9 | 6 | 6 | 6 | 6 | 3 | 3 | 1 | 3 | 3 |
|                         |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                         |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                         |           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
|                         |           | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |
|                         |           | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| <b>* TOTALS</b>         |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

|                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Mammary Gland          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |
| Hyperplasia            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
|                        | 3 | 2 | 1 | 3 | 4 | 3 | 3 | 3 | 2 | 3 | 3 | 1 | 1 | 1 | 2 | 2 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 49 2.5 |
| Skin                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |
| Hemorrhage             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Hyperkeratosis         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   | 1 2.0  |
| Ulcer                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   | 1 3.0  |
| Epidermis, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   | 1 4.0  |

**MUSCULOSKELETAL SYSTEM**

|          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
| Fracture | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
|          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |

**NERVOUS SYSTEM**

|                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |
|------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Brain            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |
| Compression      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Gliosis          |   |   |   |   | 4 |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   | 2 | 9 3.3 |
| Hemorrhage       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   | 1 2.0 |
| Necrosis         |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 2.5 |
|                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 1.0 |
| Peripheral Nerve |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   | 2     |
| Spinal Cord      |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + | 2     |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | 0 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|                                | 7 | 4 | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 7 | 5 | 6 | 6 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |          |
|                                | 3 | 0 | 1 | 2 | 2 | 3 | 3 | 6 | 3 | 2 | 7 | 8 | 8 | 7 | 0 | 1 | 9 | 3 | 3 | 0 | 3 | 1 | 3 | 3 | 3        |
|                                | 3 | 4 | 1 | 7 | 7 | 1 | 1 | 3 | 1 | 3 | 5 | 9 | 2 | 5 | 9 | 6 | 6 | 6 | 6 | 3 | 3 | 1 | 3 | 3 | 3        |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
| <b>0 PPM</b>                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
| ANIMAL ID                      | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2        |
|                                | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5        |
|                                | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |

**RESPIRATORY SYSTEM**

|                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |        |
|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|--------|
| Lung                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |        |
| Edema                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   | 1 2.0 |        |
| Hemorrhage                          | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   | 2 |   |   | 6 2.2 |        |
| Hyperplasia, Lymphoid               |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 2.0 |        |
| Infiltration Cellular, Histiocyte   |   |   |   |   | 1 | 1 | 1 | 1 | 1 | 3 |   |   | 1 |   | 2 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 2 | 1 | 1     | 39 1.1 |
| Inflammation, Chronic               |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   | 1 | 2 |   |   |   | 1 | 1 |   | 1     | 18 1.1 |
| Alveolar Epithelium, Hyperplasia    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |       | 7 1.4  |
| Nose                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |        |
| Foreign Body                        |   |   |   |   |   |   |   | X |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       | 4      |
| Inflammation, Chronic               |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |       | 2 1.5  |
| Respiratory Epithelium, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       | 1 1.0  |
| Trachea                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |        |

**SPECIAL SENSES SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Eye                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Cataract             |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 | 3 |   | 4 2.8 |
| Retina, Degeneration |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 | 4 |   | 4 3.3 |
| Harderian Gland      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Hyperplasia, Focal   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 1.0 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
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 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
| 7                              | 4         | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 7 | 5 | 6 | 6 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0        |
| 3                              | 0         | 1 | 2 | 2 | 3 | 3 | 6 | 3 | 2 | 7 | 8 | 8 | 7 | 0 | 1 | 9 | 3 | 3 | 0 | 3 | 1 | 3 | 3 | 3 | 0        |
| 3                              | 4         | 1 | 7 | 7 | 1 | 1 | 3 | 1 | 3 | 5 | 9 | 2 | 5 | 9 | 6 | 6 | 6 | 6 | 3 | 3 | 1 | 3 | 3 | 3 | 0        |
| <b>FISCHER 344 RATS FEMALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
| <b>0 PPM</b>                   | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
|                                | 2         | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2        |
|                                | 2         | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | 2        |
|                                | 6         | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |

**URINARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         |       |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|-------|
| Kidney                                      | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | +       | 49    |
| Cyst  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         | 1     |
| Inflammation, Suppurative                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         | 1 3.0 |
| Metaplasia, Osseous                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         | 1 1.0 |
| Nephropathy                                 |   |   |   | 1 |   | 1 | 1 | 1 |   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 36 1.0  |       |
| Papilla, Necrosis                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 3.0   |       |
| Renal Tubule, Accumulation, Hyaline Droplet | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 | 2 3.0   |       |
| Renal Tubule, Necrosis                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 3.0   |       |
| Renal Tubule, Pigmentation                  |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 2.0   |       |
| Transitional Epithelium, Hyperplasia        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 2.5   |       |
| Urinary Bladder                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50      |       |
| Edema                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 1 2.0 |       |
| Transitional Epithelium, Hyperplasia        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 1 2.0 |       |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                                      | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  | 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 6 7 5 7 7 7 6 7 7   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS FEMALE<br>3000 PPM<br>ANIMAL ID | 3 3 3 3 3 3 3 3 6 3 3 3 3 3 3 0 2 3 8 3 3 3 4 3 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 2 2 2 2 2 1 1 1 8 1 3 3 3 3 3 9 7 6 9 6 1 1 2 1 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

females (cont...)

**ALIMENTARY SYSTEM**

|                                   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Esophagus                         | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Intestine Large, Cecum            | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Intestine Large, Colon            | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Intestine Large, Rectum           | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Intestine Small, Duodenum         | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Intestine Small, Ileum            | + + + + + + + + + + + + M + + + + + + + + + + + + + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Intestine Small, Jejunum          | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Liver                             | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Angiectasis                       | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Basophilic Focus                  | X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Clear Cell Focus                  | X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Eosinophilic Focus                | X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hemorrhage                        |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hepatodiaphragmatic Nodule        | X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Infiltration Cellular, Mixed Cell | 4 1 3 1 3 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mixed Cell Focus                  | X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Bile Duct, Hyperplasia            | 1 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hepatocyte, Degeneration          | 1 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
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

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 | 0 |   |
|                                | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 3 | 8 | 3 | 3 | 3 | 4 | 3 | 2 |   |
|                                | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 8 | 1 | 3 | 3 | 3 | 3 | 3 | 9 | 7 | 6 | 9 | 6 | 1 | 1 | 2 | 1 | 6 |   |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>3000 PPM</b>                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| ANIMAL ID                      | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   |
|                                | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 |   |
|                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   |

females  
(cont...)

|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hepatocyte, Hypertrophy               | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Hepatocyte, Vacuolization Cytoplasmic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Kupffer Cell, Pigmentation            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mesentery                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Accessory Spleen                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Fat, Necrosis                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Pancreas                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Atrophy                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Cyst                                  | X |   |   |   | X |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Acinus, Cytoplasmic Alteration        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Acinus, Hyperplasia, Focal            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Salivary Glands                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Stomach, Forestomach                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Edema                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Ulcer                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Epithelium, Hyperplasia               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Stomach, Glandular                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Edema                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Erosion                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**CARDIOVASCULAR SYSTEM**

|       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Heart |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ .. Tissue examined microscopically  
x .. Lesion present  
l .. Insufficient tissue  
M .. Missing tissue  
A .. Autolysis precludes evaluation  
BLANK .. Not examined microscopically  
1-4 .. Lesion qualified as:  
1) Minimal 3) Moderate  
2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                                      | 0   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|  | 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 6 7 5 7 7 7 6 7 7   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| FISCHER 344 RATS FEMALE<br>3000 PPM<br>ANIMAL ID | 3 3 3 3 3 3 3 3 6 3 3 3 3 3 3 0 2 3 8 3 3 3 4 3 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
|  | 2 2 2 2 2 1 1 1 8 1 3 3 3 3 3 9 7 6 9 6 1 1 2 1 6 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
|  | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | females<br>(cont...) |
|  | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|  | 2   | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |                      |
|  | 5   | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |                      |
|  | 1   | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                      |
| Cardiomyopathy<br>Thrombosis                     | 1   |   |   | 1 | 2 |   |   | 1 | 1 |   |   | 1 | 1 |   |   |   | 1 | 2 |   |   |   |   | 1 |   | 2 |                      |

**ENDOCRINE SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex                          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Accessory Adrenal Cortical Nodule       |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Degeneration, Fatty                     |   |   | 3 |   |   |   |   | 3 | 1 |   |   | 3 | 2 |   |   | 2 |   | 1 |   |   |   | 1 | 1 |   | 2 |
| Hyperplasia, Focal                      |   |   | 3 |   |   |   |   |   |   |   |   | 2 | 2 |   | 1 |   |   |   |   |   |   | 2 |   |   |   |
| Hypertrophy, Focal                      |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |
| Necrosis                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Adrenal Medulla                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia                             |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Infiltration Cellular, Mononuclear Cell |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Islets, Pancreatic                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Parathyroid Gland                       | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |
| Pituitary Gland                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Infiltration Cellular, Mononuclear Cell |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pars Distalis, Angiectasis              |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |
| Pars Distalis, Cyst                     | X | X |   |   | X |   |   |   |   |   |   | X | X |   | X |   |   |   | X | X | X |   |   |   |   |
| Pars Distalis, Hyperplasia, Focal       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |
| Pars Intermedia, Angiectasis            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 Page 88  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| 7                              | 7         | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 |   |                      |
| 3                              | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 3 | 8 | 3 | 3 | 3 | 4 | 3 | 2 |   |                      |
| 2                              | 2         | 2 | 2 | 2 | 1 | 1 | 1 | 8 | 1 | 3 | 3 | 3 | 3 | 3 | 9 | 7 | 6 | 9 | 6 | 1 | 1 | 2 | 1 | 6 |   |                      |
| .....                          |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| <b>FISCHER 344 RATS FEMALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                      |
| <b>3000 PPM</b>                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                      |
|                                | 2         | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   |                      |
|                                | 5         | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 |   |   |                      |
|                                | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 |   |   |                      |
|                                |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 5 |   |   |                      |

|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Thyroid Gland                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| C-cell, Hyperplasia          | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   | 1 |   |   |
| Follicle, Cyst               |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Follicular Cell, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia, Focal    |   |   |   |   |   |   |   |   |   |   |   |   | 3 | 2 |   |   |   | 2 |   |   |   |   |   |
| Inflammation, Chronic | 2 |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |
| Ovary                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst                  |   |   |   | X |   |   |   |   |   |   |   | X |   | X |   |   |   | X |   |   |   |   |   |
| Uterus                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Decidual Reaction     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |
| Hyperplasia, Cystic   |   |   | 4 | 1 | 2 |   |   |   |   | 4 |   |   | 1 | 2 |   |   |   |   |   |   | 2 |   |   |
| Vagina                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + | + |

**HEMATOPOIETIC SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                        | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |
|------------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|                                    | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|                                    | 7         | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 | 0 | 0 |                      |
|                                    | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 3 | 8 | 3 | 3 | 3 | 4 | 3 | 2 | 2 |                      |
|                                    | 2         | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 8 | 1 | 3 | 3 | 3 | 3 | 9 | 7 | 6 | 9 | 6 | 1 | 1 | 2 | 1 | 6 | 6 |                      |
| <b>FISCHER 344 RATS FEMALE</b>     | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| <b>3000 PPM</b>                    | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|                                    | 2         | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |                      |
|                                    | 5         | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |   |                      |
|                                    | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                      |
| Bone Marrow                        | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |                      |
| Hyperplasia                        |           |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |                      |
| Infiltration Cellular, Histiocyte  |           |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |                      |
| Myelofibrosis                      |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Lymph Node                         |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Mediastinal, Hemorrhage            |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Mediastinal, Hyperplasia, Lymphoid |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Mediastinal, Pigmentation          |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Pancreatic, Hemorrhage             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Pancreatic, Pigmentation           |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Lymph Node, Mandibular             | M         | M | M | + | M | M | M | M | M | M | M | M | M | M | + | M | M | M | M | M | M | + | M | M | M |                      |
| Ectasia                            |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Hyperplasia, Lymphoid              |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Lymph Node, Mesenteric             | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |                      |
| Hemorrhage                         |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Hyperplasia, Lymphoid              |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Spleen                             | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |                      |
| Fibrosis                           |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Hematopoietic Cell Proliferation   | 3         | 2 | 2 | 3 | 2 | 2 | 2 | 2 |   | 3 | 3 |   | 3 | 1 | 3 | 3 |   | 3 | 3 | 2 | 2 |   |   | 2 |   |                      |
| Thymus                             | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |                      |
| Atrophy                            |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |

**INTEGUMENTARY SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 90

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |
|-------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|             | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| 7           | 7         | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 | 0 | 0 |                      |
| 3           | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 3 | 8 | 3 | 3 | 3 | 4 | 3 | 2 | 2 |                      |
| 2           | 2         | 2 | 2 | 2 | 1 | 1 | 1 | 8 | 1 | 3 | 3 | 3 | 3 | 3 | 9 | 7 | 6 | 9 | 6 | 1 | 1 | 2 | 1 | 6 | 6 |                      |

**FISCHER 344 RATS FEMALE**  
 3000 PPM

|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland<br>Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|                              |   |   | 1 | 4 | 2 | 2 | 2 | 1 |   | 2 | 3 | 4 | 1 | 1 | 2 | 3 | 3 | 2 | 3 | 2 | 2 | 2 | 3 | 4 | 4 |
| Skin                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**MUSCULOSKELETAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone<br>Osteopetrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

**NERVOUS SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brain<br>Compression | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|                      |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   | 4 | 4 |   |   |   |   | 4 | 3 | 4 |   |
| Peripheral Nerve     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Spinal Cord          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**RESPIRATORY SYSTEM**

|                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung<br>Edema<br>Foreign Body | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|                               |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
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 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 |   |
|                                | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 3 | 8 | 3 | 3 | 3 | 4 | 3 | 2 |   |   |   |
|                                | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 8 | 1 | 3 | 3 | 3 | 3 | 3 | 9 | 7 | 6 | 9 | 6 | 1 | 1 | 2 | 1 | 6 |   |   |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| ANIMAL ID                      | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>3000 PPM</b>                | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   |
|                                | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |   |   |
|                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   |   |

**females (cont...)**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Infiltration Cellular, Histiocyte<br>Inflammation, Chronic<br>Metaplasia, Osseous<br>Alveolar Epithelium, Hyperplasia<br>Serosa, Hyperplasia | 1 |   | 1 |   |   | 1 | 1 | 1 |   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   | 1 | 1 |   |   | 1 |   |
|  |   |   | 1 |   | 1 | 2 |   | 1 |   | 1 | 1 |   | 1 |   | 1 |   | 1 |   | 1 |   |   |   |   |   |   | 1 |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   | 1 |   |   |   |   |   |   |   |
| Nose   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Foreign Body   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Trachea  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**SPECIAL SENSES SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cataract             |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Retina, Degeneration |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Harderian Gland      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**URINARY SYSTEM**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Infarct  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Infiltration Cellular, Mononuclear Cell<br>Nephropathy |   | 1 | 1 |   | 1 | 1 | 1 |   |   | 1 | 1 |   |   | 1 | 1 | 1 | 1 | 1 |   |   | 1 | 1 | 1 |   |   |   |
| Renal Tubule, Pigmentation                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 Page 92  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                                | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |   |                              |
|--|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|---|------------------------------|
|  | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |   |                              |
| 7  | 7         | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 | 0 | 0                    |   |                              |
| 3  | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 3 | 8 | 3 | 3 | 3 | 4 | 3 | 2 | 0 | 0                    |   |                              |
| 2  | 2         | 2 | 2 | 2 | 1 | 1 | 1 | 8 | 1 | 3 | 3 | 3 | 3 | 3 | 9 | 7 | 6 | 9 | 6 | 1 | 1 | 2 | 1 | 6 | 0 | 0                    |   |                              |
| .....                                      |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |   |                              |
| <b>FISCHER 344 RATS FEMALE</b><br>3000 PPM | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                    | 0 |                              |
|  | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                    | 0 |                              |
|  | 2         | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2                    | 2 |                              |
|  | 5         | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7                    | 7 |                              |
|  | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                      |   | <b>females<br/>(cont...)</b> |
| Urinary Bladder                            | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   | +                    |   |                              |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
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 Page 93

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

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

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
|                                | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 0 |                 |
|                                | 3 | 3 | 3 | 3 | 3 | 3 | 8 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 6 | 5 |                 |
|                                | 2 | 2 | 2 | 2 | 2 | 2 | 5 | 7 | 7 | 2 | 2 | 2 | 2 | 9 | 5 | 1 | 1 | 1 | 1 | 3 | 6 | 6 | 6 | 1 | 9 |                 |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
| <b>3000 PPM</b>                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
| ANIMAL ID                      | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |                 |
|                                | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |                 |
|                                | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | <b>* TOTALS</b> |

ALIMENTARY SYSTEM

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              |              |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|--------------|
| Esophagus                         | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +            | <b>49</b>    |
| Intestine Large, Cecum            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +            | <b>50</b>    |
| Intestine Large, Colon            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +            | <b>50</b>    |
| Intestine Large, Rectum           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | I | + | + | + | + | + | + | + | + | + | +            | <b>49</b>    |
| Intestine Small, Duodenum         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | I | + | + | + | + | + | + | + | + | + | +            | <b>48</b>    |
| Intestine Small, Ileum            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | +            | <b>48</b>    |
| Intestine Small, Jejunum          | + | + | + | + | + | + | A | + | + | + | + | + | + | + | A | A | + | + | + | + | + | + | + | + | + | +            | <b>47</b>    |
| Liver                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +            | <b>50</b>    |
| Angiectasis                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              | <b>1 2.0</b> |
| Basophilic Focus                  | X | X | X | X | X | X | X | X |   | X | X | X | X |   |   | X | X | X | X |   | X | X | X |   |   | <b>44</b>    |              |
| Clear Cell Focus                  | X |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   | X |   |   | <b>5</b>     |              |
| Eosinophilic Focus                | X |   | X |   | X | X |   |   |   | X | X |   |   |   |   | X | X | X |   |   |   | X | X |   |   | <b>24</b>    |              |
| Hemorrhage                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              | <b>1 2.0</b> |
| Hepatodiaphragmatic Nodule        | X | X | X | X | X |   |   |   |   | X | X |   | X |   |   |   |   |   |   |   | X |   |   |   |   | <b>17</b>    |              |
| Infiltration Cellular, Mixed Cell | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>7 2.0</b> |              |
| Mixed Cell Focus                  |   | X |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>5</b>     |              |
| Bile Duct, Hyperplasia            |   |   |   |   |   |   |   | 3 | 2 |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   | <b>4 2.0</b> |              |
| Hepatocyte, Degeneration          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2 1.0</b> |              |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
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 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
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TDMS No. 99007 - 05  
Test Type: CHRONIC  
Route: DOSED FEED  
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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

| DAY ON TEST                           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |     |     |     |     |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|-----|-----|-----|-----|
| FISCHER 344 RATS FEMALE               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |     |     |     |     |
| ANIMAL ID                             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |     |     |     |     |
| 3000 PPM                              | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3        |     |     |     |     |
|                                       | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | 0        |     |     |     |     |
|                                       | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |     |     |     |     |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |     |     |     |     |
| Hepatocyte, Hypertrophy               |   |   | 1 |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 10       | 1.3 |     |     |     |
| Hepatocyte, Vacuolization Cytoplasmic |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   | 4 |   | 3        | 4   | 3.0 |     |     |
| Kupffer Cell, Pigmentation            |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   | 3 |   |   |   |   |   |   |   |   |          |     | 2   | 2.5 |     |
| Mesentery                             |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   |   |   | + |   |   | + |   |   |   |          | 7   |     |     |     |
| Accessory Spleen                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   | X |          |     | 2   |     |     |
| Fat, Necrosis                         |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     | 5   | 3.0 |
| Pancreas                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
| Atrophy                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
| Cyst                                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
| Acinus, Cytoplasmic Alteration        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
| Acinus, Hyperplasia, Focal            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
| Salivary Glands                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
| Stomach, Forestomach                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
| Edema                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
| Ulcer                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
| Epithelium, Hyperplasia               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
| Stomach, Glandular                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
| Edema                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
| Erosion                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |     |     |     |

CARDIOVASCULAR SYSTEM

|       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Heart |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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+ .. Tissue examined microscopically  
x .. Lesion present  
I .. Insufficient tissue  
M .. Missing tissue  
A .. Autolysis precludes evaluation  
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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
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Goldenseal root powder  
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 Lab: SRI

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 6 | 0 |
|                                | 3 | 3 | 3 | 3 | 3 | 3 | 8 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 6 | 5 |   |
|                                | 2 | 2 | 2 | 2 | 2 | 2 | 5 | 7 | 7 | 2 | 2 | 2 | 2 | 9 | 5 | 1 | 1 | 1 | 1 | 3 | 6 | 6 | 6 | 1 | 9 |   |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>3000 PPM</b>                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>ANIMAL ID</b>               | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |   |
|                                | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |   |
|                                | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |   |

\* TOTALS

|                |   |   |  |   |   |   |  |   |   |   |  |   |   |   |  |   |   |  |   |   |  |  |  |  |  |           |            |            |
|----------------|---|---|--|---|---|---|--|---|---|---|--|---|---|---|--|---|---|--|---|---|--|--|--|--|--|-----------|------------|------------|
| Cardiomyopathy | 1 | 3 |  | 1 | 1 | 1 |  | 3 | 2 | 1 |  | 1 | 1 | 1 |  | 1 | 1 |  | 1 | 1 |  |  |  |  |  | <b>24</b> | <b>1.3</b> |            |
| Thrombosis     |   |   |  |   |   |   |  |   |   |   |  |   | 3 |   |  |   |   |  |   |   |  |  |  |  |  |           | <b>1</b>   | <b>3.0</b> |

**ENDOCRINE SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |            |            |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|------------|------------|
| Adrenal Cortex                          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |            |            |
| Accessory Adrenal Cortical Nodule       |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |           | <b>3</b>   | <b>3.0</b> |
| Degeneration, Fatty                     |   | 1 | 4 |   |   |   |   | 2 | 3 |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |           | <b>15</b>  | <b>2.1</b> |
| Hyperplasia, Focal                      |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>6</b>   | <b>2.2</b> |
| Hypertrophy, Focal                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>2</b>   | <b>2.5</b> |
| Necrosis                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |           | <b>1</b>   | <b>1.0</b> |
| Adrenal Medulla                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |            |            |
| Hyperplasia                             |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>2</b>   | <b>1.0</b> |
| Infiltration Cellular, Mononuclear Cell |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>   | <b>2.0</b> |
| Islets, Pancreatic                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |            |            |
| Parathyroid Gland                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>49</b> |            |            |
| Hyperplasia                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>   | <b>3.0</b> |
| Pituitary Gland                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |            |            |
| Infiltration Cellular, Mononuclear Cell |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>   | <b>3.0</b> |
| Pars Distalis, Angiectasis              |   |   | 2 |   | 4 |   |   |   |   |   |   |   | 3 | 2 |   |   |   |   |   |   |   |   | 1 |   |   |           | <b>7</b>   | <b>2.1</b> |
| Pars Distalis, Cyst                     |   |   | X |   |   |   | X | X | X | X |   | X | X | X |   |   |   | X | X |   |   | X | X |   |   | <b>23</b> | <b>4.2</b> |            |
| Pars Distalis, Hyperplasia, Focal       |   |   |   |   |   | 2 |   |   |   | 1 |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   | <b>4</b>  | <b>2.0</b> |            |
| Pars Intermedia, Angiectasis            |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>  | <b>4.0</b> |            |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 l .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 Page 96  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
| 7                              | 7         | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 0 |   |          |
| 3                              | 3         | 3 | 3 | 3 | 3 | 8 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 6 | 5 |   |          |
| 2                              | 2         | 2 | 2 | 2 | 2 | 5 | 7 | 7 | 2 | 2 | 2 | 2 | 9 | 5 | 1 | 1 | 1 | 1 | 3 | 6 | 6 | 6 | 1 | 9 |   |          |
| <b>FISCHER 344 RATS FEMALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |          |
| <b>3000 PPM</b>                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |          |
|                                | 2         | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |   |          |
|                                | 7         | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |   |          |
|                                | 6         | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |   |          |

|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |       |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Thyroid Gland                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |
| C-cell, Hyperplasia          |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   | 2 |   |    | 5 1.4 |
| Follicle, Cyst               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |    | 2     |
| Follicular Cell, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |    | 2 2.0 |

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |       |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Clitoral Gland        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |
| Cyst                  |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   | X |    | 2     |
| Hyperplasia           |   |   |   |   |   |   |   |   | 2 |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |    | 2 2.0 |
| Hyperplasia, Focal    |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |    | 5 2.0 |
| Inflammation, Chronic | 3 |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 4 2.8 |
| Ovary                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |
| Cyst                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |    | 5     |
| Uterus                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |
| Decidual Reaction     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 3.0 |
| Hyperplasia, Cystic   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   | 1 |   |   |   |   |    | 9 2.1 |
| Vagina                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   | + |    | 4     |

**HEMATOPOIETIC SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

Page 97

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked



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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |  |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|--|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |  |
| 7                              | 7         | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 0 |          |  |
| 3                              | 3         | 3 | 3 | 3 | 3 | 8 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 6 | 5        |  |
| 2                              | 2         | 2 | 2 | 2 | 2 | 5 | 7 | 7 | 2 | 2 | 2 | 2 | 9 | 5 | 1 | 1 | 1 | 1 | 3 | 6 | 6 | 6 | 1 | 9 |          |  |
| <b>FISCHER 344 RATS FEMALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |  |
| <b>3000 PPM</b>                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |  |
|                                | 2         | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3        |  |
|                                | 7         | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0        |  |
|                                | 6         | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |  |

|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |        |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--------|
| Mammary Gland<br>Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |        |
|                              | 4 | 2 | 2 | 2 | 2 | 4 | 2 | 3 | 3 | 2 | 1 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 4 | 2 | 4 | 1 | 3 |    | 46 2.4 |
| Skin                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |        |

**MUSCULOSKELETAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |       |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Bone<br>Osteopetrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |
|                       |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 2.0 |

**NERVOUS SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |       |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Brain<br>Compression | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |
|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 8 3.3 |
| Peripheral Nerve     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 2     |
| Spinal Cord          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 2     |

**RESPIRATORY SYSTEM**

|                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |       |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Lung<br>Edema<br>Foreign Body | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |
|                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 2.0 |
|                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1     |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0  | 0                                 | * TOTALS                                    |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----------------------------------|---|
|  | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 0 |    |                                   |   |
|  | 3 | 3 | 3 | 3 | 3 | 3 | 8 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 6 | 5 |   |   |   |    |                                   |   |
|  | 2 | 2 | 2 | 2 | 2 | 2 | 5 | 7 | 7 | 2 | 2 | 2 | 2 | 9 | 5 | 1 | 1 | 1 | 1 | 3 | 6 | 6 | 6 | 1 | 9 |   |   |   |   |    |                                   |   |
| <b>FISCHER 344 RATS FEMALE</b>   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0  |                                   |   |
| <b>ANIMAL ID</b>   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0  |                                   |   |
| <b>3000 PPM</b>  | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2  | 3                                 |   |
|  | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0  |                                   |   |
|  | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |   |   |   |   |    |                                   |   |
| Infiltration Cellular, Histiocyte<br>Inflammation, Chronic<br>Metaplasia, Osseous<br>Alveolar Epithelium, Hyperplasia<br>Serosa, Hyperplasia | 1 | 2 | 1 | 1 | 1 | 1 |   |   |   | 1 | 1 | 1 | 1 | 2 |   | 1 | 1 | 1 |   | 1 | 1 | 1 |   |   |   |   |   |   |   |    |                                   | 34 1.1<br>21 1.0<br>2 1.0<br>7 1.6<br>1 2.0 |
| Nose Foreign Body  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 3                                 |   |
| Trachea  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |                                   |   |
| <b>SPECIAL SENSES SYSTEM</b>   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |                                   |   |
| Eye<br>Cataract<br>Retina, Degeneration  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 2 2.5<br>2 3.0                    |   |
| Harderian Gland  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |                                   |   |
| <b>URINARY SYSTEM</b>  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |                                   |   |
| Kidney<br>Infarct<br>Infiltration Cellular, Mononuclear Cell<br>Nephropathy<br>Renal Tubule, Pigmentation                                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 1.0<br>1 2.0<br>24 1.1<br>1 3.0 |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

|  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST                                      |  | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |   |   |   |
|  |  | 7   | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |   |
| .....  |  | 3   | 3 | 3 | 3 | 3 | 3 | 8 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 6 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |   |   |
|  |  | 2   | 2 | 2 | 2 | 2 | 2 | 5 | 7 | 7 | 2 | 2 | 2 | 2 | 9 | 5 | 1 | 1 | 1 | 1 | 3 | 6 | 6 | 6 | 6 | 1 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |   |
| FISCHER 344 RATS FEMALE<br>3000 PPM<br>ANIMAL ID |  | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |   |
|  |  | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|  |  | 2   | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |
|  |  | 7   | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |   |
|  |  | 6   | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | <b>* TOTALS</b>   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Urinary Bladder                                  |  | + <b>49</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

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 x .. Lesion present  
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 M .. Missing tissue  
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 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 101

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| 7                              | 5         | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | 6 | 7 | 7 | 7 | 7 | 7 | 0 |                      |
| 3                              | 6         | 3 | 3 | 3 | 6 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 5 | 3 | 3 | 3 | 3 | 3 | 3 |                      |
| 2                              | 9         | 2 | 2 | 2 | 6 | 1 | 3 | 1 | 1 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 3 | 2 | 6 | 6 | 6 | 6 | 6 | 6 |                      |
| .....                          |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| <b>FISCHER 344 RATS FEMALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| <b>9000 PPM</b>                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|                                | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                      |
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 |   |                      |
|                                | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                      |

**ALIMENTARY SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | A | + | + | + | + | + |
| Liver                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |
| Basophilic Focus                  | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Clear Cell Focus                  | X |   | X |   |   |   | X |   |   |   |   |   |   | X |   |   |   |   |   |   |   | X |   | X |
| Cyst                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |
| Eosinophilic Focus                |   |   | X |   | X | X | X |   |   |   | X | X |   |   | X | X |   |   | X | X |   | X |   | X |
| Hemorrhage                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hepatodiaphragmatic Nodule        |   |   | X |   |   | X | X |   | X |   |   |   | X |   |   |   |   |   |   |   |   |   |   | X |
| Infiltration Cellular, Mixed Cell |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mixed Cell Focus                  | X |   | X |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   | X | X |   |
| Bile Duct, Hyperplasia            |   |   |   |   | 1 |   | 1 |   |   |   |   |   | 1 | 1 | 2 |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                           | FISCHER 344 RATS FEMALE<br>9000 PPM |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |
|---------------------------------------|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|                                       | ANIMAL ID                           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|                                       | 0                                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|                                       | 7                                   | 5 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | 6 | 7 | 7 | 7 | 7 | 7 |                      |
|                                       | 3                                   | 6 | 3 | 3 | 3 | 6 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 5 | 3 | 3 | 3 | 3 | 3 | 3 |                      |
|                                       | 2                                   | 9 | 2 | 2 | 2 | 6 | 1 | 3 | 1 | 1 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 3 | 2 | 6 | 6 | 6 | 6 | 6 |                      |
|                                       | 0                                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|                                       | 0                                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|                                       | 3                                   | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                      |
|                                       | 0                                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 |                      |
|                                       | 1                                   | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 1                    |
| Centrilobular, Necrosis               |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |                      |
| Hepatocyte, Degeneration              |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   | 1 |                      |
| Hepatocyte, Hypertrophy               |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Hepatocyte, Vacuolization Cytoplasmic |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Kupffer Cell, Pigmentation            |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Mesentery                             |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Accessory Spleen                      |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Fat, Necrosis                         |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Oral Mucosa                           |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Ulcer                                 |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Pancreas                              |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Atrophy                               |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Cyst                                  |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Acinus, Hyperplasia, Focal            |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Salivary Glands                       |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Atrophy                               |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Stomach, Forestomach                  |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Edema                                 |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Epithelium, Hyperplasia               |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Stomach, Glandular                    |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Erosion                               |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Tooth                                 |                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                    |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                |  | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | 6 | 7 | 7 | 7 | 7 | 7 |
|                                |  | 3 | 6 | 3 | 3 | 3 | 6 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 5 | 3 | 3 | 3 | 3 | 3 | 3 |
|                                |  | 2 | 9 | 2 | 2 | 2 | 6 | 1 | 3 | 1 | 1 | 3 | 3 | 3 | 3 | 6 | 6 | 3 | 2 | 6 | 6 | 6 | 6 | 6 |
| <b>FISCHER 344 RATS FEMALE</b> |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| <b>9000 PPM</b>                |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID                      |  | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|                                |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                |  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 |

**females  
(cont...)**

**CARDIOVASCULAR SYSTEM**

Blood Vessel

|                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Heart          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cardiomyopathy | 1 |   | 1 | 1 |   |   |   |   | 1 | 2 | 2 |   |   | 1 | 1 | 2 |   |   | 1 | 1 |   |   |   |   |

**ENDOCRINE SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Accessory Adrenal Cortical Nodule |   |   |   |   | 3 |   |   |   |   |   |   |   | 3 |   |   |   | 3 |   | 3 |   |   |   |   |   |
| Angiectasis                       |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Degeneration, Fatty               |   |   |   |   |   | 4 |   |   | 1 | 1 | 2 |   |   |   | 2 |   | 1 | 1 |   |   |   | 3 |   |   |
| Hyperplasia, Focal                |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   | 2 | 1 |   |   |   |   |   |   |
| Hypertrophy, Focal                |   |   |   |   | 1 | 3 |   |   |   |   | 1 |   |   |   |   | 2 |   |   |   |   |   | 3 |   |   |

|                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia     |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |

|                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia        |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |

|                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Parathyroid Gland | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|-------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

|                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pituitary Gland            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pars Distalis, Angiectasis |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
|                                | 3 | 6 | 3 | 3 | 3 | 6 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 5 | 3 | 3 | 3 | 3 | 3 | 3 |
|                                | 2 | 9 | 2 | 2 | 2 | 6 | 1 | 3 | 1 | 1 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 3 | 2 | 6 | 6 | 6 | 6 | 6 | 6 |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| <b>9000 PPM</b>                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID                      | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|                                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 |
|                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

females  
(cont...)

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pars Distalis, Cyst               | X |   | X | X |   | X | X | X |   |   |   |   | X | X | X |   |   | X | X | X | X | X |   |   |
| Pars Distalis, Hyperplasia, Focal | 2 |   | 1 | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   | 2 |   |   |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| C-cell, Hyperplasia               |   |   |   |   |   | 2 |   |   |   |   |   |   | 1 |   |   | 1 |   |   |   |   |   |   |   | 1 |
| Follicle, Cyst                    |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland                           | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |
| Hyperplasia, Focal                       |   |   |   |   | 3 |   |   |   | 3 |   |   |   | 2 |   | 3 |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Ovary                                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst                                     |   |   | X | X |   |   |   |   |   | X |   |   |   |   | X |   |   |   |   | X |   |   |   |   |
| Corpus Luteum, Vacuolization Cytoplasmic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Uterus                                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia, Cystic                      | 1 | 3 |   |   |   |   |   |   |   |   |   | 3 | 3 |   |   |   |   |   |   |   |   |   | 2 |   |
| Inflammation, Suppurative                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Myometrium, Hypertrophy                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Vagina                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 105

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|             | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
|             | 3 | 6 | 3 | 3 | 3 | 6 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 5 | 3 | 3 | 3 | 3 | 3 | 3 |
|             | 2 | 9 | 2 | 2 | 2 | 6 | 1 | 3 | 1 | 1 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 3 | 2 | 6 | 6 | 6 | 6 | 6 | 6 |

  

| FISCHER 344 RATS FEMALE<br>9000 PPM | ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|-------------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                     |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                     |           | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|                                     |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
|                                     |           | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

**females (cont...)**

**HEMATOPOIETIC SYSTEM**

|                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow                        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia                        |   |   |   |   |   | 2 |   | 4 |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |
| Infiltration Cellular, Histiocyte  |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |
| Infiltration Cellular, Mixed Cell  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Lymph Node                         |   | + | + |   |   |   |   | + | + |   |   |   |   | + |   |   |   |   |   | + |   |   |   |   |   |
| Deep Cervical, Ectasia             |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mediastinal, Hemorrhage            |   | 3 | 2 |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   | 3 |   |   |   |   |   |
| Mediastinal, Hyperplasia, Lymphoid |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mediastinal, Pigmentation          |   |   | 3 |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |
| Lymph Node, Mandibular             | M | + | M | M | M | M | M | M | M | M | + | M | M | M | + | M | M | M | M | M | M | M | M | M | M |
| Lymph Node, Mesenteric             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hemorrhage                         |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia, Lymphoid              |   | 3 |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   | 2 |
| Spleen                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hematopoietic Cell Proliferation   | 3 |   | 2 |   | 3 | 3 | 2 | 3 |   | 3 | 2 | 2 |   | 2 | 2 | 2 | 2 |   | 4 | 3 | 2 | 2 |   | 2 | 2 |
| Thymus                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia, Lymphoid              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
|                                | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |  |
|                                | 3 | 6 | 3 | 3 | 3 | 6 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 5 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |  |
|                                | 2 | 9 | 2 | 2 | 2 | 6 | 1 | 3 | 1 | 1 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 3 | 2 | 6 | 6 | 6 | 6 | 6 | 6 |  |
| .....                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |
| <b>ANIMAL ID</b>               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |
| <b>9000 PPM</b>                | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |  |
|                                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |  |
|                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 5 |  |

**females  
(cont...)**

**INTEGUMENTARY SYSTEM**

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Mammary Gland             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Hyperplasia               | 2 | 3 | 3 | 2 | 4 |   |   |   | 3 | 3 | 1 | 2 | 2 | 1 | 1 | 4 | 3 |   | 1 | 3 | 3 | 2 | 4 | 3 | 3 |   |  |
| .....                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Skin                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Cyst Epithelial Inclusion |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Hyperkeratosis            |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Inflammation, Chronic     |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Epidermis, Hyperplasia    |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

**MUSCULOSKELETAL SYSTEM**

|      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

**NERVOUS SYSTEM**

|             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brain       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Compression |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hemorrhage  |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**RESPIRATORY SYSTEM**

|              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Foreign Body |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                                 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|   | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | 6 | 7 | 7 | 7 | 7 | 7 |
|   | 3 | 6 | 3 | 3 | 3 | 6 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 5 | 3 | 3 | 3 | 3 | 3 |
|   | 2 | 9 | 2 | 2 | 2 | 6 | 1 | 3 | 1 | 1 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 3 | 2 | 6 | 6 | 6 | 6 |
| <b>FISCHER 344 RATS FEMALE</b><br>ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 |
|   | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 |

**females (cont...)**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hemorrhage                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |
| Infiltration Cellular, Histiocyte | 1 |   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   | 1 | 1 | 1 | 1 | 1 |   | 1 | 1 | 1 | 1 |   | 1 | 1 |   |
| Inflammation, Chronic             | 1 |   |   |   |   | 1 |   | 2 |   |   |   |   |   | 1 |   | 1 |   |   |   |   |   |   | 1 | 1 |   |
| Metaplasia, Osseous               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |
| Alveolar Epithelium, Hyperplasia  |   |   |   |   |   |   |   |   |   |   |   | 1 | 1 |   |   |   |   |   |   |   |   |   |   |   |   |
| Serosa, Hyperplasia               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |
| Nose                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Foreign Body                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Trachea                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |

**SPECIAL SENSES SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cataract             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Retina, Degeneration |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Harderian Gland      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Zymbal's Gland       |   |   |   |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**URINARY SYSTEM**

|        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                                 | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |
|---|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|   | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| 7   | 5         | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 0                    |
| 3   | 6         | 3 | 3 | 3 | 6 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 5 | 3 | 3 | 3 | 3 | 3 | 3 | 0                    |
| 2   | 9         | 2 | 2 | 2 | 6 | 1 | 3 | 1 | 1 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 3 | 2 | 6 | 6 | 6 | 6 | 6 | 6 | 0                    |
| .....                                       |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| <b>FISCHER 344 RATS FEMALE</b>              | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                    |
| <b>9000 PPM</b>                             | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                    |
|   | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3                    |
|   | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 |                      |
|   | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                      |
| .....                                       |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Inflammation, Suppurative                   |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Nephropathy                                 | 1         | 1 | 1 | 1 | 1 |   | 1 |   | 1 |   |   |   | 1 |   | 1 | 1 | 3 |   |   | 1 |   | 1 | 1 | 1 |   |                      |
| Renal Tubule, Accumulation, Hyaline Droplet |           |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Renal Tubule, Pigmentation                  |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |                      |
| Transitional Epithelium, Hyperplasia        |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |                      |
| .....                                       |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Urinary Bladder                             | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |                      |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

|  | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|--|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|  | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
|  | 7           | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 4 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 0        |
|  | 3           | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 7 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 0        |
|  | 2           | 2 | 2 | 2 | 2 | 6 | 6 | 6 | 6 | 6 | 2 | 2 | 3 | 2 | 2 | 2 | 2 | 4 | 5 | 2 | 2 | 2 | 2 | 2 | 2 | 0        |

---

| FISCHER 344 RATS FEMALE<br>9000 PPM | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|-------------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|                                     | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
|                                     | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
|                                     | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 0        |
|                                     | 2         | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | 3        |
|                                     | 6         | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 0        |

**ALIMENTARY SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Esophagus                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | 49    |
| Intestine Large, Cecum            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Intestine Large, Colon            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Intestine Large, Rectum           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Intestine Small, Duodenum         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Intestine Small, Ileum            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Intestine Small, Jejunum          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48    |
| Liver                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Angiectasis                       |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 2.0 |
| Basophilic Focus                  | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |   |   |   | X | X | X | X | X | 46    |
| Clear Cell Focus                  |   |   | X |   | X | X |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   | X |   |   |   | 10    |
| Cyst                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1     |
| Eosinophilic Focus                | X | X | X | X | X | X |   | X |   | X |   | X | X |   | X |   | X |   |   |   |   | X | X | X | X | 29    |
| Hemorrhage                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 2.0 |
| Hepatodiaphragmatic Nodule        |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   | X |   |   | 8     |
| Infiltration Cellular, Mixed Cell |   |   |   |   | 1 |   | 1 |   | 1 |   | 3 |   | 2 |   | 3 |   |   |   |   | 2 |   |   |   |   |   | 9 1.8 |
| Mixed Cell Focus                  |   |   |   | X | X |   | X |   |   |   | X |   |   |   |   |   |   |   |   |   |   | X | X |   |   | 13    |
| Bile Duct, Hyperplasia            | 1 |   |   |   | 1 |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   | 9 1.1 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                           | 0 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |        |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|--------|
|                                       | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |          |        |
|                                       | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3        |        |
|                                       | 2 | 2 | 2 | 2 | 2 | 6 | 6 | 6 | 6 | 6 | 2 | 2 | 3 | 2 | 2 | 2 | 2 | 4 | 5 | 2 | 2 | 2 | 2 | 2 | 2        |        |
| <b>FISCHER 344 RATS FEMALE</b>        | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |        |
| <b>9000 PPM</b>                       | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |        |
| ANIMAL ID                             | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3        |        |
|                                       | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3        |        |
|                                       | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |        |
| Centrilobular, Necrosis               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1 2.0  |
| Hepatocyte, Degeneration              |   | 1 | 1 |   | 1 |   | 1 | 1 |   |   |   | 2 |   |   | 1 |   |   |   | 1 | 1 |   |   | 1 |   |          | 12 1.1 |
| Hepatocyte, Hypertrophy               | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 |   | 1 |   | 1 | 2 |   | 1 |   |   | 1 | 2 | 2 | 2 | 1 | 1 |   |          | 27 1.5 |
| Hepatocyte, Vacuolization Cytoplasmic |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |          | 1 3.0  |
| Kupffer Cell, Pigmentation            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |          | 1 2.0  |
| Mesentery                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   | + |   |   |          | 4      |
| Accessory Spleen                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 2      |
| Fat, Necrosis                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   | 3 |   |   |          | 3 2.7  |
| Oral Mucosa                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |        |
| Ulcer                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   |   |   |   |          | 1      |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |          | 4 1.0  |
| Pancreas                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 50     |
| Atrophy                               |   | 2 |   |   |   |   |   | 3 |   | 2 |   | 1 |   | 2 |   | 2 |   |   |   |   |   |   | 2 | 1 |          | 17 1.6 |
| Cyst                                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 6      |
| Acinus, Hyperplasia, Focal            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |          | 1 2.0  |
| Salivary Glands                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 50     |
| Atrophy                               |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   | 1 |          | 5 1.0  |
| Stomach, Forestomach                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 50     |
| Edema                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |          | 1 2.0  |
| Epithelium, Hyperplasia               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |          | 1 3.0  |
| Stomach, Glandular                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 50     |
| Erosion                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1 3.0  |
| Tooth                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1      |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
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TDMS No. 99007 - 05

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008

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

Lab: SRI

| DAY ON TEST                    |                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
|--------------------------------|------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|
|                                |                  | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 4 | 5 | 7 | 7 | 7               | 7 |
|                                |                  | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 7 | 6 | 3 | 3 | 3               | 3 |
|                                |                  | 2 | 2 | 2 | 2 | 2 | 6 | 6 | 6 | 6 | 6 | 2 | 2 | 3 | 2 | 2 | 2 | 2 | 4 | 5 | 2 | 2 | 2               | 2 |
| <b>FISCHER 344 RATS FEMALE</b> | <b>ANIMAL ID</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
| <b>9000 PPM</b>                |                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
|                                |                  | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3               | 3 |
|                                |                  | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4               | 5 |
|                                |                  | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7               | 8 |
|                                |                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |   |

**CARDIOVASCULAR SYSTEM**

|                |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |               |
|----------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|---------------|
| Blood Vessel   |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          | <b>+</b> | <b>1</b>      |
| Heart          | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>50</b>     |
| Cardiomyopathy |          |          |          |          | 2        | 1        | 2        |          | 1        | 1        |          |          |          |          | 1        | 1        |          |          |          |          | 1        | 1        | 2        | <b>21 1.3</b> |

**ENDOCRINE SYSTEM**

|                                   |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |               |
|-----------------------------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|---------------|
| Adrenal Cortex                    | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>50</b>     |
| Accessory Adrenal Cortical Nodule |          |          |          |          |          |          |          |          |          |          |          |          |          |          | 3        |          |          | 3        | 3        |          | 3        |          | 3        | <b>9 3.0</b>  |
| Angiectasis                       |          |          |          |          |          |          |          |          |          |          |          |          | 4        |          |          |          |          |          |          |          |          |          |          | <b>2 3.5</b>  |
| Degeneration, Fatty               |          |          |          |          |          | 1        |          |          |          | 1        | 3        |          |          |          |          |          |          |          |          |          |          |          |          | <b>11 1.8</b> |
| Hyperplasia, Focal                |          |          | 2        |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          | <b>4 2.0</b>  |
| Hypertrophy, Focal                |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          | 3        |          |          |          |          | <b>6 2.2</b>  |
| Adrenal Medulla                   | <b>+</b> | <b>+</b> | <b>+</b> | <b>M</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>49</b>     |
| Hyperplasia                       |          |          |          |          |          |          | 1        |          |          |          |          |          |          |          |          |          |          | 2        |          |          |          |          | 2        | <b>5 1.4</b>  |
| Islets, Pancreatic                | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>50</b>     |
| Hyperplasia                       |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          | <b>1 1.0</b>  |
| Parathyroid Gland                 | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>M</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>48</b>     |
| Pituitary Gland                   | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>+</b> | <b>50</b>     |
| Pars Distalis, Angiectasis        |          |          |          |          | 3        |          |          |          |          |          |          |          |          |          |          |          |          | 3        |          |          |          |          |          | <b>3 3.3</b>  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
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 x .. Lesion present  
 I .. Insufficient tissue  
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 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
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**TDMS No.** 99007 - 05  
**Test Type:** CHRONIC  
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**CAS Number:** GOLDENSEALRT

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**Lab:** SRI

| DAY ON TEST                    | 0 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 4 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3                              | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 7 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |   |
| 2                              | 2 | 2 | 2 | 2 | 2 | 6 | 6 | 6 | 6 | 6 | 6 | 2 | 2 | 3 | 2 | 2 | 2 | 2 | 2 | 4 | 5 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   |   |
| .....                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>9000 PPM</b>                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID                      | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |   |
|                                | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | 5 | 5 |   |
|                                | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |   |   |   |   |   |   |   |   |   |   |
| .....                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| <b>* TOTALS</b>                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |               |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|---------------|
| Pars Distalis, Cyst               |   |   |   | X | X | X | X | X | X | X |   |   |   |   |   |   |   | X | X | X |   |   | X | X |   |   |   |   |   |   |   |   |   | <b>27</b> |               |
| Pars Distalis, Hyperplasia, Focal |   |   |   |   |   |   |   | 2 |   |   | 1 |   |   | 1 |   |   |   | 3 | 3 | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>12 2.0</b> |
| .....                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |               |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |               |
| C-cell, Hyperplasia               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>6 1.2</b>  |
| Follicle, Cyst                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |           | <b>2</b>      |

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |               |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|---------------|
| Clitoral Gland                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>49</b> |               |
| Cyst                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>      |
| Hyperplasia, Focal                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>6 2.7</b>  |
| Inflammation, Chronic                    |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>2 2.0</b>  |
| .....                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |               |
| Ovary                                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |               |
| Cyst                                     |   |   | X |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   | X |   | X |   |   |   |   |   |   |   | X | X | <b>14</b> |               |
| Corpus Luteum, Vacuolization Cytoplasmic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1 3.0</b>  |
| .....                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |               |
| Uterus                                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |               |
| Hyperplasia, Cystic                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |               |
| Inflammation, Suppurative                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>14 2.4</b> |
| Myometrium, Hypertrophy                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1 3.0</b>  |
| .....                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |               |
| Vagina                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>      |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ .. Tissue examined microscopically  
x .. Lesion present  
I .. Insufficient tissue  
M .. Missing tissue  
A .. Autolysis precludes evaluation  
BLANK .. Not examined microscopically  
1-4 .. Lesion qualified as:  
1) Minimal 3) Moderate  
2) Mild 4) Marked  
Page 113

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                                 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
|   | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 4 | 5 | 7 | 7 | 7 | 7 | 7 | 7 |                 |
|   | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 7 | 6 | 3 | 3 | 3 | 3 | 3 | 3 |                 |
|   | 2 | 2 | 2 | 2 | 2 | 6 | 6 | 6 | 6 | 6 | 2 | 2 | 3 | 2 | 2 | 2 | 4 | 5 | 2 | 2 | 2 | 2 | 2 | 2 |                 |
| <b>FISCHER 344 RATS FEMALE</b><br>ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
| <b>9000 PPM</b>                             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
|   | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                 |
|   | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |                 |
|   | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | <b>* TOTALS</b> |

**HEMATOPOIETIC SYSTEM**

|                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |     |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|-----|
| Bone Marrow                        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |    |     |     |
| Hyperplasia                        |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   | 4 |   |   |   |   |   |   |    | 5  | 3.2 |     |
| Infiltration Cellular, Histiocyte  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1  | 2.0 |     |
| Infiltration Cellular, Mixed Cell  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |    | 1  | 3.0 |     |
| Lymph Node                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 7  |     |     |
| Deep Cervical, Ectasia             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    | 1   | 4.0 |
| Mediastinal, Hemorrhage            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    | 4   | 2.3 |
| Mediastinal, Hyperplasia, Lymphoid |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    | 1   | 3.0 |
| Mediastinal, Pigmentation          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    | 2   | 3.0 |
| Lymph Node, Mandibular             | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M  | 3  |     |     |
| Lymph Node, Mesenteric             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 50 |     |     |
| Hemorrhage                         |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    | 3   | 1.3 |
| Hyperplasia, Lymphoid              |   |   |   |   |   | 2 | 3 |   | 2 |   |   |   |   |   | 2 |   |   |   |   | 2 |   |   |   |   |    | 10 | 2.2 |     |
| Spleen                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 50 |     |     |
| Hematopoietic Cell Proliferation   | 2 | 2 | 1 | 2 | 2 |   | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   | 1 | 3 | 3 | 2 | 2 | 2 | 2 | 3 | 2  | 42 | 2.2 |     |
| Thymus                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | +  | 49 |     |     |
| Cyst                               |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1  |     |     |
| Hyperplasia, Lymphoid              | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1  | 2.0 |     |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 114

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
|                                | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 4 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |                 |
|                                | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 7 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                 |
|                                | 2 | 2 | 2 | 2 | 2 | 6 | 6 | 6 | 6 | 6 | 2 | 2 | 3 | 2 | 2 | 2 | 4 | 5 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |                 |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
| <b>9000 PPM</b>                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
| ANIMAL ID                      | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                 |
|                                | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |                 |
|                                | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | <b>* TOTALS</b> |

**INTEGUMENTARY SYSTEM**

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |       |        |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|--------|
| Mammary Gland             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |        |
| Hyperplasia               | 3 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 1 | 1 | 2 | 3 | 3 | 2 | 3 | 2 | 2 | 4 | 3 | 2 | 2  |       | 45 2.5 |
| Skin                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |        |
| Cyst Epithelial Inclusion |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1     |        |
| Hyperkeratosis            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |    | 1 4.0 |        |
| Inflammation, Chronic     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 2.0 |        |
| Epidermis, Hyperplasia    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 3.0 |        |

**MUSCULOSKELETAL SYSTEM**

|      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |  |
|------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |  |
|------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--|

**NERVOUS SYSTEM**

|             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |       |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Brain       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |
| Compression |   |   |   |   |   |   |   |   |   |   |   | 3 | 3 |   |   |   |   |   |   |   |   |   |   |   |   |    | 3 3.3 |
| Hemorrhage  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 2.0 |

**RESPIRATORY SYSTEM**

|              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |
|--------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|
| Lung         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Foreign Body |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

|                                   | DAY ON TEST                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |     |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|-----|
|                                   | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          | 0   |
|                                   | 7   | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 4 | 5 | 7 | 7 | 7 | 7 | 7 | 7 |          |     |
|                                   | 3   | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 7 | 6 | 3 | 3 | 3 | 3 | 3 | 3 |          |     |
|                                   | 2   | 2 | 2 | 2 | 2 | 6 | 6 | 6 | 6 | 6 | 2 | 2 | 3 | 2 | 2 | 2 | 2 | 4 | 5 | 2 | 2 | 2 | 2 | 2 | 2 |   |          |     |
| <b>FISCHER 344 RATS FEMALE</b>    | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |          |     |
| <b>9000 PPM</b>                   | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |          |     |
| ANIMAL ID                         | 3   | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |   |          |     |
|                                   | 2   | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |   |          |     |
|                                   | 6   | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |   |          |     |
| Hemorrhage                        | 2   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2        | 2.0 |
| Infiltration Cellular, Histiocyte | 1 1 1 1 1 2 1 1 1 1 1 4 1 1 1 1 1 1             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 37       | 1.1 |
| Inflammation, Chronic             | 1 1 1 1 1 1 1 1 1 1 1 4 1 1 1 1 1 1 1 1 1       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 19       | 1.2 |
| Metaplasia, Osseous               | 1   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2        | 1.0 |
| Alveolar Epithelium, Hyperplasia  | 1   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 5        | 1.6 |
| Serosa, Hyperplasia               | 3   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2        | 2.0 |
| Nose                              | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50       |     |
| Foreign Body                      | X   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2        |     |
| Inflammation, Chronic             | X   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1        | 1.0 |
| Trachea                           | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50       |     |
| <b>SPECIAL SENSES SYSTEM</b>      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |
| Eye                               | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50       |     |
| Cataract                          | 2   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1        | 2.0 |
| Retina, Degeneration              | 3   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1        | 3.0 |
| Harderian Gland                   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50       |     |
| Zymbal's Gland                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1        |     |
| <b>URINARY SYSTEM</b>             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |     |
| Kidney                            | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50       |     |
| Cyst                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1        |     |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically M .. Missing tissue 1-4 .. Lesion qualified as:  
 x .. Lesion present A .. Autolysis precludes evaluation 1) Minimal 3) Moderate  
 I .. Insufficient tissue BLANK .. Not examined microscopically 2) Mild 4) Marked  
 Page 116

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

|   | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |               |
|---|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---------------|
|   | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |               |
| <b>FISCHER 344 RATS FEMALE</b>              | 7           | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 4 | 5 | 7 | 7 | 7 | 7 | 7 | 7 |                 |               |
| <b>9000 PPM</b>                             | 3           | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 7 | 6 | 3 | 3 | 3 | 3 | 3 | 3 |                 |               |
|   | 2           | 2 | 2 | 2 | 2 | 6 | 6 | 6 | 6 | 6 | 2 | 2 | 3 | 2 | 2 | 2 | 2 | 4 | 5 | 2 | 2 | 2 | 2 | 2 | 2 |                 |               |
| <b>ANIMAL ID</b>                            | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |               |
|   | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |               |
|   | 3           | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                 |               |
|   | 2           | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |                 |               |
|   | 6           | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | <b>* TOTALS</b> |               |
| Inflammation, Suppurative                   |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 | <b>1 2.0</b>    |               |
| Nephropathy                                 | 1           | 1 |   |   |   | 1 | 1 | 2 | 1 |   | 1 | 2 |   |   |   |   | 1 | 2 | 1 | 1 |   | 1 | 1 | 1 | 1 | 3               | <b>33 1.2</b> |
| Renal Tubule, Accumulation, Hyaline Droplet |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 | <b>1 2.0</b>  |
| Renal Tubule, Pigmentation                  |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 | <b>1 3.0</b>  |
| Transitional Epithelium, Hyperplasia        |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 | <b>2 2.0</b>    |               |
| Urinary Bladder                             | +           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>       |               |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
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

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                | 7 | 7 | 7 | 7 | 1 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 |   |
|                                | 2 | 2 | 2 | 2 | 2 | 8 | 3 | 3 | 7 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 1 | 4 | 6 |
|                                | 9 | 9 | 9 | 9 | 2 | 4 | 3 | 3 | 5 | 3 | 9 | 9 | 9 | 6 | 9 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 6 | 1 | 8 |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>25000 PPM</b>               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| ANIMAL ID                      | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |   |
|                                | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |   |
|                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

**females (cont...)**

**ALIMENTARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum<br>Edema                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | I | + | + | + | + | + | + | + |
| Intestine Large, Colon                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + |
| Intestine Small, Ileum                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + |
| Intestine Small, Jejunum<br>Epithelium, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Basophilic Focus                                    |   |   |   |   |   |   |   |   |   | X | X | X |   |   | X | X |   | X | X | X | X | X |   |   |
| Clear Cell Focus                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Cyst  |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Eosinophilic Focus                                  |   |   | X |   | X |   |   | X |   | X |   |   | X |   | X | X | X | X |   | X | X |   |   |   |
| Hemorrhage  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hepatodiaphragmatic Nodule                          | X | X |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |
| Infiltration Cellular, Mixed Cell                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 | 3 |   |   |   |   |   | 2 |   |   |
| Mixed Cell Focus                                    |   |   | X |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ .. Tissue examined microscopically  
x .. Lesion present  
I .. Insufficient tissue  
M .. Missing tissue  
A .. Autolysis precludes evaluation  
BLANK .. Not examined microscopically  
Page 118  
1-4 .. Lesion qualified as:  
1) Minimal 3) Moderate  
2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| 7                              | 7         | 7 | 7 | 1 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 |                      |
| 2                              | 2         | 2 | 2 | 2 | 8 | 3 | 3 | 7 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 4 | 6 |                      |
| 9                              | 9         | 9 | 9 | 2 | 4 | 3 | 3 | 5 | 3 | 9 | 9 | 9 | 6 | 9 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 1 | 8 |                      |
| .....                          |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| <b>FISCHER 344 RATS FEMALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| <b>25000 PPM</b>               | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|                                | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                      |
|                                | 5         | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |   |                      |
|                                | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                      |

|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Necrosis, Focal                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |
| Bile Duct, Hyperplasia                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hepatocyte, Degeneration              | 1 | 2 | 1 |   |   |   | 1 | 2 |   |   |   |   |   | 1 | 1 |   |   | 1 | 1 |   |   | 2 | 2 |   |   | 1 |
| Hepatocyte, Hypertrophy               | 2 | 2 | 1 | 1 |   |   |   | 2 | 3 |   |   | 2 | 2 | 2 | 2 |   |   | 2 | 1 | 2 | 2 | 3 | 1 | 3 | 2 | 2 |
| Hepatocyte, Vacuolization Cytoplasmic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 |
| Kupffer Cell, Pigmentation            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mesentery                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Accessory Spleen                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Fat, Necrosis                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pancreas                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Atrophy                               | 3 |   |   | 1 |   |   |   |   |   |   |   |   |   | 1 |   |   | 3 | 2 |   |   | 1 |   |   | + |   |   |
| Cyst                                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Acinus, Cytoplasmic Alteration        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Salivary Glands                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Atrophy                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Stomach, Forestomach                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Edema                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |
| Ulcer                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |
| Epithelium, Hyperplasia               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Stomach, Glandular                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Erosion                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |
| Ulcer                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Tongue                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                          | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|--------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|                                      | 7 7 7 7 1 6 7 7 5 7 7 7 7 7 7 7 7 7 7 7 7 7 7 6 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS FEMALE<br>25000 PPM | 2 2 2 2 2 8 3 3 7 3 2 2 2 2 2 3 0 3 3 3 3 3 1 4 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                      | 9 9 9 9 2 4 3 3 5 3 9 9 9 6 9 2 1 2 2 2 2 2 6 1 8 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ANIMAL ID                            | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                      | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 25000 PPM                            | 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                      | 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ANIMAL ID                            | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                      | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

females (cont...)

Inflammation, Granulomatous

**CARDIOVASCULAR SYSTEM**

|                |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|----------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Heart          | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cardiomyopathy | 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**ENDOCRINE SYSTEM**

|                                   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Adrenal Cortex                    | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accessory Adrenal Cortical Nodule | 3     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Angiectasis                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Degeneration, Fatty               | 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia, Focal                | 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hypertrophy, Focal                | 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Necrosis                          | 3     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Adrenal Medulla                   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia                       | 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Islets, Pancreatic                | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Parathyroid Gland                 | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pituitary Gland                   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pars Distalis, Angiectasis        | 4 3     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pars Distalis, Cyst               | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



TDMS No. 99007 - 05

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                | 7 | 7 | 7 | 7 | 1 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 |
|                                | 2 | 2 | 2 | 2 | 2 | 8 | 3 | 3 | 7 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 4 | 6 |
|                                | 9 | 9 | 9 | 9 | 2 | 4 | 3 | 3 | 5 | 3 | 9 | 9 | 9 | 6 | 9 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 1 | 8 |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| <b>25000 PPM</b>               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID                      | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |   |
|                                | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |   |
|                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   |

females (cont...)

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pars Distalis, Hyperplasia, Focal |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pars Intermedia, Angiectasis      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pars Intermedia, Cyst             | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| C-cell, Hyperplasia               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Follicle, Cyst                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

|                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Ovary                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + |   |
| Cyst                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Uterus                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia, Cystic    | 1 | 1 | 3 |   |   | 1 |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   | 1 |   |   |   | 3 |   |   |
| Cervix, Cyst, Squamous |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Vagina                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST                                       | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   | 7 | 7 | 7 | 7 | 1 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 |
|   | 2 | 2 | 2 | 2 | 2 | 8 | 3 | 3 | 7 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 1 | 4 |
|   | 9 | 9 | 9 | 9 | 2 | 4 | 3 | 3 | 5 | 3 | 9 | 9 | 9 | 6 | 9 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 6 | 1 |
| FISCHER 344 RATS FEMALE<br>ANIMAL ID<br>25000 PPM | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|   | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 |
|   | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 |

females  
(cont...)

HEMATOPOIETIC SYSTEM

|                                    |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
|------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|--|--|---|---|--|---|--|---|---|---|---|---|--|---|---|--|--|---|--|--|---|---|--|---|--|--|---|--|--|---|--|--|---|--|--|---|
| Bone Marrow                        | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
| Hyperplasia                        |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3 |  |  |   |   |  |   |  |   |   | 1 |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
| Infiltration Cellular, Histiocyte  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  | 3 |  |   |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
| Myelofibrosis                      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 4 |  |  |   |   |  | 2 |  |   |   |   |   | 3 |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
| Lymph Node                         |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
| Mediastinal, Hemorrhage            |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   | + |   |  |   | + |  |  |   |  |  |   | + |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
| Mediastinal, Hyperplasia, Lymphoid |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   |   |   |  |   |   |  |  | 2 |  |  |   |   |  | 3 |  |  |   |  |  |   |  |  |   |  |  |   |
| Mediastinal, Pigmentation          |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  | 3 |  |  |   |  |  |   |  |  |   |  |  |   |
| Pancreatic, Hemorrhage             |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
| Lymph Node, Mandibular             | M |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
| Lymph Node, Mesenteric             | + M + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
| Ectasia                            |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
| Hemorrhage                         |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   | 1 |  |   |  | 3 |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
| Hyperplasia, Lymphoid              |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   | 2 |   |   |  | 2 |   |  |  | 2 |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
| Spleen                             | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
| Fibrosis                           |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  | 2 |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  |   |
| Hematopoietic Cell Proliferation   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 |  |  | 2 |   |  | 2 |  |   | 1 |   |   | 1 |  |   | 1 |  |  | 2 |  |  | 2 |   |  | 2 |  |  | 3 |  |  | 2 |  |  | 2 |  |  | 1 |
| Hemorrhage                         |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  | 3 |  |  |   |  |  |   |  |  |   |  |  |   |
| Infiltration Cellular, Mixed Cell  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  | 4 |  |  |   |  |  |   |
| Necrosis                           |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  | 4 |  |  |   |  |  |   |
| Lymphoid Follicle, Atrophy         |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |   |   |  |   |  |   |   |   |   |   |  |   |   |  |  |   |  |  |   |   |  |   |  |  |   |  |  |   |  |  |   |  |  | 3 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ .. Tissue examined microscopically  
x .. Lesion present  
I .. Insufficient tissue  
M .. Missing tissue  
A .. Autolysis precludes evaluation  
BLANK .. Not examined microscopically  
Page 122  
1-4 .. Lesion qualified as:  
1) Minimal 3) Moderate  
2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

|                                | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |  |
|--------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|--|
|                                | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |  |
|                                | 7           | 7 | 7 | 7 | 1 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5                    |  |
|                                | 2           | 2 | 2 | 2 | 2 | 8 | 3 | 3 | 7 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 4 | 6                    |  |
|                                | 9           | 9 | 9 | 9 | 2 | 4 | 3 | 3 | 5 | 3 | 9 | 9 | 9 | 6 | 9 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 1 | 8                    |  |
| <b>FISCHER 344 RATS FEMALE</b> | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                    |  |
| <b>25000 PPM</b>               | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                    |  |
| ANIMAL ID                      | 3           | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3                    |  |
|                                | 5           | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6                    |  |
|                                | 1           | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                      |  |

|         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|---------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Thymus  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Atrophy |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

**INTEGUMENTARY SYSTEM**

|                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Mammary Gland  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Hyperplasia    | 3 | 3 |   | 2 |   | 3 | 3 | 3 |   |   |   | 4 | 1 | 4 | 1 | 1 |   | 2 | 3 | 2 | 4 | 1 | 4 |   |   | + |  |
| Skin           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Edema          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |  |
| Hyperkeratosis |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

**MUSCULOSKELETAL SYSTEM**

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Bone                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Skeletal Muscle           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Hemorrhage                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Inflammation, Suppurative |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

**NERVOUS SYSTEM**

|             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Brain       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Compression |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Hemorrhage  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Necrosis    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 123

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST  | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |   |   |  |
|--|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|---|---|--|
|  | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |   |   |  |
| 7  | 7         | 7 | 7 | 1 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6                    | 5 |   |  |
| 2  | 2         | 2 | 2 | 2 | 8 | 3 | 3 | 7 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 4 | 6 | 6                    |   |   |  |
| 9  | 9         | 9 | 9 | 2 | 4 | 3 | 3 | 5 | 3 | 9 | 9 | 9 | 6 | 9 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 1 | 8 | 8                    |   |   |  |
| <hr/>  |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |   |   |  |
| <b>FISCHER 344 RATS FEMALE</b><br><b>25000 PPM</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                    | 0 |   |  |
|  | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                    | 0 | 0 |  |
|  | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3                    | 3 | 3 |  |
|  | 5         | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7                    | 7 | 7 |  |
|  | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 5                    | 5 | 5 |  |

|                  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |   |
|------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|---|---|
| Peripheral Nerve |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | + | + |   |
| Spinal Cord      |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | + | + |

**RESPIRATORY SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Lung                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |  |
| Hemorrhage                        | 3 | 3 | 2 | 4 |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   | 2 | 2 |   | 3 |   |   |   |   |   |  |
| Infiltration Cellular, Histiocyte |   | 1 | 1 | 1 |   | 1 | 1 | 1 |   | 1 | 1 | 1 |   |   |   |   |   |   | 1 | 1 | 1 | 1 | 2 | 1 |   | 2 | 2 | 1 |  |
| Inflammation, Chronic             |   |   | 2 |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   | 1 | 1 |   |   | 1 | 2 |   |   |   |   |  |
| Metaplasia, Osseous               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Alveolar Epithelium, Hyperplasia  |   |   |   |   |   | 1 |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Serosa, Hyperplasia               |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

|                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Nose                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Foreign Body                        | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Inflammation, Chronic               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Respiratory Epithelium, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

|         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|---------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
|---------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|

**SPECIAL SENSES SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |   |
| Cataract             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 | 4 |
| Retina, Degeneration |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 | 4 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ .. Tissue examined microscopically  
x .. Lesion present  
I .. Insufficient tissue  
M .. Missing tissue  
A .. Autolysis precludes evaluation  
BLANK .. Not examined microscopically  
1-4 .. Lesion qualified as:  
1) Minimal 3) Moderate  
2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

|             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|             | 7 | 7 | 7 | 7 | 1 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 |   |
|             | 2 | 2 | 2 | 2 | 2 | 8 | 3 | 3 | 7 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 1 | 4 | 6 |
|             | 9 | 9 | 9 | 9 | 2 | 4 | 3 | 3 | 5 | 3 | 9 | 9 | 9 | 6 | 9 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 6 | 1 | 8 |

**FISCHER 344 RATS FEMALE**  
 ANIMAL ID  
**25000 PPM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   |

**females  
(cont...)**

|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Harderian Gland Inflammation, Chronic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**URINARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney                                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Glomerulosclerosis                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Nephropathy                                 | 2 | 2 |   | 2 |   | 1 | 1 |   | 1 | 2 | 1 | 1 | 1 |   | 2 | 1 | 1 | 1 | 2 | 1 | 2 | 1 | 1 | 2 | 1 |
| Renal Tubule, Accumulation, Hyaline Droplet |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Renal Tubule, Necrosis                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Renal Tubule, Pigmentation                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |
| Urinary Bladder                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 125

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------------|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                | 7               | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 |
|                                | 3               | 3 | 1 | 3 | 1 | 3 | 3 | 3 | 7 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 8 | 3 | 3 | 3 |
|                                | 2               | 2 | 6 | 2 | 8 | 6 | 6 | 6 | 8 | 6 | 2 | 3 | 2 | 2 | 2 | 3 | 3 | 6 | 3 | 3 | 2 | 7 | 2 | 2 | 2 |
| <b>FISCHER 344 RATS FEMALE</b> | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| <b>25000 PPM</b>               | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID                      | 3               | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 |
|                                | 7               | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |
|                                | 6               | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
|                                | <b>* TOTALS</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**ALIMENTARY SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Esophagus                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Intestine Large, Cecum            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49     |
| Edema                             |   |   |   |   |   |   |   |   | 2 |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   | 2 2.5  |
| Intestine Large, Colon            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Intestine Large, Rectum           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Intestine Small, Duodenum         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49     |
| Intestine Small, Ileum            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49     |
| Intestine Small, Jejunum          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Epithelium, Hyperplasia           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 3.0  |
| Liver                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Basophilic Focus                  | X | X |   | X |   | X | X |   |   |   |   | X | X | X | X | X | X | X | X |   | X |   | X | X | 27     |
| Clear Cell Focus                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2      |
| Cyst                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1      |
| Eosinophilic Focus                | X |   |   | X | X |   |   |   |   | X | X |   |   | X |   |   |   | X | X |   | X |   | X | X | 22     |
| Hemorrhage                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   | 1 1.0  |
| Hepatodiaphragmatic Nodule        |   |   |   |   |   |   | X | X |   |   |   | X |   |   |   |   |   | X | X |   |   |   | X |   | 9      |
| Infiltration Cellular, Mixed Cell |   |   |   | 1 | 3 | 3 |   |   |   |   |   |   | 3 |   | 3 |   |   |   | 1 |   |   | 4 |   | 1 | 11 2.4 |
| Mixed Cell Focus                  |   |   |   |   |   |   | X |   |   |   |   |   |   |   | X | X |   |   | X | X |   | X | X |   | 9      |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                           | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        | * TOTALS |
|---------------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|----------|
|                                       | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0      |          |
|                                       | 7         | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 |        |          |
|                                       | 3         | 3 | 1 | 3 | 1 | 3 | 3 | 3 | 7 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 8 | 3 | 3 | 3      |          |
|                                       | 2         | 2 | 6 | 2 | 8 | 6 | 6 | 6 | 8 | 6 | 2 | 3 | 2 | 2 | 2 | 3 | 3 | 6 | 3 | 3 | 2 | 7 | 2 | 2      |          |
| <b>FISCHER 344 RATS FEMALE</b>        | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |        |          |
| <b>25000 PPM</b>                      | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |        |          |
|                                       | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4      |          |
|                                       | 7         | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0      |          |
|                                       | 6         | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9      |          |
| Necrosis, Focal                       |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 1.0  |          |
| Bile Duct, Hyperplasia                | 1         |   |   |   |   |   | 1 |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   | 3 1.3  |          |
| Hepatocyte, Degeneration              | 2         |   |   |   |   |   | 1 | 1 |   |   |   | 1 | 1 |   | 1 |   | 1 | 2 | 2 |   | 1 | 1 |   | 24 1.3 |          |
| Hepatocyte, Hypertrophy               | 3         | 1 |   | 3 |   | 2 | 2 | 3 |   | 4 | 1 |   | 4 | 2 | 1 | 2 | 2 | 1 | 2 | 3 | 1 | 3 | 1 | 38 2.1 |          |
| Hepatocyte, Vacuolization Cytoplasmic |           |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 3.0  |          |
| Kupffer Cell, Pigmentation            |           |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 2.3  |          |
| Mesentery                             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + | + | 2      |          |
| Accessory Spleen                      |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   | 1      |          |
| Fat, Necrosis                         |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 | 1 3.0  |          |
| Pancreas                              | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |          |
| Atrophy                               |           | 3 |   |   | 1 |   |   |   |   |   |   | 1 | 1 |   |   | 2 | 1 |   |   |   |   | 3 | 2 | 14 1.8 |          |
| Cyst                                  | X         |   | X |   |   |   | X |   |   |   |   | X |   |   |   |   |   |   | X | X | X | X |   | 13     |          |
| Acinus, Cytoplasmic Alteration        |           |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 3.0  |          |
| Salivary Glands                       | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |          |
| Atrophy                               |           |   |   |   |   |   |   |   |   | 1 |   |   | 1 |   |   |   |   |   |   |   |   |   |   | 3 1.7  |          |
| Stomach, Forestomach                  | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |          |
| Edema                                 |           |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 3.5  |          |
| Ulcer                                 |           |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 2.7  |          |
| Epithelium, Hyperplasia               |           |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 2.5  |          |
| Stomach, Glandular                    | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |          |
| Erosion                               |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 3.0  |          |
| Ulcer                                 |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 2.0  |          |
| Tongue                                |           |   |   |   |   |   |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   | 1      |          |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

|                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |   |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|
| DAY ON TEST             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
|                         | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7               | 7 |
|                         | 3 | 3 | 1 | 3 | 1 | 3 | 3 | 3 | 7 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 8 | 3 | 3 | 3               | 3 |
|                         | 2 | 2 | 6 | 2 | 8 | 6 | 6 | 6 | 8 | 6 | 2 | 3 | 2 | 2 | 2 | 3 | 3 | 6 | 3 | 3 | 2 | 7 | 2 | 2               | 2 |
| FISCHER 344 RATS FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
| ANIMAL ID               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
| 25000 PPM               | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3               | 4 |
|                         | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9               | 0 |
|                         | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9               | 0 |
|                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |   |

|                             |   |       |
|-----------------------------|---|-------|
| Inflammation, Granulomatous | 4 | 1 4.0 |
|-----------------------------|---|-------|

CARDIOVASCULAR SYSTEM

|                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Heart          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Cardiomyopathy | 1 |   |   |   | 1 | 1 | 3 |   |   |   |   |   |   | 2 | 1 |   |   |   |   |   |   |   |   |   | 15 1.3 |

ENDOCRINE SYSTEM

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Adrenal Cortex                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Accessory Adrenal Cortical Nodule |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   | 6 3.0  |
| Angiectasis                       |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 3.0  |
| Degeneration, Fatty               |   |   |   |   |   |   | 3 |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   | 1 | 11 2.3 |
| Hyperplasia, Focal                |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   | 5 1.6  |
| Hypertrophy, Focal                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 | 1 | 5 1.4  |
| Necrosis                          |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 2.5  |
| Adrenal Medulla                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Hyperplasia                       | 2 |   |   |   |   | 1 |   |   |   |   |   | 1 | 1 | 1 |   |   |   |   |   |   |   |   | 1 |   | 7 1.1  |
| Islets, Pancreatic                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Parathyroid Gland                 | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 46     |
| Pituitary Gland                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Pars Distalis, Angiectasis        | 3 |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 8 2.1  |
| Pars Distalis, Cyst               | X |   | X |   |   |   |   | X | X | X |   |   | X |   |   |   |   |   |   | X | X |   |   |   | 20     |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
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TDMS No. 99007 - 05

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|
|                                | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7               | 7 |
|                                | 3 | 3 | 1 | 3 | 1 | 3 | 3 | 3 | 7 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 8 | 3 | 3 | 3               | 3 |
|                                | 2 | 2 | 6 | 2 | 8 | 6 | 6 | 6 | 8 | 6 | 2 | 3 | 2 | 2 | 2 | 3 | 3 | 6 | 3 | 3 | 2 | 7 | 2 | 2               | 2 |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
| <b>25000 PPM</b>               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
| ANIMAL ID                      | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3               | 4 |
|                                | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9               | 0 |
|                                | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9               | 0 |
|                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |   |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |   |   |   |     |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|---|---|---|-----|
| Pars Distalis, Hyperplasia, Focal |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 | 1  | 2 | 1 | 3 | 9 | 1.8 |
| Pars Intermedia, Angiectasis      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |   |   | 2 | 2.5 |
| Pars Intermedia, Cyst             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |    |   |   |   | 2 |     |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |   |   |   |     |
| C-cell, Hyperplasia               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 | 1  |   |   |   | 5 | 1.2 |
| Follicle, Cyst                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | X |   |   | 1 |     |

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|                        |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |   |    |     |
|------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|---|----|-----|
| Clitoral Gland         |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |    |   |    |     |
| Cyst                   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    | 1 |    |     |
| Inflammation, Chronic  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    | 3 |    |     |
| Ovary                  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 49 |   |    |     |
| Cyst                   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    | X | 8  |     |
| Uterus                 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 50 |   |    |     |
| Cyst                   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    | X | 1  |     |
| Hyperplasia, Cystic    |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2 | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |   | 13 | 2.0 |
| Cervix, Cyst, Squamous |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |   | 1  | 3.0 |
| Vagina                 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |   | 1  |     |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ .. Tissue examined microscopically  
x .. Lesion present  
I .. Insufficient tissue  
M .. Missing tissue  
A .. Autolysis precludes evaluation  
BLANK .. Not examined microscopically  
1-4 .. Lesion qualified as:  
1) Minimal 3) Moderate  
2) Mild 4) Marked  
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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
| 7                              | 7         | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 0        |
| 3                              | 3         | 1 | 3 | 1 | 3 | 3 | 3 | 7 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 8 | 3 | 3 | 3 | 3 | 0        |
| 2                              | 2         | 6 | 2 | 8 | 6 | 6 | 6 | 8 | 6 | 2 | 3 | 2 | 2 | 2 | 3 | 3 | 6 | 3 | 3 | 2 | 7 | 2 | 2 | 2 | 2 | 0        |
| .....                          |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |
| <b>FISCHER 344 RATS FEMALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
| <b>25000 PPM</b>               | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
|                                | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4        |
|                                | 7         | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0        |
|                                | 6         | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 0        |

**HEMATOPOIETIC SYSTEM**

|                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Bone Marrow                        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |
| Hyperplasia                        |   |   | 3 | 3 |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   | 6  | 2.5 |
| Infiltration Cellular, Histiocyte  |   |   |   | 1 |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   | 3  | 2.0 |
| Myelofibrosis                      |   |   |   |   |   |   |   |   | 4 |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   | 5  | 3.2 |
| .....                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |
| Lymph Node                         |   | + |   |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 8  |     |
| Mediastinal, Hemorrhage            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 3.0 |
| Mediastinal, Hyperplasia, Lymphoid |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  | 2.5 |
| Mediastinal, Pigmentation          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 3.0 |
| Pancreatic, Hemorrhage             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   | 1  | 2.0 |
| .....                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |
| Lymph Node, Mandibular             | M | M | M | M | M | + | + | + | M | + | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 5  |     |
| .....                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |
| Lymph Node, Mesenteric             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |     |
| Ectasia                            |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 3.0 |
| Hemorrhage                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   | 3  | 1.7 |
| Hyperplasia, Lymphoid              |   |   | 2 |   |   |   |   |   |   |   | 2 |   |   |   |   | 2 |   |   |   | 2 |   |   |   | 2 |   | 9  | 2.0 |
| .....                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |
| Spleen                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |
| Fibrosis                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  | 2.5 |
| Hematopoietic Cell Proliferation   | 2 | 3 | 3 | 3 | 2 | 2 | 2 |   |   |   |   | 3 | 3 | 2 | 2 |   |   |   |   | 1 | 1 | 2 | 1 | 2 |   | 35 | 2.0 |
| Hemorrhage                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 3.0 |
| Infiltration Cellular, Mixed Cell  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   | 4 |   |   | 3  | 4.0 |
| Necrosis                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 4.0 |
| Lymphoid Follicle, Atrophy         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 3.0 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 130

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST                                       | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 |
|   | 3 | 3 | 1 | 3 | 1 | 3 | 3 | 3 | 7 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 8 | 3 | 3 | 3 |
| 2   | 2 | 6 | 2 | 8 | 6 | 6 | 6 | 6 | 8 | 6 | 2 | 3 | 2 | 2 | 2 | 3 | 3 | 6 | 3 | 3 | 2 | 7 | 2 | 2 |
| .....   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| FISCHER 344 RATS FEMALE<br>25000 PPM<br>ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 |
|   | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|   | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| * TOTALS  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

|                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |     |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|-----|
| Thymus Atrophy | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | +  | + |     |
|                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 49 | 1 | 3.0 |

INTEGUMENTARY SYSTEM

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|
| Mammary Gland Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | +  |     |
|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50 | 34 | 2.6 |
| Skin Edema Hyperkeratosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | +  |     |
|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50 | 1  | 4.0 |
|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1  | 3.0 |

MUSCULOSKELETAL SYSTEM

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |   |     |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|---|-----|
| Bone   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | + |   |     |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50 |   |   |     |
| Skeletal Muscle Hemorrhage Inflammation, Suppurative |   |   |   |   |   |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   |    | 2 | 1 | 4.0 |
|  |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |    |   | 1 | 4.0 |

NERVOUS SYSTEM

|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |     |     |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|-----|-----|
| Brain Compression Hemorrhage Necrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | + |     |     |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50 | 8 | 3.1 |     |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   | 3 | 4 | 3  | 4 | 2   | 3.5 |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |    |   | 1   | 4.0 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 131

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST                    | 0 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|                                | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 |          |
|                                | 3 | 3 | 1 | 3 | 1 | 3 | 3 | 3 | 7 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 8 | 3 | 3 | 3 |          |
|                                | 2 | 2 | 6 | 2 | 8 | 6 | 6 | 6 | 8 | 6 | 2 | 3 | 2 | 2 | 2 | 3 | 3 | 6 | 3 | 3 | 2 | 7 | 2 | 2 |          |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
| <b>25000 PPM</b>               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
| ANIMAL ID                      | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 |          |
|                                | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |          |
|                                | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |          |

Peripheral Nerve

2

Spinal Cord

2

**RESPIRATORY SYSTEM**

|                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |
|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Lung                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Hemorrhage                          |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   | 10 2.6 |
| Infiltration Cellular, Histiocyte   | 1 | 1 |   | 1 |   | 1 | 1 | 1 | 1 | 1 |   | 1 | 1 | 1 | 1 | 1 | 1 | 2 |   | 1 | 1 | 2 | 1 | 39 1.1 |
| Inflammation, Chronic               |   |   | 1 |   |   | 1 |   |   |   |   |   |   |   |   |   | 1 |   |   |   | 1 |   | 2 | 1 | 14 1.3 |
| Metaplasia, Osseous                 |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   | 2 1.0  |
| Alveolar Epithelium, Hyperplasia    |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   | 2 | 1 | 6 1.3  |
| Serosa, Hyperplasia                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 2.0  |
| Nose                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Foreign Body                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2      |
| Inflammation, Chronic               |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   | 2 1.5  |
| Respiratory Epithelium, Hyperplasia |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 2.0  |
| Trachea                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |

**SPECIAL SENSES SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Eye                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Cataract             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 3.5 |
| Retina, Degeneration |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 4.0 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 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

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
|                                | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7               |
|                                | 3 | 3 | 1 | 3 | 1 | 3 | 3 | 3 | 7 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 8 | 3 | 3 | 3 | 3 | 3               |
|                                | 2 | 2 | 6 | 2 | 8 | 6 | 6 | 6 | 8 | 6 | 2 | 3 | 2 | 2 | 2 | 3 | 3 | 6 | 3 | 3 | 2 | 7 | 2 | 2 | 2 | 2               |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
| <b>25000 PPM</b>               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
| ANIMAL ID                      | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4               |
|                                | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0               |
|                                | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | <b>* TOTALS</b> |

Harderian Gland  
 Inflammation, Chronic + 49 2 2.0

**URINARY SYSTEM**

Kidney + 50

Glomerulosclerosis 3 1 3.0

Nephropathy 2 1 1 2 2 1 1 1 2 2 1 1 1 2 1 1 3 1 1 1 1 1 1 1 45 1.4

Renal Tubule, Accumulation, Hyaline Droplet 2 2.0

Renal Tubule, Necrosis 3 1 3.0

Renal Tubule, Pigmentation 2 2 2.5

Urinary Bladder + 50

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

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 Page 133  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked